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(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 March 2010 to 30 June 2010

[Published pursuant to Article 13 or Article 38 of Regulation (CE) No 726/2004 of the European Parliament and of the Council [1]]

(2010/C 258/01)

[1] OJ L 136, 30.4.2004, p. 1.

— **Issuing of a marketing authorization (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): Accepted**

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
11.3.2010	Revolade	Eltrombopag	GlaxoSmithKline Trading Services Limited 6900 CorkAirport Business Park, Kinsale Road, Cork, Ireland	EU/1/10/612/001-006	Film-coated tablet	B02BX05	15.3.2010
15.3.2010	DuoCover	clopidogrel / acetylsalicylic acid	Bristol-MyersSquibbPharma EEIG Uxbridge BusinessPark, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/10/623/001-014	Film-coated tablet	B01AC30	17.3.2010
15.3.2010	DuoPlavin	clopidogrel / acetylsalicylic acid	Sanofi Pharma Bristol-Myers Squibb SNC 174 Avenue de France, F-75013 Paris, France	EU/1/10/619/001-014	Film-coated tablet	B01AC30	17.3.2010
15.3.2010	ImmunoGam	Human Hepatitis B Immunoglobulin	Cangene Europe Limited Parkshot House, 5 Kew Road, Richmond, Surrey TW9 2PR, United Kingdom	EU/1/10/613/001-002	Solution for injection	J06BB04	17.3.2010
15.3.2010	Menveo	Meningococcal Group A, C, W135 and Y Conjugate Vaccine	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1 - Siena, Italia	EU/1/10/614/001	Powder and solution for injection	Pending	17.3.2010
15.3.2010	Ristaben	sitagliptin	Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, HertfordshireEN11 9BU, United Kingdom	EU/1/10/621/001-018	Film-coated tablet	A10BH01	17.3.2010
15.3.2010	Ristfor	sitagliptin / metformin hydrochloride	Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, HertfordshireEN11 9BU, United Kingdom	EU/1/10/620/001-016	Film-coated tablet	A10BD07	17.3.2010
15.3.2010	Temozolomide HEXAL	temozolomide	HEXAL AG Industriestrasse 25, D-83607 Holzkirchen, Deutschland	EU/1/10/616/001-024	Capsule, hard	L01AX03	17.3.2010
15.3.2010	Temozolomide Hospira	temozolomide	Hospira UK Ltd. Queensway, Royal Leamington Spa, Royal Leamington Spa, Warwickshire CV31 3RW, United Kingdom	EU/1/10/615/001-024	Capsule, hard	L01AX03	17.3.2010

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
15.3.2010	Temozolomide Sandoz	temozolomide	Sandoz Pharmaceuticals GmbH Raiffeisenstraße 11, 83607 Holzkirchen, Deutschland	EU/1/10/617/001-024	Capsule, hard	L01AX03	17.3.2010
15.3.2010	Tepadina	Thiotepa	ADIENNE S.r.l. via Broseta, 64/B, 24128 Bergamo, Italia	EU/1/10/622/001-002	powder for concentrate for solution for infusion	L01AC01	17.3.2010
23.3.2010	Arepanrix	Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted) A/California/7/2009 (H1N1)v like strain (X-179A)	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/10/624/001	Suspension and emulsion for emulsion for injection	J07BB02	25.3.2010
6.4.2010	Ribavirin BioPartners	Ribavirin	BioPartners GmbH Kaiserpassage 11 - D-72764 Reutlingen, Deutschland	EU/1/10/626/001-004	Film-coated tablet	J05AB04	9.4.2010
19.4.2010	Arzerra	Ofatumumab	Glaxo Group Ltd Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/10/625/001-002	Concentrate for solution for infusion	L01XC10	21.4.2010
29.4.2010	Raloxifene Teva	Raloxifene hydrochloride	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/10/627/001-003	Film-coated tablet	G03XC01	3.5.2010
10.5.2010	Docefrez	Docetaxel	Sun Pharmaceuticals Industries Europe B.V. Polarisavenue 87, 2132 JH Hoofddorp, Nederland	EU/1/10/630/001-002	Powder and solvent for concentrate for solution for infusion	L01CD02	12.5.2010
26.5.2010	Prolia	denosumab	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/10/618/001-004	Solution for injection	M05BX04	28.5.2010
4.6.2010	Tolura	telmisartan	KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/10/632/001-021	Tablet	C09CA07	8.6.2010
8.6.2010	Humenza	Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted) A/California/7/2009 (H1N1)v like strain (X-179A)	Sanofi Pasteur SA 2, avenue Pont Pasteur, F-69007 Lyon, France	EU/1/10/629/001	Suspension and emulsion for emulsion for injection	J07BB02	10.6.2010

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
8.6.2010	Nivestim	Filgrastim	Hospira UK Limited Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, United Kingdom	EU/1/10/631/001-009	Solution for injection or infusion	L03AA02	10.6.2010
10.6.2010	Olanzapine Apotex	Olanzapine	Apotex Europe B.V. Darwingweg 20, 2333 CR Leiden, Nederland	EU/1/10/635/001-014	Film-coated tablet Orodispersible tablet	N05AH03	14.6.2010
10.6.2010	Ribavirin Three Rivers	Ribavirin	Three Rivers Global Pharma Limited 20-22 Bedford Row, London WC1R4JS, United Kingdom	EU/1/10/634/001-004	Capsule, hard	J05AB04	14.6.2010
10.6.2010	Topotecan Hospira	Topotecan	Hospira UK Limited Queensway, Royal Leamington Spa, Warwickshire CV31 3RW, United Kingdom	EU/1/10/633/001-002	Concentrate for solution for infusion	L01XX17	14.6.2010
14.6.2010	Votrient	Pazopanib hydrochloride	Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/10/628/001-004	Film-coated tablet	L01XE11	16.6.2010

— **Issuing of a marketing authorization (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): Rejected**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
8.4.2010	Impulsor	Pierre Fabre Médicament 45, Place Abel Gance, 92654 Boulogne Billancourt Cedex, France		12.4.2010
8.4.2010	Milnacipran Pierre Fabre Medicament	Pierre Fabre Médicament 45, Place Abel Gance, 92654 Boulogne Billancourt Cedex, France		12.4.2010

— **Modification of a marketing authorization (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
11.3.2010	Cancidas	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/01/196/001 EU/1/01/196/003	15.3.2010
11.3.2010	Dafiro	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/371/001-036	15.3.2010
11.3.2010	Diacomit	Biocodex 7 avenue Gallieni, 94250 Gentilly, France	EU/1/06/367/001-012	15.3.2010
11.3.2010	Eporatio	ratiopharm GmbH Graf-Arco-Straße 3, D-89079 Ulm, Deutschland	EU/1/09/573/001-028	15.3.2010
11.3.2010	Inovelon	Eisai Limited European Knowledge Centre, Mosquito Way, Hatfield, Herts, AL10 9SN, United Kingdom	EU/1/06/378/001-016	15.3.2010
11.3.2010	Stelara	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België	EU/1/08/494/003-004	15.3.2010
11.3.2010	Zopya	Norpharm Regulatory Services Ltd 26 Laurence Street, Drogheda, Co. Louth, Ireland	EU/1/09/562/001-009	15.3.2010
15.3.2010	Abraxane	Abraxis BioScience Limited Rosanne House, Parkway, WelwynGarden City, Herts, AL8 6HG, United Kingdom	EU/1/07/428/001	17.3.2010
15.3.2010	Aerinaze	SP Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/07/399/001-006	17.3.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
15.3.2010	Afinitor	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/538/001-008	17.3.2010
15.3.2010	Aldara	Meda AB Pipers väg 2A, Solna 170 73, Svërige	EU/1/98/080/002	17.3.2010
15.3.2010	Altargo	Glaxo Group Limited Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/390/001-004	17.3.2010
15.3.2010	Arcalyst	Regeneron UK Limited 40 Bank Street, E14 5DS London, United Kingdom	EU/1/09/582/001	17.3.2010
15.3.2010	Atripla	Bristol-Myers Squibb and Gilead Sciences Limited IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland	EU/1/07/430/001-002	19.3.2010
15.3.2010	Avonex	Biogen Idec Ltd Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	EU/1/97/033/002-004	17.3.2010
15.3.2010	BeneFIX	Wyeth Europa Ltd. Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/97/047/001-007	17.3.2010
15.3.2010	Biopoin	CT Arzneimittel GmbH Lengeder Straße 42a, D-13407 Berlin, Deutschland	EU/1/09/565/001-028	17.3.2010
15.3.2010	Byetta	Eli Lilly Nederland B.V. Grootslag 1-5, 3991 RA Houten, Nederland	EU/1/06/362/001-004	17.3.2010
15.3.2010	Carbaglu	Orphan Europe Immeuble Le Wilson, 70 Avenue du General de Gaulle, 92800 Puteaux, France	EU/1/02/246/001-003	17.3.2010
15.3.2010	Cayston	GileadSciencesInternational Limited Granta Park, Abington, Cambridge CB21 6GT, United Kingdom	EU/1/09/543/001	17.3.2010
15.3.2010	Clopidogrel DURA	Mylan dura GmbH Wittichstraße 6, D-64295 Darmstadt, Deutschland	EU/1/09/560/001-009	17.3.2010
15.3.2010	Clopidogrel Hexal	Acino Pharma GmbH Am Windfeld 35, Miesbach 83714, Deutschland	EU/1/09/534/001-007	17.3.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
15.3.2010	Clopidogrel Teva Pharma	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/561/001-010	17.3.2010
15.3.2010	Copalia	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/372/001-036	17.3.2010
15.3.2010	Cubicin	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/05/328/001-002	17.3.2010
15.3.2010	Doribax	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België	EU/1/08/467/001-002	17.3.2010
15.3.2010	Duloxetine Boehringer Ingelheim	Boehringer Ingelheim International GmbH Binger Strasse 173 - D - 55216 Ingelheim am Rhein, Deutschland	EU/1/08/471/001-012	17.3.2010
15.3.2010	Dynastat	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/02/209/001-008	17.3.2010
15.3.2010	Effentora	Cephalon Europe 5 Rue Charles Martigny, Maisons-Alfort 94700, France	EU/1/08/441/001-010	22.3.2010
15.3.2010	Elaprase	Shire Human Genetic Therapies AB Svärdvägen 11D, 182 33 Danderyd, Sverige	EU/1/06/365/001-003	17.3.2010
15.3.2010	Eucreas	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/425/001-018	17.3.2010
15.3.2010	Evoltra	Genzyme Europe BV Gooimeer 10, 1411 DD Naarden, Nederland	EU/1/06/334/001-005	17.3.2010
15.3.2010	Exjade	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/356/001-009	17.3.2010
15.3.2010	Faslodex	AstraZenecaUK Limited Alderley Park, Macclesfield, Cheshire, SK10 4TG United Kingdom	EU/1/03/269/001	17.3.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
15.3.2010	Firazyr	Jerini AG Invalidenstr. 130, D-10115 Berlin, Deutschland	EU/1/08/461/001	17.3.2010
15.3.2010	GONAL-f	Merck Serono Europe Ltd. 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/95/001/001 EU/1/95/001/003-005 EU/1/95/001/009 EU/1/95/001/012 EU/1/95/001/021-022 EU/1/95/001/025-028 EU/1/95/001/031-035	17.3.2010
15.3.2010	Humira	Abbott Laboratories Limited Abbott House, VanwallBusinessPark, Vanwall Road, Maidenhead, Berkshire SL 6 4XE, United Kingdom	EU/1/03/256/001-010	17.3.2010
15.3.2010	Icandra	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/484/001-018	23.3.2010
15.3.2010	IntronA	Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/99/127/011-044	17.3.2010
15.3.2010	Invirase	Roche Registration Limited 6 Falcon Way, ShirePark, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/96/026/001-002	17.3.2010
15.3.2010	Iscover	Bristol-MyersSquibbPharma EEIG Uxbridge BusinessPark, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/98/070/012	17.3.2010
15.3.2010	Kepivance	BiovitrumAB (publ) SE-112 76 Stockholm, Sverige	EU/1/05/314/001	17.3.2010
15.3.2010	Luveris	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/00/155/001-007	17.3.2010
15.3.2010	Mircera	Roche Registration Limited 6 Falcon Way, ShirePark, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/07/400/001-024	17.3.2010
15.3.2010	M-M-RVAXPRO	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/06/337/001-013	17.3.2010
15.3.2010	Mozobil	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/09/537/001	19.3.2010
15.3.2010	Neupro	Schwarz Pharma Ltd Shannon, Industrial Estate, Co. Clare, Ireland	EU/1/05/331/001-055	18.3.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
15.3.2010	Nimvastid	KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/525/047-050	17.3.2010
15.3.2010	Norvir	Abbott Laboratories Ltd Abbott House, VanwallBusinessPark, Vanwall Road, Maidenhead, Berkshire SL6 4XE, United Kingdom	EU/1/96/016/001 EU/1/96/016/003-004	17.3.2010
15.3.2010	Ovitrelle	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/00/165/001-007	17.3.2010
15.3.2010	Pergoveris	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/07/396/001-003	17.3.2010
15.3.2010	Plavix	Sanofi Pharma Bristol-Myers Squibb SNC 174 avenue de France - 75013 Paris, France	EU/1/98/069/012	17.3.2010
15.3.2010	Prezista	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België	EU/1/06/380/001-005	17.3.2010
15.3.2010	Rapamune	Wyeth Europa Limited Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/01/171/007-010	17.3.2010
15.3.2010	Remicade	Centocor B.V. Einsteinweg 101, 2333 CB Leiden, Nederland	EU/1/99/116/001-005	17.3.2010
15.3.2010	Removab	Fresenius Biotech GmbH Am Haag 6-7, D-82166 Graefelfing, Deutschland	EU/1/09/512/001-002	17.3.2010
15.3.2010	Revlimid	Celgene Europe Limited Riverside House, Riverside Walk, Windsor, Berkshire SL4 1NA, United Kingdom	EU/1/07/391/001-004	17.3.2010
15.3.2010	Reyataz	Bristol-MyersSquibbPharma EEIG Uxbridge BusinessPark, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/03/267/001-010	17.3.2010
15.3.2010	Sebivo	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/388/001-003	17.3.2010
15.3.2010	Sebivo	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/388/001-003	17.3.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
15.3.2010	Stelara	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België	EU/1/08/494/001-002	17.3.2010
15.3.2010	Sutent	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/06/347/001-008	17.3.2010
15.3.2010	Tamiflu	Roche Registration Limited 6 Falcon Way, ShirePark, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/02/222/001-004	17.3.2010
15.3.2010	Thalidomide Celgene	Celgene Europe Limited Riverside House, Riverside Walk, Windsor SL4 1NA, United Kingdom	EU/1/08/443/001	17.3.2010
15.3.2010	Twinrix Adult	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, Rixensart, B-1330 Belgique	EU/1/96/020/001-009	17.3.2010
15.3.2010	Valtropin	BioPartners GmbH Kaiserpassage 11 - D-72764 Reutlingen, Deutschland	EU/1/06/335/001	17.3.2010
15.3.2010	Vaniqa	Laboratorios Almirall, S.A. Ronda General Mitre, 151, 08022 Barcelona, España	EU/1/01/173/001-003	17.3.2010
15.3.2010	Vantavo (ex Alendronate sodium and colecalciferol, MSD)	Merck Sharp & Dohme Ltd. Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/09/572/001-009	17.3.2010
15.3.2010	Vectibix	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/07/423/001-003	17.3.2010
15.3.2010	Viread	Gilead Sciences International Limited Cambridge CB21 6GT United Kingdom	EU/1/01/200/001-002	18.3.2010
15.3.2010	Zomarist	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/483/001-018	17.3.2010
15.3.2010	Zylagren	KRKA, d. d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/558/001-010	17.3.2010
19.3.2010	Clopidogrel ratiopharm GmbH	Acino Pharma GmbH Am Windfeld 35, 83714 Miesbach, Deutschland	EU/1/09/541/001-008	23.3.2010
19.3.2010	Copalia	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/372/001-036	23.3.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
19.3.2010	Dafiro	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/371/001-036	23.3.2010
19.3.2010	Evoltra	Genzyme Europe BV Gooimeer 10, 1411 DD Naarden, Nederland	EU/1/06/334/001-005	23.3.2010
19.3.2010	Kineret	BiovitrumAB (publ) SE-112 76, Stockholm, Sverige	EU/1/02/203/001-003	23.3.2010
19.3.2010	Renvela	Genzyme Europe B.V. Gooimeer 10, 1411 DD Naarden, Nederland	EU/1/09/521/001-007	23.3.2010
19.3.2010	Ventavis	Bayer Schering Pharma AG Müllerstrasse 170-178, D-13342 Berlin, Deutschland	EU/1/03/255/001-008	23.3.2010
22.3.2010	Fuzeon	Roche Registration Limited 6 Falcon Way, ShirePark, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/03/252/001-003	24.3.2010
23.3.2010	Abilify	Otsuka Pharmaceutical Europe Ltd Hunton House, HighbridgeBusinessPark, Oxford Road, Uxbridge, Middlesex UB8 1HU, United Kingdom	EU/1/04/276/001-020 EU/1/04/276/024-036	25.3.2010
23.3.2010	Aerius	Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/00/160/001-069	25.3.2010
23.3.2010	Aloxi	Helsinn Birex Pharmaceuticals Ltd Damastown, Mulhuddart, Dublin 15, Republic of Ireland	EU/1/04/306/001	25.3.2010
23.3.2010	Aranesp	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/01/185/001-022 EU/1/01/185/031-099	25.3.2010
23.3.2010	Axura	Merz Pharmaceuticals GmbH Eckenheimer Landstr. 100, D-60318 Frankfurt/Main - Deutschland	EU/1/02/218/001-003 EU/1/02/218/007-010 EU/1/02/218/012-016 EU/1/02/218/023	25.3.2010
23.3.2010	Azomyr	Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/00/157/001-067	23.3.2010
23.3.2010	Cetrotide	SERONO EUROPE LIMITED 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/99/100/001-003	25.3.2010
23.3.2010	Cholestagel	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/03/268/001-004	25.3.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
23.3.2010	Clopidogrel Krka	KRKA, d. d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/556/001-011	25.3.2010
23.3.2010	Clopidogrel ratiopharm	Acino Pharma GmbH Am Windfeld 35, 83714 Miesbach, Deutschland	EU/1/09/554/001-008	25.3.2010
23.3.2010	Clopidogrel Sandoz	Acino Pharma GmbH Am Windfeld 35, 83714 Miesbach, Deutschland	EU/1/09/547/001-007	25.3.2010
23.3.2010	Clopidogrel TAD	TAD Pharma GmbH Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Deutschland	EU/1/09/555/001-009	25.3.2010
23.3.2010	Clopidogrel Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/540/001-016	25.3.2010
23.3.2010	Copalia HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/575/001-060	25.3.2010
23.3.2010	Dafiro HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/574/001-060	25.3.2010
23.3.2010	Enviage	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/406/001-020	25.3.2010
23.3.2010	Exelon	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/98/066/001-026	25.3.2010
23.3.2010	Exforge	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/370/001-036	25.3.2010
23.3.2010	Humira	Abbott Laboratories Limited Abbott House, VanwallBusinessPark, Vanwall Road, Maidenhead, Berkshire SL 6 4XE, United Kingdom	EU/1/03/256/001-010	25.3.2010
23.3.2010	IDflu	Sanofi Pasteur SA 2, avenue Pont Pasteur, F-69007 Lyon, France	EU/1/08/507/001-006	25.3.2010

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23.3.2010	Imprida	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/373/001-036	25.3.2010
23.3.2010	Ixiaro	Intercell AG Campus Vienna Biocenter 3 A-1030 Wien, Österreich	EU/1/08/501/001-002	25.3.2010
23.3.2010	Mabthera	Roche Registration Limited 6 Falcon Way, ShirePark, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/98/067/001-002	25.3.2010
23.3.2010	Mycophenolate mofetil Teva	Teva Pharma B.V. Computerweg 10, DR Utrecht 3542, Nederland	EU/1/07/439/001-004	25.3.2010
23.3.2010	Myfenax	Teva Pharma B.V. Computerweg 10, DR Utrecht 3542, Nederland	EU/1/07/438/001-004	23.3.2010
23.3.2010	Neoclarityn	Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/00/161/001-067	23.3.2010
23.3.2010	Norvir	Abbott Laboratories Ltd Abbott House, VanwallBusinessPark, Vanwall Road, Maidenhead, Berkshire SL6 4XE, United Kingdom	EU/1/96/016/001 EU/1/96/016/003-006	25.3.2010
23.3.2010	Oslif Breezhaler	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/09/586/001-010	25.3.2010
23.3.2010	Prometax	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/98/092/001-026	25.3.2010
23.3.2010	Revlimid	Celgene Europe Limited Riverside House, Riverside Walk, Windsor, Berkshire SL4 1NA, United Kingdom	EU/1/07/391/001-004	25.3.2010
23.3.2010	Riprazo	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/409/001-020	25.3.2010
23.3.2010	Simponi	Centocor B.V. Einsteinweg 101, 2333 CB Leiden, Nederland	EU/1/09/546/001-004	25.3.2010

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23.3.2010	Sprimeo	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/407/001-020	25.3.2010
23.3.2010	Stalevo	Orion Corporation Orionintie 1, FIN-02200 Espoo, Suomi	EU/1/03/260/001-033	25.3.2010
23.3.2010	Sutent	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/06/347/001-008	25.3.2010
23.3.2010	Synagis	Abbott Laboratories Ltd Abbott House, VanwallBusinessPark, Vanwall Road, Maidenhead, Berkshire SL6 4XE, United Kingdom	EU/1/99/117/001-002	23.3.2010
23.3.2010	Tandemact	Takeda Global Research and Development Centre (Europe) Ltd. 61 Aldwich, LondonWC2B 4AE, United Kingdom	EU/1/06/366/005-022	25.3.2010
23.3.2010	Tasigna	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/422/001-004	25.3.2010
23.3.2010	Thalidomide Celgene	Celgene Europe Limited Riverside House, Riverside Walk, Windsor SL4 1NA, United Kingdom	EU/1/08/443/001	25.3.2010
23.3.2010	Visudyne	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/00/140/001	25.3.2010
23.3.2010	Volibris	Glaxo Group Ltd Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/08/451/001-004	25.3.2010
23.3.2010	Xeloda	Roche Registration Limited 6 Falcon Way, ShirePark, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/00/163/001-002	25.3.2010
26.3.2010	Adcirca	Eli Lilly Nederland B.V. Grootslag 1-5, NL-3991 RA, Houten, Nederland	EU/1/08/476/005-006	30.3.2010
26.3.2010	Avandamet	SmithKline Beecham Ltd. 980 Great West Road, Brentford, Middlesex, TW8 9GS United Kingdom	EU/1/03/258/001-022	30.3.2010

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26.3.2010	Avandia	SmithKline Beecham Ltd. 980 Great West Road, Brentford, Middlesex, TW8 9GS United Kingdom	EU/1/00/137/002-018	30.3.2010
26.3.2010	Celsentri	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/418/001-010	29.3.2010
26.3.2010	Celsentri	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/418/001-010	29.3.2010
26.3.2010	Clopidogrel Qualimed	Qualimed 117, Allée des Parcs, 69800 Saint Priest, France	EU/1/09/557/001-010	30.3.2010
26.3.2010	Competact	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/06/354/001-009	30.3.2010
26.3.2010	Cubicin	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/05/328/001-002	30.3.2010
26.3.2010	Ebixa	H. Lundbeck A/S Ottiliavej 9, DK-2500 Valby, Danmark	EU/1/02/219/001-003 EU/1/02/219/007-012 EU/1/02/219/014-022 EU/1/02/219/036	30.3.2010
26.3.2010	Exforge HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/569/001-060	30.3.2010
26.3.2010	Galvus	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/414/001-010 EU/1/07/414/018	30.3.2010
26.3.2010	Glivec	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/01/198/001-013	29.3.2010
26.3.2010	Glivec	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/01/198/001-013	29.3.2010

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26.3.2010	Helixate NexGen	Bayer Schering Pharma AG 13342 Berlin, Deutschland	EU/1/00/144/001-004	30.3.2010
26.3.2010	Hirobriz Breezhaler	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom	EU/1/09/594/001-010	30.3.2010
26.3.2010	Ilaris	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/564/001-002	30.3.2010
26.3.2010	Imprida HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/570/001-060	30.3.2010
26.3.2010	InductOs	Wyeth Europa Ltd. Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/02/226/001	30.3.2010
26.3.2010	Intanza	Sanofi Pasteur MSD SNC 8, rue Jonas Salk, Lyon 69007, France	EU/1/08/505/001-006	30.3.2010
26.3.2010	IntronA	Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/99/127/011-039 EU/1/99/127/041-044	30.3.2010
26.3.2010	Invega	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België	EU/1/07/395/001-095	29.3.2010
26.3.2010	Invirase	Roche Registration Limited 6 Falcon Way, ShirePark, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/96/026/001-002	30.3.2010
26.3.2010	Isentress	Merck Sharp & Dohme Limited Hertford Road, Hodderson, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/436/001-002	30.3.2010
26.3.2010	Ivemend	Merck Sharp & Dohme Limited Hertford Road, Hodderson, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/437/001	30.3.2010
26.3.2010	Jalra	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/485/001-011	30.3.2010

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26.3.2010	Kogenate Bayer	Bayer Schering Pharma AG 13342 Berlin, Deutschland	EU/1/00/143/001-011	30.3.2010
26.3.2010	Onbrez Breezhaler	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/593/001-010	30.3.2010
26.3.2010	Panretin	Eisai Limited European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, AL10 9SN, United Kingdom	EU/1/00/149/001	30.3.2010
26.3.2010	Rasilez HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/491/001-080	30.3.2010
26.3.2010	Remicade	Centocor B.V. Einsteinweg 101, 2333 CB Leiden, Nederland	EU/1/99/116/001-005	30.3.2010
26.3.2010	Sustiva	Bristol-MyersSquibbPharma EEIG Uxbridge BusinessPark, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/99/110/001-005 EU/1/99/110/008-010	30.3.2010
26.3.2010	Temomedac	ALFRED E. TIEFENBACHER, (GmbH & Co. KG) Van-der-Smissen-Straße 1, Hamburg 22767, Deutschland	EU/1/09/605/001-012	30.3.2010
26.3.2010	Tygacil	Wyeth Europa Ltd. Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/06/336/001	29.3.2010
26.3.2010	Vistide	Gilead Sciences International Limited Cambridge, CB21 6GT, United Kingdom	EU/1/97/037/001	30.3.2010
26.3.2010	Xagrid	ShirePharmaceutical Contracts Ltd Hampshire InternationalBusinessPark, Chineham, Basingstoke, HampshireRG24 8EP, United Kingdom	EU/1/04/295/001	29.3.2010
26.3.2010	Xiliarx	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/486/001-011	30.3.2010

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30.3.2010	Aclasta	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/05/308/001-002	1.4.2010
30.3.2010	Actos	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, London WC2B 4AE, United Kingdom	EU/1/00/150/001-024	1.4.2010
30.3.2010	Afinitor	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/538/001-008	1.4.2010
30.3.2010	Celvapan	Baxter AG Industriestraße 67, A-1221 Wien, Österreich	EU/1/08/506/001	1.4.2010
30.3.2010	Clopidogrel Mylan	Mylan S.A.S 117 allée des Parcs, 69800 Saint Priest, France	EU/1/09/559/001-016	1.4.2010
30.3.2010	Evicel	OMRIX biopharmaceuticals S.A. / N.V. 200 Chaussée de Waterloo / Waterloosesteenweg 200, B-1640 Rhode-St-Genèse / B-1640 Sint-Genesius-Rode, Belgique / België	EU/1/08/473/001-003	1.4.2010
30.3.2010	Extavia	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/454/001-002 EU/1/08/454/005-007	1.4.2010
30.3.2010	Glubrava	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, LondonWC2B 4AE, United Kingdom	EU/1/07/421/001-009	1.4.2010
30.3.2010	Glustin	Takeda Global Research and Development Centre (Europe) Ltd 61 Aldwych, LondonWC2B 4AE, United Kingdom	EU/1/00/151/001-024	1.4.2010
30.3.2010	INCRELEX	Ipsen Pharma 65, quai Georges Gorse, 92100 Boulogne-Billancourt, France	EU/1/07/402/001	1.4.2010

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30.3.2010	Intelence	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België	EU/1/08/468/001	1.4.2010
30.3.2010	Kaletra	Abbott Laboratories Limited Abbott House, VanwallBusinessPark, Vanwall Road, Maidenhead, Berkshire SL 6 4XE, United Kingdom	EU/1/01/172/004-007	31.3.2010
30.3.2010	Levemir	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/04/278/010-011	6.4.2010
30.3.2010	Lucentis	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/06/374/001	1.4.2010
30.3.2010	Rasilez	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/405/001-040	31.3.2010
30.3.2010	RoActemra	Roche Registration Limited 6 Falcon Way, ShirePark, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/08/492/001-006	1.4.2010
30.3.2010	Rotarix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, Rixensart, B-1330 Belgique	EU/1/05/330/001-011	1.4.2010
30.3.2010	RotaTeq	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, Lyon 69007, France	EU/1/06/348/001-002	1.4.2010
30.3.2010	Xolair	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/05/319/001-010	31.3.2010
6.4.2010	Retacrit	HOSPIRA Enterprises B.V. Taurusavenue 19-21, 2132 LS HOOFDDORP, Nederland	EU/1/07/431/001-025	14.4.2010
6.4.2010	Silapo	STADA Arzneimittel AG Stadastrasse 2-18, 61118 Bad Vilbel, Deutschland	EU/1/07/432/001-022	9.4.2010
9.4.2010	Avaglim	SmithKline Beecham Ltd. 980 Great West Road, Brentford, Middlesex, TW8 9GS United Kingdom	EU/1/06/349/001-010	13.4.2010
9.4.2010	Ketek	Aventis Pharma S.A. 20 avenue Raymond Aron, F-92160 Antony, France	EU/1/01/191/001-005	13.4.2010

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9.4.2010	Viread	Gilead Sciences International Limited Cambridge CB21 6GT United Kingdom	EU/1/01/200/001-002	13.4.2010
15.4.2010	Firdapse	EUSA Pharma SAS 3 Allée des Séquoias, Limonest 69760, FRANCE	EU/1/09/601/001	20.4.2010
19.4.2010	Ifirmasta	KRKA, d.d., Novo mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/08/480/001-018	23.4.2010
22.4.2010	Sildenafil Teva	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht, Nederland	EU/1/09/584/001-018	26.4.2010
22.4.2010	Tracleer	ActelionRegistration Ltd BSI Building 13th Floor, 389 Chiswick High Road, LondonW4 4AL, United Kingdom	EU/1/02/220/001-006	26.4.2010
27.4.2010	Afinitor	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/09/538/001-008	29.4.2010
27.4.2010	Aldara	Meda AB Pipers väg 2A, Solna 170 73, Svërige	EU/1/98/080/001-002	29.4.2010
27.4.2010	Aldurazyme	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/03/253/001-003	29.4.2010
27.4.2010	Altargo	Glaxo Group Limited Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/390/001-004	29.4.2010
27.4.2010	Bridion	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/08/466/001-002	29.4.2010
27.4.2010	Doribax	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België	EU/1/08/467/001-002	29.4.2010
27.4.2010	Exelon	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/98/066/001-026	29.4.2010
27.4.2010	Focetria	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1 - Siena, Italia	EU/1/07/385/001-002 EU/1/07/385/004	29.4.2010
27.4.2010	Fuzeon	Roche Registration Limited 6 Falcon Way, ShirePark, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/03/252/001-003	29.4.2010

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27.4.2010	Kinzalkomb	Bayer Schering Pharma AG D-13342 Berlin, Deutschland	EU/1/02/214/001-015	29.4.2010
27.4.2010	MicardisPlus	Boehringer Ingelheim International GmbH Binger Strasse 173- D-55216 Ingelheim am Rhein, Deutschland	EU/1/02/213/001-023	3.5.2010
27.4.2010	Remicade	Centocor B.V. Einsteinweg 101, 2333 CB Leiden, Nederland	EU/1/99/116/001-005	29.4.2010
27.4.2010	RoActemra	Roche Registration Limited 6 Falcon Way, ShirePark, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/08/492/001-006	29.4.2010
27.4.2010	Tamiflu	Roche Registration Limited 6 Falcon Way, ShirePark, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/02/222/001-004	29.4.2010
27.4.2010	Tarceva	Roche Registration Limited 6 Falcon Way, ShirePark, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/05/311/001-003	29.4.2010
27.4.2010	Taxotere	Aventis Pharma S.A. 20 avenue Raymond Aron, F-92165 Antony Cedex, France	EU/1/95/002/001-005	29.4.2010
27.4.2010	Tyverb	Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/440/001-002	29.4.2010
27.4.2010	Velcade	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/04/274/001-002	29.4.2010
27.4.2010	Vimpat	UCB Pharma SA. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef, 60, Brussel 1070, België	EU/1/08/470/014-015	29.4.2010
29.4.2010	Aclasta	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/05/308/001-002	3.5.2010
29.4.2010	Arava	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/99/118/001-010	3.5.2010
29.4.2010	Ceplene	EpiCept GmbH Goethestrasse 4, D-80336 München, Deutschland	EU/1/08/477/001	3.5.2010
29.4.2010	Clopidogrel Winthrop	Sanofi-Aventis 174, avenue de France, F-75013 Paris, France	EU/1/08/465/001-020	3.5.2010

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29.4.2010	Epivir	Glaxo Group Ltd. Greenford Road, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/96/015/001-005	4.5.2010
29.4.2010	Focetria	Novartis Vaccines and Diagnostics S.r.l. Via Fiorentina, 1 - Siena, Italia	EU/1/07/385/001-002 EU/1/07/385/004	3.5.2010
29.4.2010	Humira	Abbott Laboratories Limited Abbott House, VanwallBusinessPark, Vanwall Road, Maidenhead, Berkshire SL 6 4XE, United Kingdom	EU/1/03/256/001-010	4.5.2010
29.4.2010	Insulatard	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/233/001-017	3.5.2010
29.4.2010	Intelence	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België	EU/1/08/468/001	3.5.2010
29.4.2010	Iscover	Bristol-MyersSquibbPharma EEIG Uxbridge BusinessPark, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/98/070/001a-001b EU/1/98/070/002a-002b EU/1/98/070/003a-003b EU/1/98/070/004a-004b EU/1/98/070/005a-005b EU/1/98/070/006a-006b EU/1/98/070/007a-007b EU/1/98/070/008-010 EU/1/98/070/011a-011b EU/1/98/070/012	4.5.2010
29.4.2010	Kepivance	BiovitrumAB (publ) SE-112 76 Stockholm, Sverige	EU/1/05/314/001	3.5.2010
29.4.2010	Lyrica	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/04/279/001-043	4.5.2010
29.4.2010	Mircera	Roche Registration Limited 6 Falcon Way, ShirePark, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/07/400/001-024	4.5.2010
29.4.2010	NeoRecormon	Roche Registration Limited 6 Falcon Way, ShirePark, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/97/031/019-046	4.5.2010
29.4.2010	Plavix	Sanofi Pharma Bristol-Myers Squibb SNC 174 avenue de France - 75013 Paris, France	EU/1/98/069/001a-001b EU/1/98/069/002a-002b EU/1/98/069/003a-003b EU/1/98/069/004a-004b EU/1/98/069/005a-005b EU/1/98/069/006a-006b EU/1/98/069/007a-007b EU/1/98/069/008-010 EU/1/98/069/011a-011b EU/1/98/069/012	3.5.2010

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29.4.2010	PritorPlus	Bayer Schering Pharma AG 13342 Berlin, Deutschland	EU/1/02/215/001-021	3.5.2010
29.4.2010	Prometax	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/98/092/001-026	4.5.2010
29.4.2010	Protaphane	Novo Nordisk A/S Novo Allé, DK-2880 Bagsvaerd, Danmark	EU/1/02/234/001-017	3.5.2010
29.4.2010	Tygacil	Wyeth Europa Ltd. Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/06/336/001	3.5.2010
29.4.2010	Tyverb	Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/440/001-002	3.5.2010
29.4.2010	Vectibix	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/07/423/001-003	3.5.2010
5.5.2010	Aloxi	Helsinn Birex Pharmaceuticals Ltd Damastown, Mulhuddart, Dublin 15, Republic of Ireland	EU/1/04/306/001-003	7.5.2010
5.5.2010	BeneFIX	Wyeth Europa Ltd. Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/97/047/001-007	7.5.2010
5.5.2010	Bondenza	Roche Registration Limited 6 Falcon Way, ShirePark, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/03/266/003-006	7.5.2010
5.5.2010	Bonviva	Roche Registration Limited 6 Falcon Way, ShirePark, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/03/265/003-006	7.5.2010
5.5.2010	Celsentri	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/418/001-010	7.5.2010
5.5.2010	Docetaxel Winthrop	Aventis Pharma S.A. 20 avenue Raymond Aron, F-92165 Antony Cedex, France	EU/1/07/384/001-005	7.5.2010
5.5.2010	Enbrel	Wyeth Europa Limited Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 0PH, United Kingdom	EU/1/99/126/001-021	7.5.2010
5.5.2010	Kiovig	Baxter AG Industriestraße 67, A - 1221 Wien, Österreich	EU/1/05/329/001-006	7.5.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
5.5.2010	Lantus	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/134/001-037	7.5.2010
5.5.2010	Optisulin	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/133/001-032	7.5.2010
5.5.2010	PegIntron	Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/00/131/001-050	7.5.2010
5.5.2010	Silgard	Merck Sharp & Dohme Ltd Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/06/358/001-021	7.5.2010
5.5.2010	Sprycel	Bristol-MyersSquibbPharma EEIG Uxbridge BusinessPark, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/06/363/001-011	7.5.2010
5.5.2010	Tyverb	Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/440/001-003	7.5.2010
5.5.2010	ViraferonPeg	Schering Plough Europe Rue de Stalle, 73, 1180 Bruxelles, Belgique - Stallestraat, 73 - 1180 Brussel, België	EU/1/00/132/001-050	7.5.2010
5.5.2010	Visudyne	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/00/140/001	7.5.2010
10.5.2010	Atripla	Bristol-Myers Squibb and Gilead Sciences Limited IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland	EU/1/07/430/001-002	12.5.2010
10.5.2010	Combivir	Glaxo Group Ltd. Greenford Road, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/98/058/001-002	12.5.2010
10.5.2010	Infanrix hexa	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, Rixensart, B-1330 Belgique	EU/1/00/152/001-020	12.5.2010
10.5.2010	Optimark	Covidien Deutschland GmbH Gewerbepark 1, Neustadt/Donau 93333, Deutschland	EU/1/07/398/001-014	12.5.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
10.5.2010	Orgalutran	N.V. Organon P.O. Box 20, Kloosterstraat 6, 5340 BH Oss, Nederland	EU/1/00/130/001-002	12.5.2010
10.5.2010	Ranexa	Menarini International Operations Luxembourg S.A. 1, Avenue de la Gare, L-1611 Luxembourg, Luxembourg	EU/1/08/462/001-012	12.5.2010
10.5.2010	Tysabri	Elan Pharma International Ltd. Monksland, Athlone, County Westmeath, Ireland	EU/1/06/346/001	12.5.2010
10.5.2010	Xeristar	Boehringer Ingelheim International GmbH Binger Strasse 173-D-55216 Ingelheim am Rhein, Deutschland	EU/1/04/297/001-008	12.5.2010
10.5.2010	Ziagen	Glaxo Group Ltd. Greenford Road, Greenford, Middlesex UB6 0NN United Kingdom	EU/1/99/112/001-002	12.5.2010
12.5.2010	Aclasta	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/05/308/001-002	18.5.2010
12.5.2010	Gardasil	Sanofi Pasteur MSD, SNC 8, rue Jonas Salk, 69007 Lyon, France	EU/1/06/357/001-021	18.5.2010
12.5.2010	Kuvan	Merck KGaA Frankfurter Straße 250, 64293 Darmstadt, Deutschland	EU/1/08/481/001-003	18.5.2010
12.5.2010	Olazax	GlenmarkPharmaceuticals s.r.o. City Tower, Hvězdova 1716/2b, 140 78 Praha 4, Česká republika	EU/1/09/597/001-005	18.5.2010
26.5.2010	Avandia	SmithKline Beecham Ltd. 980 Great West Road, Brentford, Middlesex, TW8 9GS United Kingdom	EU/1/00/137/002-018	28.5.2010
26.5.2010	Cyanokit	Merck Santé s.a.s. 37, rue Saint-Romain, 69379 Lyon Cedex 08, France	EU/1/07/420/001	28.5.2010
26.5.2010	Kivexa	Glaxo Group Ltd Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/04/298/001-003	28.5.2010
26.5.2010	Myocet	Cephalon Europe 5 Rue Charles Martigny, Maisons Alfort 94700, France	EU/1/00/141/001	28.5.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
26.5.2010	Olanzapine Glenmark	Glenmark Generics (Europe) Limited Laxmi House, 2-B Draycott Avenue, Kenton, Harrow, Middlesex HA3 OBU, United Kingdom	EU/1/09/587/001-017	1.6.2010
26.5.2010	Olanzapine Glenmark Europe	Glenmark Generics (Europe) Limited Laxmi House, 2-B Draycott Avenue, Kenton, Harrow, Middlesex HA3 OBU, United Kingdom	EU/1/09/588/001-012	1.6.2010
26.5.2010	Olazax Disperzi	GlenmarkPharmaceuticals s.r.o. City Tower, Hvězdova 1716/2b, 140 78 Praha 4, Česká republika	EU/1/09/592/001-005	28.5.2010
26.5.2010	Prevenar	Wyeth-Lederle Vaccines S.A. Rue du Bosquet, 15 - 1348 Louvain-La-Neuve, Belgique	EU/1/00/167/001-008	28.5.2010
26.5.2010	Telzir	Glaxo Group Ltd. Greenford Road, Greenford, Middlesex UB6 0NN United Kingdom	EU/1/04/282/001-002	28.5.2010
26.5.2010	Trizivir	Glaxo Group Ltd. Greenford Road, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/00/156/002-004	28.5.2010
26.5.2010	Xagrid	ShirePharmaceutical Contracts Ltd Hampshire InternationalBusinessPark, Chineham, Basingstoke, HampshireRG24 8EP, United Kingdom	EU/1/04/295/001	28.5.2010
2.6.2010	Abraxane	Abraxis BioScience Limited Rosanne House, Parkway, WelwynGarden City, Herts, AL8 6HG, United Kingdom	EU/1/07/428/001	4.6.2010
2.6.2010	Avastin	Roche Registration Limited 6 Falcon Way, ShirePark, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/04/300/001-002	7.6.2010
2.6.2010	Bridion	N.V. Organon Kloosterstraat 6, 5349 AB Oss, Nederland	EU/1/08/466/001-002	4.6.2010
2.6.2010	Celsentri	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/418/001-010	4.6.2010
2.6.2010	Cervarix	GlaxoSmithKline Biologicals S.A. rue de l'Institut 89, 1330 Rixensart, Belgique	EU/1/07/419/001-012	4.6.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
2.6.2010	Circadin	RAD Neurim Pharmaceuticals EEC Limited One Forbury Square, The Forbury, Reading, BerkshireRG1 3EB, United Kingdom	EU/1/07/392/001-002	7.6.2010
2.6.2010	Erbitux	Merck KGaA Frankfurter Straße 250, 64271 Darmstadt, Deutschland	EU/1/04/281/001-005	7.6.2010
2.6.2010	Fertavid	SP Europe Rue de Stalle, 73 B-1180 Bruxelles, Belgique	EU/1/09/510/001-019	4.6.2010
2.6.2010	Humira	Abbott Laboratories Limited Abbott House, VanwallBusinessPark, Vanwall Road, Maidenhead, Berkshire SL 6 4XE, United Kingdom	EU/1/03/256/001-010	7.6.2010
2.6.2010	Intrinsa	Warner Chilcott Pharmaceuticals UK Ltd Whitehall Lane, Egham, Surrey TW20 9NW, United Kingdom	EU/1/06/352/001-003	4.6.2010
2.6.2010	Prezista	Janssen-Cilag International NV Turnhoutseweg, 30 - 2340 Beerse - België	EU/1/06/380/001-005	4.6.2010
2.6.2010	Rasilez	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/07/405/001-040	4.6.2010
2.6.2010	Rebif	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/98/063/001-017	4.6.2010
2.6.2010	Renagel	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/99/123/005-013	7.6.2010
2.6.2010	Stalevo	Orion Corporation Orionintie 1, FIN-02200 Espoo, Suomi	EU/1/03/260/001-033	4.6.2010
2.6.2010	Velcade	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/04/274/001-002	4.6.2010
2.6.2010	Vimpat	UCB Pharma SA. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef, 60, Brussel 1070, België	EU/1/08/470/001-017	7.6.2010
2.6.2010	Zavesca	ActelionRegistration Ltd BSI Building 13th Floor, 389 Chiswick High Road, London W4 4AL, United Kingdom	EU/1/02/238/001	4.6.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
4.6.2010	DepoCyte	Pacira Limited West Forest Gate, Wellington Road, Wokingham, Berkshire, RG40 2AQ, United Kingdom	EU/1/01/187/001	8.6.2010
4.6.2010	Metalyse	Boehringer Ingelheim International GmbH Binger Strasse 173-D-55216 Ingelheim am Rhein, Deutschland	EU/1/00/169/004-006	8.6.2010
4.6.2010	Mircera	Roche Registration Limited 6 Falcon Way, ShirePark, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/07/400/001-024	8.6.2010
4.6.2010	Nymusa	CHIESI FARMACEUTICI SpA Via Palermo 26/A, I-43100 Parma, ITALIA	EU/1/09/528/001-002	8.6.2010
4.6.2010	Rasilez HCT	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/08/491/001-080	8.6.2010
4.6.2010	RoActemra	Roche Registration Limited 6 Falcon Way, ShirePark, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/08/492/001-006	8.6.2010
4.6.2010	Toviaz	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/07/386/001-018	8.6.2010
4.6.2010	Zerit	Bristol-MyersSquibbPharma EEIG Uxbridge BusinessPark, Sanderson Road, Uxbridge UB8 1DH, United Kingdom	EU/1/96/009/001-009	8.6.2010
8.6.2010	Lyrica	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/04/279/001-044	10.6.2010
10.6.2010	Comtan	Novartis Europharm Limited Wimblehurst Road, Horsham, West Sussex RH12 5AB, United Kingdom	EU/1/98/081/001-004	14.6.2010
10.6.2010	Comtess	Orion Corporation Orionintie 1, FIN-02200 Espoo, Suomi	EU/1/98/082/001-003 EU/1/98/082/005	14.6.2010
10.6.2010	ellaOne	Laboratoire HRA Pharma 15, rue Béranger, 75003 Paris, France	EU/1/09/522/001	14.6.2010
10.6.2010	Mirapexin	Boehringer Ingelheim International GmbH Binger Strasse 173-D-55216 Ingelheim am Rhein, Deutschland	EU/1/97/051/001-006 EU/1/97/051/009-033	15.6.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
10.6.2010	Opgenra	Howmedica International S. de R. L. Raheen Business Park, Limerick, Ireland	EU/1/08/489/001-002	15.6.2010
10.6.2010	Pergoveris	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/07/396/001-003	14.6.2010
10.6.2010	Vasovist	TMC Pharma Services Ltd Eversley, Hampshire, RG27 0NT, United Kingdom	EU/1/05/313/001-009	14.6.2010
14.6.2010	Lyrica	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/1/04/279/001-044	16.6.2010
14.6.2010	Sifrol	Boehringer Ingelheim International GmbH Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland	EU/1/97/050/001-006 EU/1/97/050/009-033	17.6.2010
17.6.2010	ATryn	GTC Biotherapeutics UK Limited 10 Norwich Street, London EC4A 1BD, United Kingdom	EU/1/06/355/001-003	21.6.2010
17.6.2010	Luveris	Merck Serono Europe Limited 56, Marsh Wall, London E14 9TP, United Kingdom	EU/1/00/155/001-007	21.6.2010
17.6.2010	Mirapexin	Boehringer Ingelheim International GmbH Binger Strasse 173-D-55216 Ingelheim am Rhein, Deutschland	EU/1/97/051/001-006 EU/1/97/051/009-033	21.6.2010
17.6.2010	Onsenal	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/03/259/001-006	21.6.2010
17.6.2010	Tyverb	Glaxo Group Limited Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/07/440/001-003	21.6.2010

— **Withdrawal of a marketing authorization (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
29.4.2010	Agenerase	Glaxo Group Limited Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN, United Kingdom	EU/1/00/148/001-004	5.5.2010
26.5.2010	Duloxetine Boehringer Ingelheim	Boehringer Ingelheim International GmbH Binger Strasse 173 - D-55216 Ingelheim am Rhein, Deutschland	EU/1/08/471/003-005 EU/1/08/471/011-012	28.5.2010

— **Modification of a marketing authorization (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
15.3.2010	Aivlosin	ECO Animal Health Ltd 78 Coombe Road New Malden Surrey KT3 4QS United Kingdom	EU/2/04/044/001-002	17.3.2010
15.3.2010	Draxxin	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/2/03/041/004	17.3.2010
15.3.2010	Incurin	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/00/018/001	17.3.2010
15.3.2010	Masivet	AB Science S.A. 3 avenue George V, 75008 Paris, France	EU/2/08/087/001-002	17.3.2010
15.3.2010	Meloxivet	Janssen Pharmaceutica N.V. Turnhoutseweg 30, B-2340 Beerse, België	EU/2/07/077/001-005	17.3.2010
15.3.2010	SevoFlo	Abbott Laboratories Limited Abbott House, VanwallBusinessPark, Vanwall Road, Maidenhead, Berkshire SL6 4XE, UNITED KINGDOM	EU/2/02/035/007	17.3.2010
16.3.2010	Rabigen SAG2	VIRBAC S.A. 1ère Avenue 2065 m L.I.D. - 06516 Carros - France	EU/2/00/021/001-002	19.3.2010
22.3.2010	Purevax FeLV	Merial 29 Avenue Tony Garnier, 69007 Lyon, France	EU/2/00/019/005-007	24.3.2010
23.3.2010	Ibraxion	Merial 29 Avenue Tony Garnier, 69007 Lyon, France	EU/2/99/017/001-006	23.3.2010
23.3.2010	Loxicom	Norbrook Laboratories Limited Station Works, Newry, Co. Down, BT35 6JP, United Kindgom	EU/2/08/090/001-009	25.3.2010
26.3.2010	Meloxidyl	CEVA SANTE ANIMALE 10 avenue de la Ballastière, 33500 Libourne, France	EU/2/06/070/001-007	30.3.2010
30.3.2010	Acticam	Omnipharm Ltd Suite 3, 24 High Street, Ruddington, Nottingham, NG11 6EA, United Kingdom	EU/2/08/088/001-004	1.4.2010
9.4.2010	Slentrol	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/2/07/071/001-003	13.4.2010

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
27.4.2010	Vaxxitek HVT+ IBD	Merial 29 Avenue Tony Garnier, 69007 Lyon, France	EU/2/02/032/001-002	29.4.2010
29.4.2010	Trocoxil	Pfizer Limited Ramsgate Road, Sandwich, Kent, CT13 9NJ United Kingdom	EU/2/08/084/001-005	4.5.2010
26.5.2010	Ibaflin	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/00/022/001a-001b EU/2/00/022/002a-002b EU/2/00/022/003a-003b EU/2/00/022/004a-004b EU/2/00/022/005-017	28.5.2010
26.5.2010	Naxcel	Pfizer Ltd Ramsgate Road, Sandwich, Kent CT 13 9NJ, United Kingdom	EU/2/05/053/001-003	28.5.2010
2.6.2010	Metacam	Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim am Rhein, Deutschland	EU/2/97/004/026 EU/2/97/004/033-034	4.6.2010
10.6.2010	Flexicam	Dechra Veterinary Products A/S Mekuvej 9, 7171 Uldum, Danmark	EU/2/06/058/001-004	14.6.2010

— **Withdrawal of a marketing authorization (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)**

Date of th e decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
14.6.2010	Pruban	Intervet International B.V. Wim de Körverstraat 35, 5831 AN Boxmeer, Nederland	EU/2/00/024/001	16.6.2010

Anyone wishing to consult the public assessment report on the medicinal products in question and the decisions relating thereto is invited to contact:

The European Medicines Agency

7, Westferry Circus, Canary Wharf

UK - LONDON E14 4H

Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 March 2010 to 30 June 2010

[Decisions taken pursuant to Article 34 of Directive 2001/83/CE [1] or Article 38 of Directive 2001/82/CE [2]]

(2010/C 258/02)

— Issuing, maintenance or modification of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	MemberState concerned	Date of notification
2.6.2010	Clopidogrel Orion	See annex I	See annex I	3.6.2010
10.6.2010	Colistin sulfate	See annex II	See annex II	11.6.2010
19.4.2010	Diovan (1219)	See annex III	See annex III	20.4.2010
15.3.2010	Lescol	See annex IV	See annex IV	17.3.2010
19.4.2010	Diovan (1220)	See annex V	See annex V	20.4.2010
10.6.2010	Losec and associated names	See annex VI	See annex VI	14.6.2010
15.4.2010	Protium and associated names	See annex VII	See annex VII	16.4.2010
26.3.2010	Cevazuril 50 mg/ml oral suspension for piglets	See annex VIII	See annex VIII	30.3.2010
30.3.2010	Pantoprazole Bluefish	See annex IX	See annex IX	31.3.2010
30.3.2010	Pantoprazole Olinka (1169)	See annex X	See annex X	31.3.2010
30.3.2010	Pantoprazole Olinka (1170)	See annex XI	See annex XI	31.3.2010
26.5.2010	Valproate-ratiopharm chrono 300/500 mg Retardtabletten	See annex XII	See annex XII	27.5.2010
4.6.2010	Clopidogrel Teva and associated names	See annex XIII	See annex XIII	7.6.2010
14.6.2010	Doxycycline hyclate	See annex XIV	See annex XIV	15.6.2010
10.6.2010	Opgenra	Howmedica International S. de R. L., RaheenBusiness-Park, Limerick, Ireland	This Decision is addressed to the Member States	14.6.2010
10.5.2010	Tysabri	Elan Pharma International Ltd., Monksland, Athlone, County Westmeath, Ireland	This Decision is addressed to the Member States	11.5.2010
10.5.2010	Ranexa	Menarini International Operations Luxembourg S.A., 1, Avenue de la Gare, L-1611 Luxembourg, Luxembourg	This Decision is addressed to the Member States	12.5.2010
11.3.2010	Revolade	GlaxoSmithKline Trading Services Limited, 6900 CorkAirportBusinessPark, Kinsale Road, Cork, Ireland	This Decision is addressed to the Member States	12.3.2010
11.3.2010	Stelara	Janssen-Cilag International NV, Turnhoutseweg, 30 - 2340 Beerse - België	This Decision is addressed to the Member States	12.3.2010

[1] OJ L 311, 28.11.2001, p. 67.
[2] OJ L 311, 28.11.2001, p. 1.

— **Refusal of a national marketing authorization**

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	MemberState concerned	Date of notification
27.4.2010	Vasotop	See annex XV	See annex XV	28.4.2010

— **Suspension of a national marketing authorization**

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	MemberState concerned	Date of notification
3.3.2010	Sibutramine	See annex XVI	See annex XVI	4.3.2010
14.6.2010	Dextropropoxyphene	See annex XVII	See annex XVII	15.6.2010

— **Revocation of a national marketing authorization**

Date of the decision	Name(s) of the medicinal product	Holder(s) of the marketing authorization	MemberState concerned	Date of notification
14.6.2010	Dextropropoxyphene	See annex XVIII	See annex XVIII	15.6.2010
14.6.2010	benfluorex	See annex XIX	See annex XIX	15.6.2010

ANNEX I

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE MEDICINAL PRODUCT, ROUTE OF ADMINISTRATION, APPLICANT IN THE MEMBER STATES

MemberState EU/EEA	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Czech Republic	Orion Corporation Orionintie 1, FI-02200 Espoo Finland	Clopidogrel Orion	75 mg	Film-coated tablet	Oral use
Denmark	Orion Corporation Orionintie 1, FI-02200 Espoo Finland	Clopidogrel Orion	75 mg	Film-coated tablet	Oral use
Finland	Orion Corporation Orionintie 1, FI-02200 Espoo Finland	Clopidogrel Orion	75 mg	Film-coated tablet	Oral use
Germany	Orion Corporation Orionintie 1, FI-02200 Espoo Finland	Clopidogrel Orion	75 mg	Film-coated tablet	Oral use
Latvia	Orion Corporation Orionintie 1, FI-02200 Espoo Finland	Clopidogrel Orion	75 mg	Film-coated tablet	Oral use
Lithuania	Orion Corporation Orionintie 1, FI-02200 Espoo Finland	Clopidogrel Orion	75 mg	Film-coated tablet	Oral use
Norway	Orion Corporation Orionintie 1, FI-02200 Espoo Finland	Clopidogrel Orion	75 mg	Film-coated tablet	Oral use
Slovak Republic	Orion Corporation Orionintie 1, FI-02200 Espoo Finland	Clopidogrel Orion	75 mg	Film-coated tablet	Oral use
Sweden	Orion Corporation Orionintie 1, FI-02200 Espoo Finland	Clopidogrel Orion	75 mg	Film-coated tablet	Oral use

ANNEX II

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE VETERINARY MEDICINAL PRODUCTS, ANIMAL SPECIES, ROUTE OF ADMINISTRATION, WITHDRAWAL PERIOD AND APPLICANTS/MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
Austria	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Colivet 2 000 000 IU/ml, Konzentrat für eine orale Lösung für Schweine und Geflügel	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Pigs Poultry	For three consecutive days in drinking water	Pigs: 100 000 IU/kg bw/day in two equally divided doses per day Poultry: 75 000 IU/kg bw/day	Pigs: meat: 1 day Broilers and laying hens: 1 day Other poultry: 7 days Eggs: Zero days
Belgium	Divasa-FarmavicS.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	COLIPLUS 2 000 000 IU/ml concentrate for oral solution for use in drinking water for cattle, sheep, swine and chickens	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product/1 tone bw/day for 3 consecutive days.	Calves, Lambs: meat and offals 7 days. Pigs: meat and offals 1 day. Broiler and laying, hens: 1 day. Eggs: Zero days. Other Poultry: meat and offals - 7 days. Eggs: Zero days
Bulgaria	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Colivet oral solution	Colistin sulfate	2 MIU/ml	Oral solution	Pigs Poutry	Orally: 3 days	Pigs: 100 000 IU/kg b.w./day Poultry: 75 000 IU/kg/b.w./day	Meat: 1 days Eggs: Zero days

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
Bulgaria	Divasa-FarmavicS.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	COLIPLUS 2 000 000 IU/ml concentrate for oral solution for use in drinking water for cattle, sheep, swine and chickens	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product/1 tone bw/day for 3 consecutive days.	Calves, Lambs: meat and offals 7 days. Pigs: meat and offals 1 day. Broiler and laying, hens: 1 day. Eggs: Zero days. Other poultry: meat and offals: 7 days. Eggs: Zero days
Cyprus	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	COLIVET 2 000 000 IU/ml	Colistin sulfate	2 MIU/ml	Oral Solution	Pigs Birds	Pigs: 100 000 IU/kg/day Poultry: 75 000 IU/kg/day	Pigs: 0,50 ml of product per 10 kg of body weight per day for 3 consecutive days Poultry: 37,5 ml of product per tonne of body weight per day for 3 consecutive days.	Meat and offal: Pigs: 1 day Broilers and laying hens: 1 day Other poultry: 7 days Eggs: Zero days
Czech Republic	Ceva Animal Health Slovakia s.r.o. Račianska 77 831 02 Bratislava SLOVAK REPUBLIC	Colivet Sol.	Colistin sulfate	2 MIU/ml	Oral solution	Pigs Chicken (broilers)	Daily.Orally	Broilers: 75 000 IU colistin per kg of bodyweight (i.e. 0,37 ml of product per 10 kg of bodyweight per day for 3-5 days via drinking water) Pigs: 50 000 IU colistin per kg of bodyweight per 12 hrs (i.e. 0,25 ml of product per 10 kg of bodyweight per 12 hrs for 3-5 days via drinking water or milk replacement).	Meat and offal: Pigs and chicken broilers: 2 days. Do not use in laying hens producing eggs for human consumption.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
Denmark	Ceva Animal Health A/S Andkærvej 19 7100 Vejle DENMARK	Colivet	Colistin sulfate	2 MIU/ml	Oral Solution	Pigs	Daily.Orally	100 000 IU colistin / kg body weight daily for 3-5 days.	1 day
Denmark	Divasa-FarmavicS.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	COLIPLUS 2 000 000 IU/ml concentrate for oral solution for use in drinking water for cattle, sheep, swine and chickens	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product/1 tone bw/day for 3 consecutive days.	Meat and offal: 7 days Eggs: Zero days
France	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	COLISTINE CEVA 2 MUI/ml concentré pour solution buvable pour porcins et volailles	Colistin sulfate	2 MIU/ml	Oral solution	Pigs Poultry	3 days	Pigs: 100 000 IU of colistin per kg body weight per day for 3 consecutive days by oral route, i.e. 0,50 ml of product per 10 kg of body weight per day for 3 consecutive days. Poultry: 75 000 IU of colistin per kg body weight per day for 3 consecutive days by oral route, i.e. 37,5 ml of product per tonne of body weight per day for 3 consecutive days.	Meat and offals: Pigs: 1 day Chickens and egg laying hens: 1 day Other poultry: 7 days Eggs: Zero days

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
France	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	COLIVET SOLUTION	Colistin sulfate	2 MIU/ml	Oral solution	Calves Lambs Pigs Poultry	3 days	Calves, Lambs, Porcine: 100 000 UI/kg/day Poultry: 75 000 UI/kg/day	Meat and offals: Calves and lambs: 7 days Porcine: 1 day Chicken and egg-laying hens: 1 day Other birds: 7 days Eggs: Zero days
France	Coophavet S.A.S Saint Herblion, B.P. 70089 44153 Ancenis Cedex FRANCE	COFACOLI SOLUTION	Colistin sulfate	2 MIU/ml	Oral solution	Calves Lambs Pigs Poultry	3 days	Calves, Lambs, Porcine: 100 000 UI/kg/day Poultry: 75 000 UI/kg/day	Meat and offals: 7 days. Eggs: Zero days
France	Franvet Zone industrielle d'Etriche Route d'Avire, BP 103 49500 Segré Cedex FRANCE	MILICOLI	Colistin sulfate	2 MIU/ml	Oral solution	Calves Lambs Pigs Poultry	3 days	Calves, Lambs, Porcine: 100 000 UI/kg/day Poultry: 75 000 UI/kg/day	Meat and offals:Porcine, calves, chicken: 1 day Lamb and poultry other than chicken: 7 days Eggs: Zero days
France	Laboratoires Biové 3 rue de Lorraine 62510 Arques FRANCE	ACTI COLI 2 MUI/ML	Colistin sulfate	2 MIU/ml	Oral solution	Calves Lambs Pigs Poultry	3 days	Calves, Lambs, Porcine: 100 000 UI/kg/day Poultry: 75 000 UI/kg/day	Meat and offals: Pigs: 0 days Chicken: 1 day Other poultry: 7 days Calves: 2 days Lamb: 7 days Eggs: Zero days
France	Laprovet 2 Chemin de la Milletière B.P. 67562 37075 Tours Cedex 2 FRANCE	COLISTINE SOLUTION E.A.F.	Colistin sulfate	2 MIU/ml	Oral solution	Calves Lambs Pigs Poultry	3 days	Calves, Lambs, Porcine: 100 000 UI/kg/day Poultry: 75 000 UI/kg/day	Meat and offals: 7 days. Eggs: Zero days

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
France	Sogeval Zone Industrielle des Touches 200, avenue de Mayenne B.P. 2227 53022 Laval Cedex 9 FRANCE	SOGECOLI 2 millions UI/ml solution buvable	Colistin sulfate	2 MIU/ml	Oral solution	Calves Lambs Pigs Poultry	3 days	Calves, Lambs, Porcine: 100 000 UI/kg/day Poultry: 75 000 UI/kg/day	Meat and offals: Pigs: 0 day Chicken: 1 day Other poultry: 7 days. Calves: 2 days. Lamb: 7 days Eggs: Zero days
France	Virbac S.A. 1ere Avenue 2065 M LID B.P. 27 06516 Carros Cedex FRANCE	COLISTINE SULFATE 2 MUI/ml buvable virbac	Colistin sulfate	2 MIU/ml	Oral solution	Calves Lambs Pigs Poultry	3 days	Calves, Lambs, Porcine: 100 000 UI/kg/day Poultry: 75 000 UI/kg/day	Meat and offals: 7 days. Eggs: Zero days
Germany	Divasa-FarmavicS.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	Coliplus	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product/1 tone bw/day for 3 consecutive days.	Meat and offal: 7 days Eggs: Zero days
Greece	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Colivet	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Pigs Poultry	Drinking water/per day	Pigs: 100 000 IU/Kg BW x 3 days Poultry:75 000 IU/Kg BW X 3 days	Pigs: 1 day Broilers and laying hens: 1 day Other poultry: 7 days Eggs: Zero days

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Greece	Divasa-FarmavicS.A. Ctra San Hipolito km 71 08503 Gurb-Vi c (Barcelona) SPAIN	COLISTIN 2 000 000 IU/ML/DIVASA- FARMANIC	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product/1 tone bw/day for 3 consecutive days.	Meat and offal: 7 days Eggs: Zero days
Hungary	Divasa-Farmavic S.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	COLIPLUS 2 000 000 IU/ml concentrate for oral solution for use in drinking water for cattle, sheep, swine and chickens	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product/1 tone bw/day for 3 consecutive days.	Meat and offal: 7 days Eggs: Zero days.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
Hungary	Coophavet S.A.S Saint Herblion, B.P. 70089 44153 Ancenis Cedex FRANCE	Cofacoli oral solution	Colistin sulfate	2 MIU/ml	Oral solution	Cattle (suckling calf) Pig Chicken	Calf, Pig: 0,25 ml product/10 kg bw twice daily for 3-4 days Chicken, Laying hen: 37,5 ml product/ton of living weight dissolved in drinking water for 3 days.	Calf, Pig: 50 000 IU/kg bw Broiler chicken, laying hen: 75 000 IU/kg bw/day.	Calf: 3 days Pig: 2 days Chicken and laying hen: 2 days Eggs: Zero days.
Ireland	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	COLISCOUR 2 000 000 IU/ml, concentrate for oral solution, pigs, poultry	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Pigs Poultry	Daily for three consecutive days. Administration is by the oral route via drinking water.	Pigs: 100 000 IU of colistin per kg body weight per day i.e. 0,50 ml of product per 10 kg of body weight per day Poultry: 75 000 IU of colistin per kg body weight per day i.e. 37,5 ml of product per tonne of body weight per day	Pigs: Meat and offal: 1 day Broilers and laying hens: Meat and offal: 1 day Other poultry: Meat and offal: 7 days. Eggs: Zero days.
Italy	Divasa-FarmavicS.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	COLIPLUS 2 000 000 IU/ml concentrate for oral solution for use in drinking water for cattle, sheep, swine and chickens	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product/1 tone bw/day for 3 consecutive days.	Calves, Lambs: Meat and offals: 7 days. Pigs: Meat and offals: 1 day. Broiler and laying, hens: 1 day. Eggs: Zero days. Other Poultry: meat and offals: 7 days. Eggs: Zero days

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Latvia	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Colivet oral solution	Colistin sulfate	2 MIU/ml	Oral solution	Pigs Poultry	Oral use. Administration vis drinking water or milk or direct application by mouth. Twice a day for 3 to 5 consecutive days.	Chicken: 75 000 IU colistin per kg per day (0,37 ml of Colivet per 10 kg twice a day) Pig: 50 000 IU of colistin per kg twice a day(0,25 ml Colivet per 10 kg twice a day).	Edible tissues: 1 day Eggs: 1 day
Lithuania	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	COLIVET SOLUTION, geriamasis tirpalas	Colistin sulfate	2 MIU/ml	Oral solution	Pigs Poultry	With drinking water or milk powder. Orally via drinking water.	Pigs: 50 000 IU/kg of body weight, i.e. 0,25 ml Colivet Solution per 10 kg of body weight twice daily for 3-5 consecutive days. Poultry: 75 000 IU/kg of body weight per day, i.e. approximately 0,37 ml of Colivet Solution per 10 kg of body weight per day for 3-5 consecutive days.	Meat: 1 day. Poultry: meat and eggs: 1 day
Lithuania	Divasa-FarmavicS.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	Colistop, geriamasis tirpalas	Colistin sulfate	2 MIU/ml	Oral solution	Pigs Poultry (broilers chickens)	For oral administration, usually via drinking water. For 3 consecutive days.	Pigs: 102500 IU/kg BW every 12 hours, for 3 days (equivalent to 0,5 ml of Colistop Solution/10 kg BW every 12 hours, for 3 consecutive days). Broilers chickens: 123 000 IU/kg BW/day, for 3 days (equivalent to 0,06 ml of Colistop Solution/kg BW/day, for 3 consecutive days)	Fattening pigs: 2 days. Broilers chickens: 7 days

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Lithuania	Divasa-FarmavicS.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	COLIPLUS 2 000 000 IU/ml concentrate for oral solution for use in drinking water for cattle, sheep, swine and chickens	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product/1 tone bw/day for 3 consecutive days.	Calves, Lambs: Meat and offals: 7 days. Pigs: Meat and offals: 1 day. Broiler and laying, hens: 1 day. Eggs: Zero days. Other Poultry: Meat and offals: 7 days. Eggs: Zero days
Poland	Ceva Santé Animale Zone Industrielle La Ballastiere B.P. 126 33500 Libourne FRANCE	Colivet solution	Colistin sulfate	2 MIU/ml	oral solution	Pig Chickens	Administration via drinking water or milk. For 3-5 days	Chickens: 75 000 I.U. colistin/1 kg b.w./day for 3 - 5 days, (0,37 ml of product/10 kg b.w.twice daily for 3 - 5 days Pigs: 50 000 I.U. colistin/1 kg b.w./day for 3 - 5 days, (0,25 ml of product/10 kg b.w. twice daily for 3 - 5 days.	Meat and offal: 1 day Eggs: 1 day

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
Poland	DIVASA - FARMAVIC, S.A. Ctra. Sant Hipòlit, km 71 08503 GURB - VIC (Barcelona) Spain	Coliplus 2 000 000 IU/ml Concentrate for Oral Solution for use in drinking water for Cattle, Sheep, Swine and Chickens	Colistin (as colistin sulfate)	2 MIU/ml	Concentrate for oral solution for use in drinking water	Cattle (calves), sheep (lambs), swine and chickens	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product/1 tone bw/day for 3 consecutive days.	Meat and offal: 7 days Eggs: Zero days Not permitted for use in animals producing milk for human consumption
Portugal	Ceva Saúde Animal - Produtos Farmacêuticos e Farmacológicos, Lda Rua Doutor António Loureiro Borges, 9/9A - 9°A Miraflores 1495-131 Algés PORTUGAL	Colivet 2 000 000 UI/ml, concentrate for oral solution for pigs and birds	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Pigs Domestic birds	3 days	Swine: 100 000 UI/kg BW/day Birds: 75 000 UI/kg BW/day	Meat and offal: Pigs: 1 day Broilers and laying hens: 1 day, Other birds: 7 days, Eggs: Zero days

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
Portugal	Divasa-FarmavicS.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	COLIPLUS 2 000 000 IU/ml concentrate for oral solution for use in drinking water for cattle, sheep, swine and chickens	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product/1 tone bw/day for 3 consecutive days.	Calves, Lambs: Meat and offals: 7 days. Pigs: Meat and offals: 1 day. Broiler and laying, hens: 1 day. Eggs: Zero days. Other Poultry: Meat and offals: 7 days. Eggs: Zero days
Romania	CENAVISA, S.A. Camí Pedra Estela S/N 43205 Reus SPAIN	ENTEROBAS SOLUCION	Colistin sulfate	2 MIU/ml	oral solution	Calves Pigs Poultry	Oral administration (drinking water or as milk replacer) treatment: 4-5 days	Calves and Pigs: 100 000 UI/kg b.w/day equivalent to 0,5 ml/10 kg b.w./day Poultry: 100 000 UI/kg b.w./day equivalent to 0,5 ml/litre drinking water/day	Meat: calves - 2 days Pigs: 5 days Poultry: 3 days Eggs: do not use in animals from which eggs are produced for human consumption
Romania	CEVA SANTE ANIMALE ROMANIA SRL 5 Chindiei, sector 4 040185 Bucharest ROMANIA	COLIVET SOLUTION	Colistin sulfate	2 MIU/ml	Oral solution	Pigs Poultry	Oral administration (drinking water) treatment: 3 consecutive days	Pigs: 100 000 I.U. of colistin (as sulfate) /1kg b.w. in two equally divided doses/day, i.e. 0,5 ml of product per 10 kg of body weight in two equally divided doses/day Poultry: 75 000 I.U. of colistin (as sulfate) /1kg b.w. per day, i.e. 37,5 ml of product per 1 tone of body weight/day	Meat and offal: pigs 1 day Broilers and layers: 1 day Eggs: Zero days

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
Romania	Divasa-Farmavic S.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	COLIPLUS 2 000 000 IU/ml concentrate for oral solution for use in drinking water for cattle, sheep, swine and chickens	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product/1 tone bw/day for 3 consecutive days.	Meat and offal: 7 day Eggs: Zero days
Romania	Divasa-FarmavicS.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	COLIPLUS SOLUTION	Colistin sulfate	2 MIU/ml	Oral solution	Pigs, Broilers	Oral administration (drinking water) treatment: 3 days	Poultry: 0,03 ml/kg b.w/day Pigs: 0,5 ml/10 kg b.w. every 12 hours	Meat: 9 days
Romania	Franvet Zone industrielle d'Etriche Route d'Avire, BP 103 49500 Segré Cedex FRANCE	MILICOLI	Colistin sulfate	2 MIU/ml	Oral solution	Calves Lambs Pigs Poultry	Oral administration (drinking water or milk replacer) treatment: 3 - 4 days	Calves, Pigs and Lambs: 50 000 I.U./kg b.w. or 0,25 ml of product/10 kg b.w Poultry: 75 000 I.U./kg/day or 0,25 ml/1 litre water	Meat and offal: 7 days Eggs: Zero days
Romania	S.C. CRIDA PHARM S.R.L. Str. Stadionului nr. 1 Oltenita ROMANIA	COLICRID	Colistin sulfate	2 MIU/ml	Oral solution	Pigs Poultry	Oral administration (drinking water) treatment: 3 - 5 days	Pigs: 100 000 I.U. of colistin sulfate/1kg b.w./day, i.e. 0,05 ml of product/kg of body weight/day Poultry: 100 000 I.U. of colistin sulfate/1kg b.w./day, i.e. 0,05 ml of product/kg of body weight/day	Meat: pigs: 7 days Poultry: 3 days

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
Romania	Sogeval Zone Industrielle des Touches 200, avenue de Mayenne B.P. 2227 53022 Laval Cedex 9 FRANCE	SOGECOLI	Colistin sulfate	2 MIU/ml	Oral solution	Calves Lambs Poultry	Oral administration treatment: 3 - 4 days	Calves, Lamb: 50 000 I.U./kg b.w. or 0,25 ml/10 kg b.w. twice a day, morning and evening Poultry: 75 000 I.U./ kg b.w. daily or 0,25 ml/1 litre water	Meat: 7 days
Slovak Republic	Ceva Animal Health Slovakia, spol. s.r.o. Račianska 77 831 02 Bratislava SLOVAK REPUBLIC	COLIVET sol. ad us.vet.	Colistin sulfate	2 MIU/ml	Oral solution	Pigs, Chickens	3 - 5 days in drinking water, milk or direct administration	Pigs: 50 000 IU colistine sulfate/kg b.w. (0,25 ml product/10 kg b.w.) (2 times). Chickens: 75 000 IU colistine sulfate/kg b.w. (0,37 ml product/10 kg b.w.	Meat: 1 day. Eggs: 1 day.
Slovak Republic	Divasa-FarmavicS.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	COLI-PLUS 2 000 000 IU/ml koncentrát na perorálny roztok na použitie v pitnej vode pre hovädzí dobytok, ovce, ošípané a kurčatá	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product/1 tone bw/day for 3 consecutive days.	Calves, Lambs: Meat and offals: 7 days. Pigs: Meat and offals: 1 day. Broiler and laying, hens: 1 day. Eggs: Zero days. Other Poultry: Meat and offals: Zero days.
Spain	CEVA SALUD ANIMAL, S.A. Carabela La Niña nº 12 5ª planta 08017 Barcelona SPAIN	COLIVET 2 000 000 UI/ML	Colistin sulfate	2 MIU/ml	Oral solution	Pigs Birds	3 days. Orally	Pigs: 100 000 UI/Kgbw Birds: 75 000 UI/Kg bw	1 day

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
Spain	Divasa-FarmavicS.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	COLIPLUS SOLUCION	Colistin sulfate	2 MIU/ml	Oral solution	Pigs Birds (Chicken)	3 days. Orally	Pigs: 102 500 UI/Kg bw/12 hours Birds: 123 000 UI/Kg bw/12 hours	Pigs: 2 days Birds: 7 days
Spain	Divasa-FarmavicS.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	COLISTINA DIVASA 2 000 000 IU/ml concentrate for oral solution for use in drinking water for cattle, sheep, swine and chickens	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product/1 tone bw/day for 3 consecutive days.	Meat: 7 days Eggs: Zero days
The Netherlands	Divasa-FarmavicS.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	COLIPLUS 2 000 000 IU/ml concentrate for oral solution for use in drinking water for cattle, sheep, swine and chickens	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product/1 tone bw/day for 3 consecutive days.	Meat: 7 days Eggs: Zero days.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)
United Kingdom	Ceva Animal Health Ltd 90 The Broadway Chesham Buckinghamshire HP5 1EG UNITED KINGDOM	Colibird	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Poultry	For three consecutive days in drinking water	75 000 IU/kg bw/day	Meat: 7 days. Eggs: Zero days.
United Kingdom	Ceva Animal Health Ltd 90 The Broadway Chesham Buckinghamshire HP5 1EG UNITED KINGDOM	Coliscour, oral solution of colistin sulphate 2 MIU/ml	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Pigs	Twice daily for five consecutive days (via drinking water or direct oral administration)	50 000 IU/kg bw given twice daily	Meat and offal: 1 day
United Kingdom	Divasa-FarmavicS.A. Ctra San Hipolito km 71 08503 Gurb-Vic (Barcelona) SPAIN	Coliplus 2 000 000 IU/ml Concentrate for Oral Solution for use in drinking water for Cattle, Sheep, Swine and Chickens	Colistin sulfate	2 MIU/ml	Concentrate for oral solution	Calves Lambs Pigs Poultry	Calves, Lambs, Pigs, Poultry: for three consecutive days in drinking water.	Calves and Lambs: 100 000 IU of colistin / kg bw/day divided in two identical doses, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Pigs: 100 000 IU of colistin / kg bw/day, i.e. 0,50 ml of product/10 kg bw/day for 3 consecutive days. Poultry: 75 000 IU of colistin / kg bw/day, i.e. 37,5 ml of product/1 tone bw/day for 3 consecutive days.	Meat: 7 days Eggs: Zero days.

ANNEX III

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION AND MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Austria	Novartis Pharma GmbH Stella-Klein-Löw-Weg 17 A–1020 Wien (Tel: + 43-1–8665 70)	Diovan 40 mg Filmtabletten	40 mg	film-coated tablets	Oral Use
Austria	Novartis Pharma GmbH Stella-Klein-Löw-Weg 17 A–1020 Wien (Tel: + 43-1–8665 70)	Angiosan 40 mg Filmtabletten	40 mg	film-coated tablets	Oral Use
Austria	Novartis Pharma GmbH Stella-Klein-Löw-Weg 17 A–1020 Wien (Tel: + 43-1–8665 70)	Diovan 80 mg Filmtabletten	80 mg	film-coated tablets	Oral Use
Austria	Novartis Pharma GmbH Stella-Klein-Löw-Weg 17 A–1020 Wien (Tel: + 43-1–8665 70)	Angiosan 80 mg Filmtabletten	80 mg	film-coated tablets	Oral Use
Austria	Novartis Pharma GmbH Stella-Klein-Löw-Weg 17 A–1020 Wien (Tel: + 43-1–8665 70)	Diovan 160 mg Filmtabletten	160 mg	film-coated tablets	Oral Use
Austria	Novartis Pharma GmbH Stella-Klein-Löw-Weg 17 A–1020 Wien (Tel: + 43-1–8665 70)	Angiosan 160 mg Filmtabletten	160 mg	film-coated tablets	Oral Use
Austria	Novartis Pharma GmbH Stella-Klein-Löw-Weg 17 A–1020 Wien (Tel: + 43-1–8665 70)	Diovan 320 mg Filmtabletten	320 mg	film-coated tablets	Oral Use
Austria	Novartis Pharma GmbH Stella-Klein-Löw-Weg 17 A–1020 Wien (Tel: + 43-1–8665 70)	Angiosan 320 mg Filmtabletten	320 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Belgium	N.V. Novartis Pharma S.A. Medialaan 40, bus 1 B–1800 Vilvoorde (Tel: +32-2-246 16 11)	Diovane 40 mg	40 mg	film-coated tablets	Oral Use
Belgium	N.V. Novartis Pharma S.A. Medialaan 40, bus 1 B–1800 Vilvoorde (Tel: +32-2-246 16 11)	Diovane 80 mg	80 mg	film-coated tablets	Oral Use
Belgium	N.V. Novartis Pharma S.A. Medialaan 40, bus 1 B–1800 Vilvoorde (Tel: +32-2-246 16 11)	Diovane 160 mg	160 mg	film-coated tablets	Oral Use
Belgium	N.V. Novartis Pharma S.A. Medialaan 40, bus 1 B–1800 Vilvoorde (Tel: +32-2-246 16 11)	Diovane 320 mg	320 mg	film-coated tablets	Oral Use
Bulgaria	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Bulgaria	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Bulgaria	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Bulgaria	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use
Cyprus	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Cyprus	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Cyprus	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Cyprus	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use
Czech Republic	NOVARTIS s.r.o. Pharma Nagano III. U Nákladového nádraží 10 130 00 Praha 3 (Tel +420-2–2577 51 11)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Czech Republic	NOVARTIS s.r.o. Pharma Nagano III. U Nákladového nádraží 10 130 00 Praha 3 (Tel +420-2–2577 51 11)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Denmark	Novartis Healthcare A/S Lyngbyvej 172 DK–2100 København Ø (Tel: +45-39-16 84 00)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Denmark	Novartis Healthcare A/S Lyngbyvej 172 DK–2100 København Ø (Tel: +45-39-16 84 00)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Denmark	Novartis Healthcare A/S Lyngbyvej 172 DK–2100 København Ø (Tel: +45-39-16 84 00)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Denmark	Novartis Healthcare A/S Lyngbyvej 172 DK–2100 København Ø (Tel: +45-39-16 84 00)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use
Estonia	Novartis Finland OY Metsänneidonkuja 10 FIN–02130 Espoo (Tel: + 358-9–6133 22 11)	Diovan	40 mg	film-coated tablets	Oral Use
Estonia	Novartis Finland OY Metsänneidonkuja 10 FIN–02130 Espoo (Tel: + 358-9–6133 22 11)	Diovan	80 mg	film-coated tablets	Oral Use
Estonia	Novartis Finland OY Metsänneidonkuja 10 FIN–02130 Espoo (Tel: + 358-9–6133 22 11)	Diovan	160 mg	film-coated tablets	Oral Use
Estonia	Novartis Finland OY Metsänneidonkuja 10 FIN–02130 Espoo (Tel: + 358-9–6133 22 11)	Diovan	320 mg	film-coated tablets	Oral Use
Finland	Novartis Finland Oy Metsänneidonkuja 10 FIN–02130 Espoo (Tel: + 358-9–6133 22 11)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Finland	Novartis Finland Oy Metsänneidonkuja 10 FIN–02130 Espoo (Tel: + 358-9–6133 22 11)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Finland	Novartis Finland Oy Metsänneidonkuja 10 FIN–02130 Espoo (Tel: + 358-9–6133 22 11)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Finland	Novartis Finland Oy Metsänneidonkuja 10 FIN–02130 Espoo (Tel: + 358-9–6133 22 11)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
France	Novartis Pharma S.A.S. 2 and 4, rue Lionel Terray 92500 RUEIL-MALMAISON France (Tel: +33-1–5547 60 00)	Tareg 40 mg	40 mg	film-coated tablets	Oral Use
France	Novartis Pharma S.A.S. 2 and 4, rue Lionel Terray 92500 RUEIL-MALMAISON France (Tel: +33-1–5547 60 00)	Tareg 80 mg	80 mg	film-coated tablets	Oral Use
France	Novartis Pharma S.A.S. 2 and 4, rue Lionel Terray 92500 RUEIL-MALMAISON France (Tel: +33-1–5547 60 00)	Tareg 160 mg	160 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Cordinate 40 mg	40 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Provas 40 mg	40 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Cordinate 80 mg	80 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Provas 80 mg	80 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 160 mg protect	160 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Cordinate 160 mg	160 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Provas 160 mg	160 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 320 mg forte	320 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Cordinate 320 mg	320 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Provas 320 mg	320 mg	film-coated tablets	Oral Use
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis GR-144 51 Athens (Tel: +30-210-281 17 12)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis GR-144 51 Athens (Tel: +30-210-281 17 12)	Dalzad 40 mg	40 mg	film-coated tablets	Oral Use
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis GR-144 51 Athens (Tel: +30-210-281 17 12)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis GR-144 51 Athens (Tel: +30-210-281 17 12)	Dalzad 80 mg	80 mg	film-coated tablets	Oral Use
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis GR-144 51 Athens (Tel: +30-210-281 17 12)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis GR-144 51 Athens (Tel: +30-210-281 17 12)	Dalzad 160 mg	160 mg	film-coated tablets	Oral Use
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis GR-144 51 Athens (Tel: +30-210-281 17 12)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis GR-144 51 Athens (Tel: +30-210-281 17 12)	Dalzad 320 mg	320 mg	film-coated tablets	Oral Use
Hungary	Novartis Hungaria Kft. Bartók Béla út 43-47 H–1114 Budapest (Tel: +36-1-457 65 00)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Hungary	Novartis Hungaria Kft. Bartók Béla út 43-47 H–1114 Budapest (Tel: +36-1-457 65 00)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Hungary	Novartis Hungaria Kft. Bartók Béla út 43-47 H–1114 Budapest (Tel: +36-1-457 65 00)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Hungary	Novartis Hungaria Kft. Bartók Béla út 43-47 H–1114 Budapest (Tel: +36-1-457 65 00)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Iceland	Novartis Healthcare A/S Lyngbyvej 172 DK–2100 København Ø (Tel: +45-39-16 84 00)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Iceland	Novartis Healthcare A/S Lyngbyvej 172 DK–2100 København Ø (Tel: +45-39-16 84 00)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Iceland	Novartis Healthcare A/S Lyngbyvej 172 DK–2100 København Ø (Tel: +45-39-16 84 00)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Iceland	Novartis Healthcare A/S Lyngbyvej 172 DK–2100 København Ø (Tel: +45-39-16 84 00)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use
Ireland	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Ireland	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Ireland	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Ireland	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 I–21040 Origgio (Tel: + 39-02–96542214)	Tareg 40 mg	40 mg	film-coated tablets	Oral Use
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 I–21040 Origgio (Tel: + 39-02–96542214)	Rixil 40 mg	40 mg	film-coated tablets	Oral Use
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 I–21040 Origgio (Tel: + 39-02–96542214)	Tareg 80 mg	80 mg	film-coated tablets	Oral Use
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 I–21040 Origgio (Tel: + 39-02–96542214)	Rixil 80 mg	80 mg	film-coated tablets	Oral Use
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 I–21040 Origgio (Tel: + 39-02–96542214)	Tareg 160 mg	160 mg	film-coated tablets	Oral Use
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 I–21040 Origgio (Tel: + 39-02–96542214)	Rixil 160 mg	160 mg	film-coated tablets	Oral Use
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 I–21040 Origgio (Tel: + 39-02–96542214)	Tareg 320 mg	320 mg	film-coated tablets	Oral Use
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 I–21040 Origgio (Tel: + 39-02–96542214)	Rixil 320 mg	320 mg	film-coated tablets	Oral Use
Latvia	Novartis Finland OY Metsänneidonkuja 10 FIN–02130 Espoo (Tel: + 358-9–6133 22 11)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Latvia	Novartis Finland OY Metsänneidonkuja 10 FIN–02130 Espoo (Tel: + 358-9–6133 22 11)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Latvia	Novartis Finland OY Metsänneidonkuja 10 FIN–02130 Espoo (Tel: + 358-9–6133 22 11)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Latvia	Novartis Finland OY Metsänneidonkuja 10 FIN–02130 Espoo (Tel: + 358-9–6133 22 11)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use
Lithuania	Novartis Finland Oy Metsänneidonkuja 10 FIN–02130 Espoo (Tel: + 358-9–6133 22 11)	Diovan 80 mg plėvele dengtos tabletės	80 mg	film-coated tablets	Oral Use
Lithuania	Novartis Finland Oy Metsänneidonkuja 10 FIN–02130 Espoo (Tel: + 358-9–6133 22 11)	Diovan 160 mg plėvele dengtos tabletės	160 mg	film-coated tablets	Oral Use
Lithuania	Novartis Finland Oy Metsänneidonkuja 10 FIN–02130 Espoo (Tel: + 358-9–6133 22 11)	Diovan 320 mg plėvele dengtos tabletės	320 mg	film-coated tablets	Oral Use
Luxembourg	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Luxembourg	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Luxembourg	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Luxembourg	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Malta	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Malta	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Malta	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Malta	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use
Netherlands	Novartis Pharma B.V. Postbus 241 NL–6824 DP Arnhem (Tel: + 31-26-378 21 00)	Diovan 40	40 mg	film-coated tablets	Oral Use
Netherlands	Novartis Pharma B.V. Postbus 241 NL–6800 LZ Arnhem (Tel: + 31-26-378 21 00)	Diovan 80	80 mg	film-coated tablets	Oral Use
Netherlands	Novartis Pharma B.V. Postbus 241 NL–6824 DP Arnhem (Tel: + 31-26-378 21 00)	Diovan 160	160 mg	film-coated tablets	Oral Use
Netherlands	Novartis Pharma B.V. Postbus 241 NL–6824 DP Arnhem (Tel: + 31-26-378 21 00)	Diovan 320	320 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Norway	Novartis Norge AS Brynsalléen 4 Postboks 237 Økern NO–0510 Oslo (Tel: +47–2305 20 00)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Norway	Novartis Norge AS Brynsalléen 4 Postboks 237 Økern NO–0510 Oslo (Tel: +47–2305 20 00)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Norway	Novartis Norge AS Brynsalléen 4 Postboks 237 Økern NO–0510 Oslo (Tel: +47–2305 20 00)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Norway	Novartis Norge AS Brynsalléen 4 Postboks 237 Økern NO–0510 Oslo (Tel: +47–2305 20 00)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use
Poland	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan	40 mg	film-coated tablets	Oral Use
Poland	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan	80 mg	film-coated tablets	Oral Use
Poland	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan	160 mg	film-coated tablets	Oral Use
Poland	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan	320 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Novartis Farma - Produtos Farmacêuticos S.A. Rua do Centro Empresarial, Edificio 8 Quinta da Beloura P–2710-444 Sintra (Tel: +351 21000 86 00)	Diovan	40 mg	film-coated tablets	Oral Use
Portugal	Laboratório Normal-Produtos Farmacêuticos, Lda Rua do Centro Empresarial, Edificio 8 Quinta da Beloura P–2710-444 Sintra (Tel: +351 21000 86 00)	Tareg	40 mg	film-coated tablets	Oral Use
Portugal	Novartis Farma - Produtos Farmacêuticos S.A. Rua do Centro Empresarial, Edificio 8 Quinta da Beloura P–2710-444 Sintra (Tel: +351 21000 86 00)	Diovan	80 mg	film-coated tablets	Oral Use
Portugal	Laboratório Normal-Produtos Farmacêuticos, Lda Rua do Centro Empresarial, Edificio 8 Quinta da Beloura P–2710-444 Sintra (Tel: +351 21000 86 00)	Tareg	80 mg	film-coated tablets	Oral Use
Portugal	Novartis Farma - Produtos Farmacêuticos S.A. Rua do Centro Empresarial, Edificio 8 Quinta da Beloura P–2710-444 Sintra (Tel: +351 21000 86 00)	Diovan	160 mg	film-coated tablets	Oral Use
Portugal	Laboratório Normal-Produtos Farmacêuticos, Lda Rua do Centro Empresarial, Edificio 8 Quinta da Beloura P–2710-444 Sintra (Tel: +351 21000 86 00)	Tareg	160 mg	film-coated tablets	Oral Use
Portugal	Novartis Farma - Produtos Farmacêuticos S.A. Rua do Centro Empresarial, Edificio 8 Quinta da Beloura P–2710-444 Sintra (Tel: +351 21000 86 00)	Diovan	320 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Romania	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 40 mg, film coated tablets	40 mg	film-coated tablets	Oral Use
Romania	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 80 mg, film coated tablets	80 mg	film-coated tablets	Oral Use
Romania	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 160 mg, film coated tablets	160 mg	film-coated tablets	Oral Use
Slovak Republic	NOVARTIS s.r.o. Pharma Nagano III. U Nákladového nádraží 10 130 00 Praha 3 Czech Republic (Tel +420-2–2577 51 11)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Slovak Republic	NOVARTIS s.r.o. Pharma Nagano III. U Nákladového nádraží 10 130 00 Praha 3 Czech Republic (Tel +420-2–2577 51 11)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Slovak Republic	NOVARTIS s.r.o. Pharma Nagano III. U Nákladového nádraží 10 130 00 Praha 3 Czech Republic (Tel +420-2–2577 51 11)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Slovak Republic	NOVARTIS s.r.o. Pharma Nagano III. U Nákladového nádraží 10 130 00 Praha 3 Czech Republic (Tel +420-2–2577 51 11)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Slovenia	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 40 mg filmsko obložene tablete	40 mg	film-coated tablets	Oral Use
Slovenia	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 80 mg filmsko obložene tablete	80 mg	film-coated tablets	Oral Use
Slovenia	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 160 mg filmsko obložene tablete	160 mg	film-coated tablets	Oral Use
Slovenia	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 320 mg filmsko obložene tablete	320 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Diován Cardio 40 mg comprimidos recubiertos con película	40 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Kalpress Cardio 40 mg comprimidos recubiertos con película	40 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Miten Cardio 40 mg comprimidos recubiertos con película	40 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Diován 80 mg comprimidos recubiertos con película	80 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Kalpress 80 mg comprimidos recubiertos con película	80 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Miten 80 mg comprimidos recubiertos con película	80 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Diován 160 mg comprimidos recubiertos con película	160 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Kalpress 160 mg comprimidos recubiertos con película	160 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Miten 160 mg comprimidos recubiertos con película	160 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Diován 320 mg comprimidos recubiertos con película	320 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Kalpress 320 mg comprimidos recubiertos con película	320 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Miten 320 mg comprimidos recubiertos con película	320 mg	film-coated tablets	Oral Use
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Diovan	40 mg	film-coated tablets	Oral Use
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Angiosan	40 mg	film-coated tablets	Oral Use
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Valsartan Novartis	40 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Diovan	80 mg	film-coated tablets	Oral Use
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Angiosan	80 mg	film-coated tablets	Oral Use
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Valsartan Novartis	80 mg	film-coated tablets	Oral Use
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Diovan	160 mg	film-coated tablets	Oral Use
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Angiosan	160 mg	film-coated tablets	Oral Use
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Valsartan Novartis	160 mg	film-coated tablets	Oral Use
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Diovan	320 mg	film-coated tablets	Oral Use
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Angiosan	320 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Valsartan Novartis	320 mg	film-coated tablets	Oral Use
United Kingdom	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
United Kingdom	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
United Kingdom	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
United Kingdom	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use

ANNEX IV

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Austria	Novartis Pharma GmbH, Brunner Strasse 59 1235 Wien, Austria	Lescol 20 mg - Kapseln	20 mg	Capsule, hard	Oral use
Austria	Novartis Pharma GmbH, Brunner Strasse 59 1235 Wien, Austria	Lescol 40 mg - Kapseln	40 mg	Capsule, hard	Oral use
Austria	Novartis Pharma GmbH, Brunner Strasse 59 1235 Wien, Austria	Fluvastatin 'Novartis' 20 mg-Kapseln	20 mg	Capsule, hard	Oral use
Austria	Novartis Pharma GmbH, Brunner Strasse 59 1235 Wien, Austria	Fluvastatin 'Novartis' 40 mg-Kapseln	40 mg	Capsule, hard	Oral use
Austria	Novartis Pharma GmbH, Brunner Strasse 59 1235 Wien, Austria	Lescol MR 80 mg – Filmtabletten	80 mg	Film-coated tablet	Oral use
Austria	Novartis Pharma GmbH, Brunner Strasse 59 1235 Wien, Austria	Fluvastatin 'Novartis' MR 80 mg – Filmtabletten	80 mg	Film-coated tablet	Oral use
Belgium	Novartis Pharma N.V. Medialaan, 40 bus 1, 1800 Vilvoorde, Belgium	Lescol 20 mg, hard capsules	20 mg	Capsule, hard	Oral use
Belgium	Novartis Pharma N.V. Medialaan, 40 bus 1, 1800 Vilvoorde, Belgium	Lescol 40, hard capsules	40 mg	Capsule, hard	Oral use
Belgium	Novartis Pharma N.V. Medialaan, 40 bus 1, 1800 Vilvoorde, Belgium	Lescol Exel 80 mg prolonged-release tablet	80 mg	Prolonged-release tablet	Oral use
Bulgaria	Novartis Pharma GmbH Roonstrasse 25, 90429 Nuremberg, Germany	Lescol caps. 40 mg	40 mg	Capsule, hard	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Bulgaria	Novartis Pharma GmbH Roonstrasse 25, 90429 Nuremberg, Germany	Lescol XL prolonged release tablet 80 mg	80 mg	Prolonged-release tablet	Oral use
Cyprus	Demetriades & Papaellinas Ltd., Kasou 21, 1086 Nicosia, Cyprus	Lescol Capsule, 20mg	20 mg	Capsule, hard	Oral use
Cyprus	Demetriades & Papaellinas Ltd., Kasou 21, 1086 Nicosia, Cyprus	Lescol Capsule, 40mg	40 mg	Capsule, hard	Oral use
Cyprus	Demetriades & Papaellinas Ltd., Kasou 21, 1086 Nicosia, Cyprus	Lescol XL Prolonged release tablet 80mg	80 mg	Film-coated tablet	Oral use
Czech Republic	Novartis, s.r.o. Na Pankráci 1724/129 140 00 Praha 4 - Nusle, Czech Republic	Lescol 20 mg	20 mg	Capsule, hard	Oral use
Czech Republic	Novartis, s.r.o. Na Pankráci 1724/129 140 00 Praha 4 - Nusle, Czech Republic	Lescol 40 mg	40 mg	Capsule, hard	Oral use
Czech Republic	Novartis, s.r.o. Na Pankráci 1724/129 140 00 Praha 4 - Nusle, Czech Republic	Lescol XL	80 mg	Film-coated tablet	Oral use
Denmark	Novartis Healthcare A/S Lyngbyvej 172, 2100 København Ø, Denmark	Lescol	20 mg	Capsule, hard	Oral use
Denmark	Novartis Healthcare A/S Lyngbyvej 172, 2100 København Ø, Denmark	Lescol	40 mg	Capsule, hard	Oral use
Denmark	Novartis Healthcare A/S Lyngbyvej 172 2100 Kopenhagen Ø, Denmark	Lescol Depot	80 mg	Prolonged-release tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Estonia	Novartis Finland OY Metsänneidonkuja 10 FIN–02130 Espoo Finland	Lescol 40 mg	40 mg	Capsule	Oral use
Estonia	Novartis Finland OY Metsänneidonkuja 10 FIN–02130 Espoo Finland	Lescol XL	80 mg	Prolonged-release tablet	Oral use
Finland	Novartis Finland Oy Metsänneidonkuja 10 FI–02130 Espoo Finland	Lescol 20 mg	20 mg	Capsule, hard	Oral use
Finland	Novartis Finland Oy Metsänneidonkuja 10 FI–02130 Espoo Finland	Lescol 40 mg	40 mg	Capsule, hard	Oral use
Finland	Novartis Finland Oy Metsänneidonkuja 10 FI–02130 Espoo Finland	Lescol Depot 80 mg	80 mg	Prolonged-release tablet	Oral use
France	Novartis Pharma S.A.S. 2 & 4, rue Lionel Terray, 92500 Rueil Malmaison Cédex, France	LESCOL 20 mg	20 mg	Capsule, hard	Oral use
France	Novartis Pharma S.A.S. 2 & 4, rue Lionel Terray, 92500 Rueil Malmaison Cédex, France	LESCOL 40 mg	40 mg	Capsule, hard	Oral use
France	Pierre FABRE MEDICAMENT 45, place Abel Gance 92100 Boulogne, France	Fractal 20 mg	20 mg	Capsule, hard	Oral use
France	Pierre FABRE MEDICAMENT 45, place Abel Gance 92100 Boulogne, France	Fractal 40 mg	40 mg	Capsule, hard	Oral use
France	Novartis Pharma S.A.S. 2 & 4, rue Lionel Terray, 92500 Rueil Malmaison Cédex, France	Lescol LP 80 mg	80 mg	Film-coated, modified-release tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
France	Pierre FABRE MEDICAMENT 45, place Abel Gance 92100 Boulogne France	Fractal LP 80 mg	80 mg	Film-coated, modified-release tablet	Oral use
Germany	Novartis Pharma GmbH Roonstrasse 25 90429 Nürnberg, Germany	Locol 20 mg Hartkapsel	20 mg	Capsules, hard	Oral use
Germany	Novartis Pharma GmbH Roonstrasse 25 90429 Nürnberg, Germany	Locol 40 mg Hartkapsel	40 mg	Capsules, hard	Oral use
Germany	Novartis Pharma GmbH Roonstrasse 25 90429 Nürnberg, Germany	Cranoc 20 mg Hartkapsel	20 mg	Capsules, hard	Oral use
Germany	Novartis Pharma GmbH Roonstrasse 25 90429 Nürnberg, Germany	Cranoc 40 mg Hartkapsel	40 mg	Capsules, hard	Oral use
Germany	Novartis Pharma GmbH Roonstrasse 25 90429 Nürnberg, Germany	Locol 80 mg Retardtabletten	80 mg	Prolonged-release tablet	Oral use
Germany	Novartis Pharma GmbH Roonstrasse 25 90429 Nürnberg, Germany	Cranoc 80mg Retardtabletten	80 mg	Prolonged-release tablet	Oral use
Germany	Grünwalder Gesundheitsproducte GmbH Ruhlandstrasse 5, 83646 Bad Töltz, Germany	Fluvastatin-Novartis 80 mg	80 mg	Prolonged-release tablet	Oral use
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km), Metamorphosis GR-144 51 Athens Greece	Lescol® Capsule, hard 20mg	20 mg	Capsule, hard	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis GR-144 51 Athens, Greece	Lescol® Capsule, hard 40mg	40 mg	Capsule, hard	Oral use
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis GR-144 51 Athens, Greece	Lescol®XL Prolonged-release tablet 80mg	80 mg	Prolonged release tablet	Oral use
Hungary	Novartis Hungária Kft. Pharma Bartók Béla út 43-47, 5th Floor, 1114 Budapest, Hungary	Lescol 40 mg hard caps	40 mg	Capsule, hard	Oral use
Hungary	Novartis Hungária Kft. Pharma Bartók Béla út 43-47, 5th Floor, 1114 Budapest, Hungary	Lescol XL 80 mg retard tablet	80 mg	Prolonged-release tablet	Oral use
Iceland	Novartis Healthcare A/S Lyngbyvej 172, 2100 København Ø, Denmark	Lescol 20 mg hard caps	20 mg	Capsule, hard	Oral use
Iceland	Novartis Healthcare A/S Lyngbyvej 172, 2100 København Ø, Denmark	Lescol 40 mg hard caps	40 mg	Capsule, hard	Oral use
Iceland	Novartis Healthcare A/S Lyngbyvej 172, 2100 København Ø, Denmark	Lescol Depot 80 mg	80 mg	Prolonged-release tablet	Oral use
Ireland	Novartis Pharmaceuticals UK Limited Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR, United Kingdom	Lescol 20mg Capsules	20 mg	Capsule, hard	Oral use
Ireland	Novartis Pharmaceuticals UK Limited Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR, United Kingdom	Lescol 40mg Capsules	40 mg	Capsule, hard	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Ireland	Novartis Pharmaceuticals UK Limited Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR, United Kingdom	Lescol XL 80mg prolonged release tablets	80 mg	Prolonged release tablet	Oral use
Italy	Novartis Farma S.p.A. Largo Boccioni, 1, 21040 Origgio (VA), Italy	Lescol	20 mg	Capsule, hard	Oral use
Italy	Novartis Farma S.p.A. Largo Boccioni, 1, 21040 Origgio (VA), Italy	Lescol	40 mg	Capsule, hard	Oral use
Italy	ITALFARMACO S.p.A. Viale Fulvio Testi, 330 20126 Milano Italy	Lipaxan	20 mg	Capsule, hard	Oral use
Italy	ITALFARMACO S.p.A. Viale Fulvio Testi, 330 20126 Milano Italy	Lipaxan	40 mg	Capsule, hard	Oral use
Italy	UCB PHARMA S.p.A Via Gadames, 57 20151 Milano Italy	Primesin	20 mg	Capsule, hard	Oral use
Italy	UCB PHARMA S.p.A Via Gadames, 57 20151 Milano Italy	Primesin	40 mg	Capsule, hard	Oral use
Italy	SANDOZ S.p.A Address: Largo Umberto Boccioni 1 I–21040 Origgio / VA Italy	FLUVASTATINA Sandoz	20 mg	Capsule, hard	Oral use
Italy	SANDOZ S.p.A Address: Largo Umberto Boccioni 1 I–21040 Origgio / VA Italy	FLUVASTATINA Sandoz 40 mg hard capsules	40 mg	Capsule, hard	Oral use
Italy	Novartis Farma S.p.A. Largo Boccioni, 1, 21040 Origgio (VA), Italy	Lescol 80 mg	80 mg	Prolonged-release tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Italy	ITALFARMACO S.p.A. Viale Fulvio Testi, 330 20126 Milano Italy	Lipaxan 80 mg	80 mg	Prolonged-release tablet	Oral use
Italy	UCB PHARMA S.p.A Via Gadames, 57 20151 Milano Italy	Primesin 80 mg	80 mg	Prolonged-release tablet	Oral use
Latvia	Novartis Finland OY Metsänneidonkuja 10 FIN–02130 Espoo Finland	Lescol XL 80 mg	80 mg	Prolonged-release tablet	Oral use
Lithuania	Novartis Finland Oy Metsänneidonkuja 10 FIN–02130 Espoo, Finland	Lescol XL	80 mg	Prolonged-release tablet	Oral use
Luxembourg	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg, Germany	Locol 20 mg hard caps	20 mg	Capsules, hard	Oral use
Luxembourg	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg, Germany	Locol 40 mg hard caps	40 mg	Capsules, hard	Oral use
Luxembourg	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg, Germany	Locol 80 mg Retard tablet	80 mg	Prolonged-release tablet	Oral use
Malta	Novartis Pharmaceuticals UK Limited Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR, United Kingdom	Lescol	20 mg	Capsule, hard	Oral use
Malta	Novartis Pharmaceuticals UK Limited Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR, United Kingdom	Lescol	40 mg	Capsule, hard	Oral use
Malta	Novartis Pharmaceuticals UK Limited Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR, United Kingdom	Lescol XL	80 mg	Film-coated tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Norway	Novartis Norge AS, Postboks 237 Økern, 0510 Oslo, Norway	LESCOL	20 mg	Capsule, hard	Oral use
Norway	Novartis Norge AS, Postboks 237 Økern, 0510 Oslo, Norway	LESCOL	40 mg	Capsule, hard	Oral use
Norway	Novartis Norge AS, Postboks 237 Økern, 0510 Oslo, Norway	LESCOL DEPOT 80 mg	80 mg	Prolonged-release tablet	Oral use
Netherlands	Novartis Pharma B.V. P.O. Box 241 6800 LZ Arnhem The Netherlands	Lescol 20 mg, capsules	20 mg	Capsule, hard	Oral use
Netherlands	Novartis Pharma B.V. Raapopseweg 1, 6824 DP Arnhem, The Netherlands	Lescol 40 mg, capsules	40 mg	Capsule, hard	Oral use
Netherlands	Novartis Pharma B.V. Raapopseweg 1, 6824 DP Arnhem, The Netherlands	Lescol XL 80, tablet	80 mg	Film-coated tablet	Oral use
Poland	Novartis Pharma GmbH Roonstrasse 25, D–90429Nürnberg, Germany	Lescol	20 mg	Capsule, hard	Oral use
Poland	Novartis Pharma GmbH Roonstrasse 25, D–90429 Nürnberg, Germany	Lescol	40 mg	Capsule, hard	Oral use
Poland	Novartis Pharma GmbH Roonstrasse 25, D–90429 Nürnberg, Germany	Lescol XL	80 mg	Prolonged-release tablet	Oral use
Portugal	Novartis Farma - Produtos Farmacêuticos S.A. Rua do Centro Empresarial, Edif. 8, Quinta de Beloura 2710-444, Sintra, Portugal	Lescol	20 mg	Capsule, hard	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Novartis Farma - Produtos Farmacêuticos S.A. Rua do Centro Empresarial, Edif. 8, Quinta de Beloura 2710-444, Sintra, Portugal	Lescol	40 mg	Capsule, hard	Oral use
Portugal	Bialport – Produtos Farmacêuticos, S.A. À Av. da Siderurgia Nacional – 4745-457 S. Mamede do Coronado Portugal	Cardiol 20	20 mg	Capsule, hard	Oral use
Portugal	Bialport – Produtos Farmacêuticos, S.A. À Av. da Siderurgia Nacional – 4745-457 S. Mamede do Coronado Portugal	Cardiol 40	40 mg	Capsule, hard	Oral use
Portugal	Laboratório Normal - Produtos Farmacêuticos, S.A. Rua do Centro empresarial, Edifício 8, Quinta da Beloura 2710-444 Sintra Portugal	Canef	20 mg	Capsule, hard	Oral use
Portugal	Laboratório Normal - Produtos Farmacêuticos, S.A. Rua do Centro empresarial, Edifício 8, Quinta da Beloura 2710-444 Sintra Portugal	Canef	40 mg	Capsule, hard	Oral use
Portugal	Novartis Farma - Produtos Farmacêuticos S.A. Rua do Centro Empresarial, Edif. 8, Quinta de Beloura 2710-444, Sintra, Portugal	Lescol XL	80 mg	Prolonged-release tablet	Oral use
Portugal	Bialport – Produtos Farmacêuticos, S.A. À Av. da Siderurgia Nacional – 4745-457 S. Mamede do Coronado Portugal	Cardiol XL	80 mg	Prolonged-release tablet	Oral use
Portugal	Laboratório Normal - Produtos Farmacêuticos, S.A. Rua do Centro empresarial, Edifício 8, Quinta da Beloura 2710-444 Sintra Portugal	Canef 80 mg	80 mg	Prolonged-release tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Romania	NOVARTIS PHARMA GmbH Roonstrasse 25, D–90429 Nürnberg, Germany	LESCOL 20 mg	20 mg	Capsule, hard	Oral use
Romania	NOVARTIS PHARMA GmbH Roonstrasse 25, D–90429 Nürnberg, Germany	LESCOL 40 mg	40 mg	Capsule, hard	Oral use
Romania	NOVARTIS PHARMA GmbH Roonstrasse 25, D–90429 Nürnberg, Germany	LESCOL XL	80 mg	Prolonged-release tablet	Oral use
Slovak Republic	Novartis, s.r.o. U Nákladového nádraží 10, 13000 Prague 3, Czech Republic	Lescol 20 mg	20 mg	Capsule, hard	Oral use
Slovak Republic	Novartis, s.r.o. U Nákladového nádraží 10, 13000 Prague 3, Czech Republic	Lescol 40 mg	40 mg	Capsule, hard	Oral use
Slovak Republic	Novartis, s.r.o. U Nákladového nádraží 10, 13000 Prague 3, Czech Republic	Lescol XL 80 mg	80 mg	Prolonged-release tablet	Oral use
Slovenia	Novartis Pharma GmbH Roonstrasse 25, D–90429 Nürnberg, Germany	Lescol 40 mg trde kapsule	40 mg	Capsule, hard	Oral use
Slovenia	Novartis Pharma GmbH Roonstrasse 25, D–90429 Nürnberg, Germany	Lescol XL 80 mg tablete s podaljšanim sproščanjem	80 mg	Prolonged-release tablet	Oral use
Spain	Novartis Farmacéutica S.A. Gran Via de les Corts Catalanas, N° 764, 08013, Barcelona, Spain	Lescol 20 mg caps	20 mg	Capsule, hard	Oral use
Spain	Novartis Farmacéutica S.A. Gran Via de les Corts Catalanas, N° 764, 08013, Barcelona, Spain	Lescol 40 mg caps	40 mg	Capsule, hard	Oral use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona, Spain	Liposit 20 mg caps	20 mg	Capsule, hard	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona, Spain	Liposit 40 mg caps	40 mg	Capsule, hard	Oral use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona, Spain	Vaditon 20 mg caps	20 mg	Capsule, hard	Oral use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona, Spain	Vaditon 40 mg caps	40 mg	Capsule, hard	Oral use
Spain	Novartis Farmacéutica, S.A. Av. Diagonal, 507 08029 Barcelona, Spain	Digaril 20 mg caps	20 mg	Capsule, hard	Oral use
Spain	Novartis Farmacéutica, S.A. Av. Diagonal, 507 08029 Barcelona, Spain	Digaril 40 mg caps	40 mg	Capsule, hard	Oral use
Spain	GRÜNENTHAL PHARMA, S.A. Doctor Zamenhof nº 36 28027 Madrid, Spain	Lymetel 20 mg caps	20 mg	Capsule, hard	Oral use
Spain	GRÜNENTHAL PHARMA, S.A. Doctor Zamenhof nº 36 28027 Madrid, Spain	Lymetel 40 mg caps	40 mg	Capsule, hard	Oral use
Spain	Novartis Farmacéutica S.A. Gran Via de les Corts Catalanas, N° 764, 08013, Barcelona, Spain	Lescol prolib 80 mg	80 mg	Prolonged-release tablet	Oral use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona Spain	Liposit Prolib 80	80 mg	Prolonged-release tablet	Oral use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona Spain	Vaditon Prolib 80 mg	80 mg	Prolonged-release tablet	Oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Spain	Novartis Farmacéutica, S.A. Av. Diagonal, 507 08029 Barcelona Spain	Digaril Prolib 80 mg	80 mg	Prolonged-release tablet	Oral use
Spain	Laboratorios Andrómaco, S.A. Doctor Zamenhof nº 36 28027 Madrid Spain	Lymetel Prolib 80 mg	80 mg	Prolonged-release tablet	Oral use
Sweden	Novartis Sverige AB Box 1150, 18311 Täby, Sweden	Lescol	20 mg	Capsule, hard	Oral use
Sweden	Novartis Sverige AB Box 1150, 18311 Täby, Sweden	Lescol	40 mg	Capsule, hard	Oral use
Sweden	Novartis Sverige AB Box 1150, 18311 Täby, Sweden	Lescol Depot	80 mg	Prolonged-release tablet	Oral use
United Kingdom	Novartis Pharmaceuticals UK Ltd (Trading as Sandoz Pharmaceuticals) FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom	LESCOL CAPSULES 20MG	20 mg	Capsule, hard	Oral use
United Kingdom	Novartis Pharmaceuticals UK Ltd (Trading as Sandoz Pharmaceuticals) FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom	LESCOL CAPSULES 40MG	40 mg	Capsule, hard	Oral use
United Kingdom	Novartis Pharmaceuticals UK Ltd (Trading as Sandoz Pharmaceuticals) FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom	LESCOLXL 80 mg Prolonged Release Tablets	80 mg	Prolonged-release tablet	Oral use

ANNEX V

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION AND MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Austria	Novartis Pharma GmbH Stella-Klein-Löw-Weg 17 A–1020 Wien (Tel: + 43-1–8665 70)	Diovan 40 mg Filmtabletten	40 mg	film-coated tablets	Oral Use
Austria	Novartis Pharma GmbH Stella-Klein-Löw-Weg 17 A–1020 Wien (Tel: + 43-1–8665 70)	Angiosan 40 mg Filmtabletten	40 mg	film-coated tablets	Oral Use
Austria	Novartis Pharma GmbH Stella-Klein-Löw-Weg 17 A–1020 Wien (Tel: + 43-1–8665 70)	Diovan 80 mg Filmtabletten	80 mg	film-coated tablets	Oral Use
Austria	Novartis Pharma GmbH Stella-Klein-Löw-Weg 17 A–1020 Wien (Tel: + 43-1–8665 70)	Angiosan 80 mg Filmtabletten	80 mg	film-coated tablets	Oral Use
Austria	Novartis Pharma GmbH Stella-Klein-Löw-Weg 17 A–1020 Wien (Tel: + 43-1–8665 70)	Diovan 160 mg Filmtabletten	160 mg	film-coated tablets	Oral Use
Austria	Novartis Pharma GmbH Stella-Klein-Löw-Weg 17 A–1020 Wien (Tel: + 43-1–8665 70)	Angiosan 160 mg Filmtabletten	160 mg	film-coated tablets	Oral Use
Austria	Novartis Pharma GmbH Stella-Klein-Löw-Weg 17 A–1020 Wien (Tel: + 43-1–8665 70)	Diovan 320 mg Filmtabletten	320 mg	film-coated tablets	Oral Use
Austria	Novartis Pharma GmbH Stella-Klein-Löw-Weg 17 A–1020 Wien (Tel: + 43-1–8665 70)	Angiosan 320 mg Filmtabletten	320 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Belgium	N.V. Novartis Pharma S.A. Medialaan 40, bus 1 B–1800 Vilvoorde (Tel: +32-2-246 16 11)	Diovane 40 mg	40 mg	film-coated tablets	Oral Use
Belgium	N.V. Novartis Pharma S.A. Medialaan 40, bus 1 B–1800 Vilvoorde (Tel: +32-2-246 16 11)	Diovane 80 mg	80 mg	film-coated tablets	Oral Use
Belgium	N.V. Novartis Pharma S.A. Medialaan 40, bus 1 B–1800 Vilvoorde (Tel: +32-2-246 16 11)	Diovane 160 mg	160 mg	film-coated tablets	Oral Use
Belgium	N.V. Novartis Pharma S.A. Medialaan 40, bus 1 B–1800 Vilvoorde (Tel: +32-2-246 16 11)	Diovane 320 mg	320 mg	film-coated tablets	Oral Use
Bulgaria	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Bulgaria	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Bulgaria	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Bulgaria	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use
Cyprus	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Cyprus	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Cyprus	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Cyprus	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use
Czech Republic	NOVARTIS s.r.o. Pharma Nagano III. U Nákladového nádraží 10 130 00 Praha 3 (Tel +420-2–2577 51 11)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Czech Republic	NOVARTIS s.r.o. Pharma Nagano III. U Nákladového nádraží 10 130 00 Praha 3 (Tel +420-2–2577 51 11)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Denmark	Novartis Healthcare A/S Lyngbyvej 172 DK–2100 København Ø (Tel: +45-39-16 84 00)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Denmark	Novartis Healthcare A/S Lyngbyvej 172 DK–2100 København Ø (Tel: +45-39-16 84 00)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Denmark	Novartis Healthcare A/S Lyngbyvej 172 DK–2100 København Ø (Tel: +45-39-16 84 00)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Denmark	Novartis Healthcare A/S Lyngbyvej 172 DK–2100 København Ø (Tel: +45-39-16 84 00)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use
Estonia	Novartis Finland OY Metsänneidonkuja 10 FIN–02130 Espoo Finland (Tel: + 358-9–6133 22 11)	Diovan	40 mg	film-coated tablets	Oral Use
Estonia	Novartis Finland OY Metsänneidonkuja 10 FIN–02130 Espoo Finland (Tel: + 358-9–6133 22 11)	Diovan	80 mg	film-coated tablets	Oral Use
Estonia	Novartis Finland OY Metsänneidonkuja 10 FIN–02130 Espoo Finland (Tel: + 358-9–6133 22 11)	Diovan	160 mg	film-coated tablets	Oral Use
Estonia	Novartis Finland OY Metsänneidonkuja 10 FIN–02130 Espoo Finland (Tel: + 358-9–6133 22 11)	Diovan	320 mg	film-coated tablets	Oral Use
Finland	Novartis Finland Oy Metsänneidonkuja 10 FIN–02130 Espoo (Tel: + 358-9–6133 22 11)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Finland	Novartis Finland Oy Metsänneidonkuja 10 FIN–02130 Espoo (Tel: + 358-9–6133 22 11)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Finland	Novartis Finland Oy Metsänneidonkuja 10 FIN–02130 Espoo (Tel: + 358-9–6133 22 11)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Finland	Novartis Finland Oy Metsänneidonkuja 10 FIN–02130 Espoo (Tel: + 358-9–6133 22 11)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
France	Novartis Pharma S.A.S. 2 and 4, rue Lionel Terray 92500 RUEIL-MALMAISON (Tel: +33-1–5547 60 00)	Tareg 40 mg	40 mg	film-coated tablets	Oral Use
France	Novartis Pharma S.A.S. 2 and 4, rue Lionel Terray 92500 RUEIL-MALMAISON (Tel: +33-1–5547 60 00)	Tareg 80 mg	80 mg	film-coated tablets	Oral Use
France	Novartis Pharma S.A.S. 2 and 4, rue Lionel Terray 92500 RUEIL-MALMAISON (Tel: +33-1–5547 60 00)	Tareg 160 mg	160 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Cordinate 40 mg	40 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Provas 40 mg	40 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Cordinate 80 mg	80 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Provas 80 mg	80 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 160 mg protect	160 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Cordinate 160 mg	160 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Provas 160 mg	160 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Diovan 320 mg forte	320 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Cordinate 320 mg	320 mg	film-coated tablets	Oral Use
Germany	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg (Tel: +49-911-273-0)	Provas 320 mg	320 mg	film-coated tablets	Oral Use
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis GR-144 51 Athens (Tel: +30-210-281 17 12)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis GR-144 51 Athens (Tel: +30-210-281 17 12)	Dalzad 40 mg	40 mg	film-coated tablets	Oral Use
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis GR-144 51 Athens (Tel: +30-210-281 17 12)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis GR-144 51 Athens (Tel: +30-210-281 17 12)	Dalzad 80 mg	80 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis GR-144 51 Athens (Tel: +30-210-281 17 12)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis GR-144 51 Athens (Tel: +30-210-281 17 12)	Dalzad 160 mg	160 mg	film-coated tablets	Oral Use
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis GR-144 51 Athens (Tel: +30-210-281 17 12)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use
Greece	Novartis (Hellas) S.A.C.I. National Road No. 1 (12th Km) Metamorphosis GR-144 51 Athens (Tel: +30-210-281 17 12)	Dalzad 320 mg	320 mg	film-coated tablets	Oral Use
Hungary	Novartis Hungaria Kft. Bartók Béla út 43-47 H–1114 Budapest (Tel: +36-1-457 65 00)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Hungary	Novartis Hungaria Kft. Bartók Béla út 43-47 H–1114 Budapest (Tel: +36-1-457 65 00)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Hungary	Novartis Hungaria Kft. Bartók Béla út 43-47 H–1114 Budapest (Tel: +36-1-457 65 00)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Hungary	Novartis Hungaria Kft. Bartók Béla út 43-47 H–1114 Budapest (Tel: +36-1-457 65 00)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use
Iceland	Novartis Healthcare A/S Lyngbyvej 172 DK–2100 København Ø Denmark (Tel: +45-39-16 84 00)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Iceland	Novartis Healthcare A/S Lyngbyvej 172 DK–2100 København Ø Denmark (Tel: +45-39-16 84 00)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Iceland	Novartis Healthcare A/S Lyngbyvej 172 DK–2100 København Ø Denmark (Tel: +45-39-16 84 00)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Iceland	Novartis Healthcare A/S Lyngbyvej 172 DK–2100 København Ø Denmark (Tel: +45-39-16 84 00)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use
Ireland	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Ireland	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Ireland	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Ireland	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 I–21040 Origgio (Tel: + 39-02–96542214)	Tareg 40 mg	40 mg	film-coated tablets	Oral Use
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 I–21040 Origgio (Tel: + 39-02–96542214)	Rixil 40 mg	40 mg	film-coated tablets	Oral Use
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 I–21040 Origgio (Tel: + 39-02–96542214)	Tareg 80 mg	80 mg	film-coated tablets	Oral Use
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 I–21040 Origgio (Tel: + 39-02–96542214)	Rixil 80 mg	80 mg	film-coated tablets	Oral Use
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 I–21040 Origgio (Tel: + 39-02–96542214)	Tareg 160 mg	160 mg	film-coated tablets	Oral Use
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 I–21040 Origgio (Tel: + 39-02–96542214)	Rixil 160 mg	160 mg	film-coated tablets	Oral Use
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 I–21040 Origgio (Tel: + 39-02–96542214)	Tareg 320 mg	320 mg	film-coated tablets	Oral Use
Italy	Novartis Farma S.p.A. Largo Umberto Boccioni 1 I–21040 Origgio (Tel: + 39-02–96542214)	Rixil 320 mg	320 mg	film-coated tablets	Oral Use
Latvia	Novartis Finland OY Metsänneidonkuja 10 FIN–02130 Espoo Finland (Tel: + 358-9–6133 22 11)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Latvia	Novartis Finland OY Metsänneidonkuja 10 FIN–02130 Espoo Finland (Tel: + 358-9–6133 22 11)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Latvia	Novartis Finland OY Metsänneidonkuja 10 FIN–02130 Espoo Finland (Tel: + 358-9–6133 22 11)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Latvia	Novartis Finland OY Metsänneidonkuja 10 FIN–02130 Espoo Finland (Tel: + 358-9–6133 22 11)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use
Lithuania	Novartis Finland Oy Metsänneidonkuja 10 FIN–02130 Espoo Finland (Tel: + 358-9–6133 22 11)	Diovan 80 mg plėvele dengtos tabletės	80 mg	film-coated tablets	Oral Use
Lithuania	Novartis Finland Oy Metsänneidonkuja 10 FIN–02130 Espoo Finland (Tel: + 358-9–6133 22 11)	Diovan 160 mg plėvele dengtos tabletės	160 mg	film-coated tablets	Oral Use
Lithuania	Novartis Finland Oy Metsänneidonkuja 10 FIN–02130 Espoo Finland (Tel: + 358-9–6133 22 11)	Diovan 320 mg plėvele dengtos tabletės	320 mg	film-coated tablets	Oral Use
Luxembourg	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Luxembourg	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Luxembourg	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Luxembourg	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use
Malta	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Malta	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Malta	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Malta	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR United Kingdom (Tel: +44–1276-69 22 55)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use
Netherlands	Novartis Pharma B.V. Postbus 241 NL–6824 DP Arnhem (Tel: + 31-26-378 21 00)	Diovan 40	40 mg	film-coated tablets	Oral Use
Netherlands	Novartis Pharma B.V. Postbus 241 NL–6800 LZ Arnhem (Tel: + 31-26-378 21 00)	Diovan 80	80 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Netherlands	Novartis Pharma B.V. Postbus 241 NL–6824 DP Arnhem (Tel: + 31-26-378 21 00)	Diovan 160	160 mg	film-coated tablets	Oral Use
Netherlands	Novartis Pharma B.V. Postbus 241 NL–6824 DP Arnhem (Tel: + 31-26-378 21 00)	Diovan 320	320 mg	film-coated tablets	Oral Use
Norway	Novartis Norge AS Brynsalléen 4 Postboks 237 Økern NO–0510 Oslo (Tel: +47–2305 20 00)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Norway	Novartis Norge AS Brynsalléen 4 Postboks 237 Økern NO–0510 Oslo (Tel: +47–2305 20 00)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
Norway	Novartis Norge AS Brynsalléen 4 Postboks 237 Økern NO–0510 Oslo (Tel: +47–2305 20 00)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Norway	Novartis Norge AS Brynsalléen 4 Postboks 237 Økern NO–0510 Oslo (Tel: +47–2305 20 00)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use
Poland	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan	40 mg	film-coated tablets	Oral Use
Poland	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan	80 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Poland	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan	160 mg	film-coated tablets	Oral Use
Poland	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan	320 mg	film-coated tablets	Oral Use
Portugal	Novartis Farma - Produtos Farmacêuticos S.A. Rua do Centro Empresarial, Edificio 8 Quinta da Beloura P–2710-444 Sintra (Tel: +351 21000 86 00)	Diovan	40 mg	film-coated tablets	Oral Use
Portugal	Laboratório Normal-Produtos Farmacêuticos, Lda Rua do Centro Empresarial, Edificio 8 Quinta da Beloura P–2710-444 Sintra (Tel: +351 21000 86 00)	Tareg	40 mg	film-coated tablets	Oral Use
Portugal	Novartis Farma - Produtos Farmacêuticos S.A. Rua do Centro Empresarial, Edificio 8 Quinta da Beloura P–2710-444 Sintra (Tel: +351 21000 86 00)	Diovan	80 mg	film-coated tablets	Oral Use
Portugal	Laboratório Normal-Produtos Farmacêuticos, Lda Rua do Centro Empresarial, Edificio 8 Quinta da Beloura P–2710-444 Sintra (Tel: +351 21000 86 00)	Tareg	80 mg	film-coated tablets	Oral Use
Portugal	Novartis Farma - Produtos Farmacêuticos S.A. Rua do Centro Empresarial, Edificio 8 Quinta da Beloura P–2710-444 Sintra (Tel: +351 21000 86 00)	Diovan	160 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Portugal	Laboratório Normal-Produtos Farmacêuticos, Lda Rua do Centro Empresarial, Edificio 8 Quinta da Beloura P–2710-444 Sintra (Tel: +351 21000 86 00)	Tareg	160 mg	film-coated tablets	Oral Use
Portugal	Novartis Farma - Produtos Farmacêuticos S.A. Rua do Centro Empresarial, Edificio 8 Quinta da Beloura P–2710-444 Sintra (Tel: +351 21000 86 00)	Diovan	320 mg	film-coated tablets	Oral Use
Romania	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan 40 mg, film coated tablets	40 mg	film-coated tablets	Oral Use
Romania	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan 80 mg, film coated tablets	80 mg	film-coated tablets	Oral Use
Romania	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan 160 mg, film coated tablets	160 mg	film-coated tablets	Oral Use
Slovak Republic	NOVARTIS s.r.o. Pharma Nagano III. U Nákladového nádraží 10 130 00 Praha 3 Czech Republic (Tel +420-2–2577 51 11)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
Slovak Republic	NOVARTIS s.r.o. Pharma Nagano III. U Nákladového nádraží 10 130 00 Praha 3 Czech Republic (Tel +420-2–2577 51 11)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Slovak Republic	NOVARTIS s.r.o. Pharma Nagano III. U Nákladového nádraží 10 130 00 Praha 3 Czech Republic (Tel +420-2–2577 51 11)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
Slovak Republic	NOVARTIS s.r.o. Pharma Nagano III. U Nákladového nádraží 10 130 00 Praha 3 Czech Republic (Tel +420-2–2577 51 11)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use
Slovenia	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan 40 mg filmsko obložene tablete	40 mg	film-coated tablets	Oral Use
Slovenia	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan 80 mg filmsko obložene tablete	80 mg	film-coated tablets	Oral Use
Slovenia	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan 160 mg filmsko obložene tablete	160 mg	film-coated tablets	Oral Use
Slovenia	Novartis Pharma GmbH Roonstrasse 25 D–90429 Nürnberg Germany (Tel: +49-911-273-0)	Diovan 320 mg filmsko obložene tablete	320 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Diován Cardio 40 mg comprimidos recubiertos con película	40 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Kalpress Cardio 40 mg comprimidos recubiertos con película	40 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Miten Cardio 40 mg comprimidos recubiertos con película	40 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Diován 80 mg comprimidos recubiertos con película	80 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Kalpress 80 mg comprimidos recubiertos con película	80 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Miten 80 mg comprimidos recubiertos con película	80 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Diován 160 mg comprimidos recubiertos con película	160 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Kalpress 160 mg comprimidos recubiertos con película	160 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Miten 160 mg comprimidos recubiertos con película	160 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Diován 320 mg comprimidos recubiertos con película	320 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Kalpress 320 mg comprimidos recubiertos con película	320 mg	film-coated tablets	Oral Use
Spain	Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona (Tel: +34-93-306 42 00)	Miten 320 mg comprimidos recubiertos con película	320 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Diovan	40 mg	film-coated tablets	Oral Use
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Angiosan	40 mg	film-coated tablets	Oral Use
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Valsartan Novartis	40 mg	film-coated tablets	Oral Use
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Diovan	80 mg	film-coated tablets	Oral Use
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Angiosan	80 mg	film-coated tablets	Oral Use
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Valsartan Novartis	80 mg	film-coated tablets	Oral Use
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Diovan	160 mg	film-coated tablets	Oral Use
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Angiosan	160 mg	film-coated tablets	Oral Use

Member State EU/EEA	Marketing Authorisation Holder	Invented name	Strength	Pharmaceutical Form	Route of administration
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Valsartan Novartis	160 mg	film-coated tablets	Oral Use
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Diovan	320 mg	film-coated tablets	Oral Use
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Angiosan	320 mg	film-coated tablets	Oral Use
Sweden	Novartis Sverige AB Kemistvägen 1B P.O. Box 1150 SE-183 11 Täby (Tel: + 46-8-732 32 00)	Valsartan Novartis	320 mg	film-coated tablets	Oral Use
United Kingdom	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR (Tel: +44–1276-69 22 55)	Diovan 40 mg	40 mg	film-coated tablets	Oral Use
United Kingdom	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR (Tel: +44–1276-69 22 55)	Diovan 80 mg	80 mg	film-coated tablets	Oral Use
United Kingdom	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR (Tel: +44–1276-69 22 55)	Diovan 160 mg	160 mg	film-coated tablets	Oral Use
United Kingdom	Novartis Pharmaceuticals UK Ltd FrimleyBusinessPark Frimley, Camberley Surrey GU16 7SR (Tel: +44–1276-69 22 55)	Diovan 320 mg	320 mg	film-coated tablets	Oral Use

ANNEX VI

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTES OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Austria	AstraZeneca Österreich GmbH, Schwarzenbergplatz 7, A-1037 Wien Austria	Losec 10mg – Kapseln	10 mg	capsule, hard	Oral use	
Austria	AstraZeneca Österreich GmbH, Schwarzenbergplatz 7, A-1037 Wien Austria	Losec 20mg – Kapseln	20 mg	capsule, hard	Oral use	
Austria	AstraZeneca Österreich GmbH, Schwarzenbergplatz 7, A-1037 Wien Austria	Losec 40 mg -Trockenstechampulle mit Lösungsmittel	40 mg	Powder for solution for injection	Intravenous use	40 mg
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Losec 40mg Forte, harde maagsapresistente capsules	40 mg	Hard Gastroresistant capsules	Oral use	
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Losec 40 mg, poeder voor oplossing voor intraveneuze infusie	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Losec-Mups 10mg, 10 mg, maagsapresistente tabletten	10 mg	Gastroresistant tablets	Oral use	
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Losec-Mups 20mg, 20 mg, maagsapresistente tabletten	20 mg	Gastroresistant tablets	Oral use	
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Losec-Mups 40mg, 40 mg, maagsapresistente tabletten	40 mg	Gastroresistant tablets	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussel Belgium	Omeprazole AstraZeneca 20mg, harde maagsapresistente capsules	20 mg	Hard Gastroresistant capsules	Oral use	
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussel Belgium	Omeprazole AstraZeneca 40mg Forte, harde maagsapresistente capsules	40 mg	Hard Gastroresistant capsules	Oral use	
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Omeprazole AstraZeneca 40mg, poeder voor oplossing voor intraveneuze infusie	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Logastric 10mg, maagsapresistente capsules	10 mg	Hard Gastroresistant capsules	Oral use	
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Logastric 20mg, maagsapresistente capsules	20 mg	Hard Gastroresistant capsules	Oral use	
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Logastric 40mg Forte, maagsapresistente capsules	40 mg	Hard Gastroresistant capsules	Oral use	
Belgium	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Logastric-Mups 40mg, 40 mg, maagsapresistente tabletten	40 mg	Gastroresistant tablets	Oral use	
Cyprus	AstraZeneca AB, 151 85 Södertälje Sweden	Losec Mups	10mg	Gastro-resistant tablets	Oral use	
Cyprus	AstraZeneca AB, 151 85 Södertälje Sweden	Losec Mups	20mg	Gastro-resistant tablets	Oral use	
Czech Republic	AstraZeneca UK Ltd., Silk Road Business Park, SK10 2NA Macclesfield, Cheshire, United Kingdom	LOSEC 20 mg	20 mg	Gastro-resistant capsule, hard	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Czech Republic	AstraZeneca UK Ltd., Silk Road Business Park, SK10 2NA Macclesfield, Cheshire, United Kingdom	LOSEC 40 mg	40 mg	Powder for solution for infusion	Intravenous use	
Denmark	AstraZeneca A/S Roskildevej 22 2620 Albertslund Denmark	Losec	10 mg	Gastroresistant tablets	Oral use	
Denmark	AstraZeneca A/S Roskildevej 22 2620 Albertslund Denmark	Losec	20 mg	Gastroresistant tablets	Oral use	
Denmark	AstraZeneca A/S Roskildevej 22 2620 Albertslund Denmark	Losec	40 mg	Gastroresistant tablets	Oral use	
Denmark	AstraZeneca A/S Roskildevej 22 2620 Albertslund Denmark	Losec	40 mg/ml	Powder and Solvens for solution for injection	Intravenous use	40 mg
Denmark	AstraZeneca A/S Roskildevej 22 2620 Albertslund Denmark	Losec	40 mg/ml	Powder for solution for infusion	Intravenous use	40 mg
Estonia	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec MUPS	20 mg	Gastroresistant tablets	Oral use	
Estonia	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec 40 MG	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Finland	AstraZeneca Oy Luomanportti 3 FI-02200 Espoo Finland	Losec Mups 10 mg enterotabletti	10 mg	Gastroresistant tablet	Oral use	
Finland	AstraZeneca Oy Luomanportti 3 FI-02200 Espoo Finland	Losec Mups 20 mg enterotabletti	20 mg	Gastroresistant tablet	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Finland	AstraZeneca Oy Luomanportti 3 FI-02200 Espoo Finland	Losec Mups 40 mg enterotabletti	40 mg	Gastroresistant tablet	Oral use	
France	AstraZeneca 1, Place Renault 92844 RUEIL-MALMAISON Cedex France	MOPRAL® 20 mg microgranules gastrorésistants en gélule	20 mg	Capsules	Oral use	
France	AstraZeneca 1, Place Renault 92844 RUEIL-MALMAISON Cedex France	MOPRAL® 10 mg microgranules gastrorésistants en gélule	10 mg	Capsules	Oral use	
France	AstraZeneca 1, Place Renault 92844 RUEIL-MALMAISON Cedex France	ZOLTUM® 20 mg microgranules gastrorésistants en gélule	20 mg	Capsules	Oral use	
France	AstraZeneca 1, Place Renault 92844 RUEIL-MALMAISON Cedex France	ZOLTUM® 10 mg microgranules gastrorésistants en gélule	10 mg	Capsules	Oral use	
France	AstraZeneca 1, Place Renault 92844 RUEIL-MALMAISON Cedex France	MOPRAL 40 mg, lyophilisat pour perfusion (IV).	40 mg	Lyophylizat for perfusion	Intravenous use	40 mg
Germany	AstraZeneca GmbH 22876 Wedel Germany	Antra pro infusione	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Germany	AstraZeneca GmbH 22876 Wedel Germany	Antra MUPS 10 mg	10 mg	Gastro-resistant tablets	Oral use	
Germany	AstraZeneca GmbH 22876 Wedel Germany	Antra MUPS 20 mg	20 mg	Gastro-resistant tablets	Oral use	
Germany	AstraZeneca GmbH 22876 Wedel Germany	Antra MUPS 40 mg	40 mg	Gastro-resistant tablets	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Greece	AstraZeneca S.A. 4 Theotokopoulou & Astronafton str 151 25 Maroussi Athens Greece	Losec®, Γαστροανθεκτικό καψάκιο σκληρό 10 mg/CAP	10 mg	Gastro-resistant capsules, hard	Oral use	
Greece	AstraZeneca S.A. 4 Theotokopoulou & Astronafton str 151 25 Maroussi Athens Greece	Losec®, Γαστροανθεκτικό καψάκιο σκληρό 20 mg/CAP	20 mg	Gastro-resistant capsules, hard	Oral use	
Greece	AstraZeneca S.A. 4 Theotokopoulou & Astronafton str 151 25 Maroussi Athens Greece	Losec®, Γαστροανθεκτικό καψάκιο σκληρό 40 mg/CAP	40 mg	Gastro-resistant capsules, hard	Oral use	
Greece	AstraZeneca S.A. 4 Theotokopoulou & Astronafton str 151 25 Maroussi Athens Greece	Losec MUPS®, Γαστροανθεκτικό δισκίο 10 mg/TAB	10 mg	Gastro-resistant tablets	Oral use	
Greece	AstraZeneca S.A. 4 Theotokopoulou & Astronafton str 151 25 Maroussi Athens Greece	Losec MUPS®, Γαστροανθεκτικό δισκίο 20 mg/TAB	20 m	Gastro-resistant tablets	Oral use	
Greece	AstraZeneca S.A. 4 Theotokopoulou & Astronafton str 151 25 Maroussi Athens Greece	Losec MUPS®, Γαστροανθεκτικό δισκίο 40 mg/TAB	40 mg	Gastro-resistant tablets	Oral use	
Greece	AstraZeneca S.A. 4 Theotokopoulou & Astronafton str 151 25 Maroussi Athens Greece	Losec®, Ενέσιμο λυόφιλο 40 mg/VIAL	40 mg	Powder and solvent for solution for injection	Intravenous use	40 mg
Greece	AstraZeneca S.A. 4 Theotokopoulou & Astronafton str 151 25 Maroussi Athens Greece	Losec®, Ενέσιμο λυόφιλο για ενδοφλέβια έγχυση 40 mg/VIAL	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Hungary	AstraZeneca Kft. H-2045 Törökbálint, Park u. 3. Hungary	Losec 10 mg kapszula	10 mg	Capsule, hard	Oral use	
Hungary	AstraZeneca Kft. H-2045 Törökbálint, Park u. 3. Hungary	Losec 20 mg kapszulaz	20 mg	Capsule, hard	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Hungary	AstraZeneca Kft. H-2045 Törökbálint, Park u. 3. Hungary	Losec 40 mg por infúzióhoz	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Iceland	AstraZeneca A/S Roskildevej 22 DK-2620 Albertslund Denmark	Losec	10 mg	Gastroresistant tablets	Oral use	
Iceland	AstraZeneca A/S Roskildevej 22 DK-2620 Albertslund Denmark	Losec	20 mg	Gastroresistant tablets	Oral use	
Iceland	AstraZeneca A/S Roskildevej 22 DK-2620 Albertslund Denmark	Losec	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Ireland	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec MUPS Tablets 10mg	10mg	Gastro-resistant, film-coated tablet	Oral use	
Ireland	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec MUPS Tablets 20mg	20mg	Gastro-resistant, film-coated tablet	Oral use	
Ireland	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec MUPS Tablets 40mg	40mg	Gastro-resistant, film-coated tablet	Oral use	
Ireland	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec Losec 40mg Powder for Solution for Infusion	40mg	Powder for solution for infusion	Intravenous use	40 mg
Ireland	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec IV 40mg Powder and Solvent for Solution for Injection	40mg	Powder and solvent for solution for injection	Intravenous use	40 mg

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Italy	AstraZeneca S.p.A. Via F. Sforza Palazzo Volta 20080 Basiglio (MI) Italy	Antra 10 mg capsule rigide a rilascio modificato	10 mg	Hard modified release capsules	Oral use	
Italy	AstraZeneca S.p.A. Via F. Sforza Palazzo Volta 20080 Basiglio (MI) Italy	Antra 20 mg capsule rigide a rilascio modificato	20 mg	Hard modified release capsules	Oral use	
Italy	AstraZeneca S.p.A. Via F. Sforza Palazzo Volta 20080 Basiglio (MI) Italy	Antra 40 mg capsule rigide a rilascio modificato	40 mg	Hard modified release capsules	Oral use	
Italy	AstraZeneca S.p.A. Via F. Sforza Palazzo Volta 20080 Basiglio (MI) Italy	Antra 40 mg polvere per soluzione per infusione	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Italy	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec 10 mg capsule rigide a rilascio modificato	10 mg	Hard modified release capsules	Oral use	
Italy	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec 20 mg capsule rigide a rilascio modificato	20 mg	Hard modified release capsules	Oral use	
Italy	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec 40 mg capsule rigide a rilascio modificato	40 mg	Hard modified release capsules	Oral use	
Italy	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec 40 mg polvere per soluzione per infusione	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Italy	Bracco S.p.A. Via E. Folli 50 20134 Milano Italy	Mepral 10 mg capsule rigide a rilascio modificato	10 mg	Hard modified release capsules	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Italy	Bracco S.p.A. Via E. Folli 50 20134 Milano Italy	Mepral 20 mg capsule rigide a rilascio modificato	20 mg	Hard modified release capsules	Oral use	
Italy	Bracco S.p.A. Via E. Folli 50 20134 Milano Italy	Mepral 40 mg capsule rigide a rilascio modificato	40 mg	Hard modified release capsules	Oral use	
Italy	Bracco S.p.A. Via E. Folli 50 20134 Milano Italy	Mepral 40 mg polvere per soluzione per infusione	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Italy	Malesci Istituto Farmacobiologico S.p.A. Via Lungo l'Ema 7 50015 Bagno a Ripoli (FI) Italy	Omeprazen 10 mg capsule rigide a rilascio modificato	10 mg	Hard modified release capsules	Oral use	
Italy	Malesci Istituto Farmacobiologico S.p.A. Via Lungo l'Ema 7 50015 Bagno a Ripoli (FI) Italy	Omeprazen 20 mg capsule rigide a rilascio modificato	20 mg	Hard modified release capsules	Oral use	
Italy	Malesci Istituto Farmacobiologico S.p.A. Via Lungo l'Ema 7 50015 Bagno a Ripoli (FI) Italy	Omeprazen 40 mg capsule rigide a rilascio modificato	40 mg	Hard modified release capsules	Oral use	
Italy	Malesci Istituto Farmacobiologico S.p.A. Via Lungo l'Ema 7 50015 Bagno a Ripoli (FI) Italy	Omeprazen 40 mg polvere per soluzione per infusione	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Latvia	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec 40 mg pulveris infūziju šķīduma pagatavošanai	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Luxembourg	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Losec Forte Gelules 40mg	40 mg	Hard gastroresis-tant capsules	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Luxembourg	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Losec poudre pour perfusion 40 mg	40 mg	Powder for solution for intravenous infusion	Intravenous use	40 mg
Luxembourg	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Losec-Mups 10mg	10 mg	Gastroresistant tablets	Oral use	
Luxembourg	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Losec-Mups 20mg	20 mg	Gastroresistant tablets	Oral use	
Luxembourg	NV AstraZeneca SA Egide Van Ophemstraat 110 1180 Brussels Belgium	Losec-Mups 40mg	40 mg	Gastroresistant tablets	Oral use	
Malta	AstraZeneca AB S-151 85 Södertälje Sweden	Losec MUPS Tablets 10mg	10mg	Gastro-resistant, film-coated tablet	Oral use	
Malta	AstraZeneca AB S-151 85 Södertälje Sweden	Losec MUPS Tablets 20mg	20mg	Gastro-resistant, film-coated tablet	Oral use	
Netherlands	AstraZeneca BV Postbus 599 2700 AN, Zoetermeer The Netherlands	Losec 10	10 mg	Gstroresistant capsules	Oral use	
Netherlands	AstraZeneca BV Postbus 599 2700 AN, Zoetermeer The Netherlands	Losec 20	20 mg	Gastroresistant capsules	Oral use	
Netherlands	AstraZeneca BV Postbus 599 2700 AN, Zoetermeer The Netherlands	Losec 40	40 mg	Gastroresistant capsules	Oral use	
Netherlands	AstraZeneca BV Postbus 599 2700 AN, Zoetermeer The Netherlands	Losec	40 mg	Powder and solvent for solution for injection	Intravenous use	40 mg

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Netherlands	AstraZeneca BV Postbus 599 2700 AN, Zoetermeer The Netherlands	Losec Infuus	40 mg	Powder for solution for intravenous infusion	Intravenous use	40 mg
Netherlands	AstraZeneca BV Postbus 599 2700 AN, Zoetermeer The Netherlands	Losec MUPS 10	10 mg	Gastroresistant tablets	Oral use	
Netherlands	AstraZeneca BV Postbus 599 2700 AN, Zoetermeer The Netherlands	Losec MUPS 20	20 mg	Gastroresistant tablets	Oral use	
Netherlands	AstraZeneca BV Postbus 599 2700 AN, Zoetermeer The Netherlands	Losec MUPS 40	40 mg	Gastroresistant tablets	Oral use	
Norway	AstraZeneca AS, Postboks 200 Vinderen, 0319 OSLO Norway	Losec® MUPS®	10 mg	Gastroresistant tablets	Oral use	
Norway	AstraZeneca AS, Postboks 200 Vinderen, 0319 OSLO Norway	Losec® MUPS®	20 mg	Gastroresistant tablets	Oral use	
Norway	AstraZeneca AS, Postboks 200 Vinderen, 0319 OSLO Norway	Losec®	40mg	Powder for solution for infusion	Intravenous use	40 mg
Poland	AstraZeneca AB S-151 85 Södertälje Sweden	Losec 10	10mg	Capsules	Oral use	
Poland	AstraZeneca AB S-151 85 Södertälje Sweden	Losec	20mg	Capsules	Oral use	
Poland	AstraZeneca AB S-151 85 Södertälje Sweden	Losec	40mg	Powder for solution for infusion	Intravenous use	40 mg
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, n.º 7, Valejas 2745-663 Barcarena Portugal	Losec	20 mg	Gastroresistant capsules	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, n.º 7, Valejas 2745-663 Barcarena Portugal	Losec	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Portugal	AstraZeneca Produtos Farmacêuticos, Lda. Rua Humberto Madeira, n.º 7, Valejas 2745-663 Barcarena Portugal	Losec	40 mg	Powder and solvent for injectable solution	Intravenous use	40 mg
Romania	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec MUPS 10 mg coprimate filmate gastrorezistente	10 mg	Film-coated gastroresistant tablets	Oral use	
Romania	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec MUPS 20 mg comprimate filmate gastrorezistene	20mg	Film-coated gastroresistant tablets	Oral use	
Romania	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec 40mg liofilizat pentru solutie perfuzabila	40mg	Lyophilisate for solution for infusion	Intravenous use	40 mg
Slovak Republic	AstraZeneca AB, S-151 85 Södertälje Sweden	Losec®	40 mg	Powder for solution for infusion	Intravenous use	40 mg
Spain	Laboratorio Tau, S.A. C/Serrano Galvache, 56 Edificio Roble 28033 Madrid Spain	LOSEC infusión i.v.	40 mg	Powder for infusion	Intravenous use	40 mg
Spain	Laboratorio Tau, S.A. C/Serrano Galvache, 56 Edificio Roble 28033 Madrid Spain	LOSEC cápsulas 20 mg	20 mg	Capsules, hard	Oral use	
Sweden	AstraZeneca AB S-151 85 Södertälje Sweden	Losec	10 mg	Gastro-resistant tablets	Oral use	
Sweden	AstraZeneca AB S-151 85 Södertälje Sweden	Losec	20 mg	Gastro-resistant tablets	Oral use	
Sweden	AstraZeneca AB S-151 85 Södertälje Sweden	Losec	40 mg	Gastro-resistant tablets	Oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Sweden	AstraZeneca AB S-151 85 Södertälje Sweden	Losec	40 mg	Powder for solution for injection	Intravenous use	40 mg
Sweden	AstraZeneca AB S-151 85 Södertälje Sweden	Losec	40 mg	Powder for solution for infusion	Intravenous use	40 mg
United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec MUPS Tablets 10mg	10mg	Film-coated Tablet	Oral use	
United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec MUPS Tablets 20mg	20mg	Film-coated Tablet	Oral use	
United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec MUPS Tablets 40mg	40mg	Film-coated Tablet	Oral use	
United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec Capsules 10mg	10mg	Hard gelatin capsules	Oral use	
United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec Capsules 20mg	20mg	Hard gelatin capsules	Oral use	
United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec Capsules 40mg	40mg	Hard gelatine capsules	Oral use	
United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec Infusion 40mg	40mg	Powder for solution for infusion	Intravenous use	40 mg
United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Losec IV Injection 40mg	40mg	Powder and solvent for solution for injection	Intravenous use	40 mg

ANNEX VII

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTES OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Austria	Nycomed Pharma GmbH Euro Plaza Gebäude F Technologiestrasse 5 1120 Vienna Austria	Pantoloc 20 mg -Filmtabletten	20 mg	Gastro-resistant tablet	oral use	
Austria	Nycomed Pharma GmbH Euro Plaza Gebäude F Technologiestrasse 5 1120 Vienna Austria	Pantoloc 40 mg -Filmtabletten	40 mg	Gastro-resistant tablet	oral use	
Austria	Nycomed Pharma GmbH Euro Plaza Gebäude F Technologiestrasse 5 1120 Vienna Austria	Pantoloc 40 mg -Trockenstech-ampulle	40 mg	Powder for solution for injection	intravenous use	40 mg
Austria	Nycomed Austria GmbH St. Peter Strasse 25 4020 Linz Austria	Zurcal 20 mg -Filmtabletten	20 mg	Gastro-resistant tablet	oral use	
Austria	Nycomed Austria GmbH St. Peter Strasse 25 4020 Linz Austria	Zurcal 40 mg -Filmtabletten	40 mg	Gastro-resistant tablet	oral use	
Austria	Nycomed Austria GmbH St. Peter Strasse 25 4020 Linz Austria	Zurcal 40 mg -Trockenstech-ampulle	40 mg	Powder for solution for injection	intravenous use	40 mg
Belgium	Nycomed Belgium SCA/CVA Gentsesteenweg 615 1080 Brussels Belgium	Pantozol	40 mg	Gastro-resistant tablet	oral use	
Belgium	Nycomed Belgium SCA/CVA Gentsesteenweg 615 1080 Brussels Belgium	Pantozol	20 mg	Gastro-resistant tablet	oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Belgium	Nycomed Belgium SCA/CVA Gentsesteenweg 615 1080 Brussels Belgium	Pantozol IV	40 mg	Powder for solution for injection	intravenous use	40 mg
Belgium	Nycomed Belgium SCA/CVA Gentsesteenweg 615 1080 Brussels Belgium	Zurcale	40 mg	Gastro-resistant tablet	oral use	
Belgium	Nycomed Belgium SCA/CVA Gentsesteenweg 615 1080 Brussels Belgium	Zurcale 20 mg	20 mg	Gastro-resistant tablet	oral use	
Belgium	Nycomed Belgium SCA/CVA Gentsesteenweg 615 1080 Brussels Belgium	Zurcale IV	40 mg	Powder for solution for injection	intravenous use	40 mg
Bulgaria	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Controloc	20 mg	Gastro-resistant tablet	oral use	
Bulgaria	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Controloc	40 mg	Gastro-resistant tablet	oral use	
Cyprus	Mundipharma Pharmaceuticals Ltd. Othellos str. 13 Dhali Industrial Zone 1685 Nicosia Cyprus	Controloc	20 mg	Gastro-resistant tablet	oral use	
Cyprus	Mundipharma Pharmaceuticals Ltd. Othellos str. 13 Dhali Industrial Zone 1685 Nicosia Cyprus	Controloc	40 mg	Gastro-resistant tablet	oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Cyprus	Mundipharma Pharmaceuticals Ltd. Othellos str. 13 Dhali Industrial Zone 1685 Nicosia Cyprus	Controloc i.v.	40 mg	Powder for solution for injection	intravenous use	40 mg
Czech Republic	Nycomed GmbH Byk-Gulden-Str.2 78467 Konstanz Germany	Controloc 20 mg	20 mg	Gastro-resistant tablet	oral use	
Czech Republic	Nycomed GmbH Byk-Gulden-Str.2 78467 Konstanz Germany	Controloc 40 mg	40 mg	Gastro-resistant tablet	oral use	
Czech Republic	Nycomed GmbH Byk-Gulden-Str.2 78467 Konstanz Germany	Controloc i.v.	40 mg	Powder for solution for injection	intravenous use	40 mg
Denmark	Nycomed Denmark ApS Langebjerg 1 4000 Roskilde Denmark	Pantoloc	20 mg	Gastro-resistant tablet	oral use	
Denmark	Nycomed Denmark ApS Langebjerg 1 4000 Roskilde Denmark	Pantoloc	40 mg	Gastro-resistant tablet	oral use	
Denmark	Nycomed Denmark ApS Langebjerg 1 4000 Roskilde Denmark	Pantoloc	40 mg	Powder for solution for injection	intravenous use	40 mg
Estonia	Nycomed GmbH Byk-Gulden-Str.2 78467 Konstanz Germany	Controloc 20 mg	20 mg	Gastro-resistant tablet	oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Estonia	Nycomed GmbH Byk-Gulden-Str.2 78467 Konstanz Germany	Controloc 40 mg	40 mg	Gastro-resistant tablet	oral use	
Finland	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Somac 20 mg enterotabletti	20 mg	Gastro-resistant tablet	oral use	
Finland	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Somac 40 mg enterotabletti	40 mg	Gastro-resistant tablet	oral use	
Finland	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Somac 40 mg injektiokuiva-aine, liuosta varten	40 mg	Powder for solution for injection	intravenous use	40 mg
France	Nycomed France 13, rue Watt 75013 Paris France	Eupantol 20 mg, comprimé gastro-résistant	20 mg	Gastro-resistant tablet	oral use	
France	Nycomed France 13, rue Watt 75013 Paris France	Eupantol 40 mg, comprimé gastro-résistant	40 mg	Gastro-resistant tablet	oral use	
France	Nycomed France 13, rue Watt 75013 Paris France	Eupantol 40 mg poudre pour solution injectable IV	40 mg	Powder for solution for injection	intravenous use	40 mg
France	Nycomed France 13, rue Watt 75013 Paris France	Inipomp 20 mg, comprimé gastro-résistant	20 mg	Gastro-resistant tablet	oral use	
France	Nycomed France 13, rue Watt 75013 Paris France	Inipomp 40 mg, comprimé gastro-résistant	40 mg	Gastro-resistant tablet	oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
France	Nycomed France 13, rue Watt 75013 Paris France	Inipomp 40 mg; poudre pour IV	40 mg	Powder for solution for injection	intravenous use	40 mg
France	Nycomed France 13, rue Watt 75013 Paris France	Pantec 20 mg, comprimé gastro-résistant	20 mg	Gastro-resistant tablet	oral use	
France	Nycomed France 13, rue Watt 75013 Paris France	Pantec 40 mg, comprimé gastro-résistant	40 mg	Gastro-resistant tablet	oral use	
France	Nycomed France 13, rue Watt 75013 Paris France	Pantipp 20 mg, comprimé gastro-résistant	20 mg	Gastro-resistant tablet	oral use	
France	Nycomed France 13, rue Watt 75013 Paris France	Pantipp 40 mg, comprimé gastro-résistant	40 mg	Gastro-resistant tablet	oral use	
Germany	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Pantoprazol NYC 20 mg	20 mg	Gastro-resistant tablet	oral use	
Germany	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Pantoprazol NYC 40 mg	40 mg	Gastro-resistant tablet	oral use	
Germany	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Pantoloc i.v.	40 mg	Powder for solution for injection	intravenous use	40 mg
Germany	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Pantoprazol 20 mg Byk	20 mg	Gastro-resistant tablet	oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Germany	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Pantoprazol-Byk i.v.	40 mg	Powder for solution for injection	intravenous use	
Germany	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Pantozol 20 mg	20 mg	Gastro-resistant tablet	oral use	
Germany	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Pantozol 40 mg	40 mg	Gastro-resistant tablet	oral use	
Germany	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Pantozol i.v.	40 mg	Powder for solution for injection	intravenous use	40 mg
Germany	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	PantoLomberg 20 mg	20 mg	Gastro-resistant tablet	oral use	
Germany	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Pantoprazole Lomberg 20 mg	20 mg	Gastro-resistant tablet	oral use	
Germany	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Rifun 20 mg	20 mg	Gastro-resistant tablet	oral use	
Germany	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Rifun 40 mg	40 mg	Gastro-resistant tablet	oral use	
Germany	Byk Tosse Arzneimittel GmbH, Moltkestr. 4 78467 Constance Germany	Zurcal S 20 mg magensaftresistente Tabletten	20 mg	Gastro-resistant tablet	oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Germany	Byk Tosse Arzneimittel GmbH, Moltkestr. 4 78467 Constance Germany	Zurcal S 40 mg magensaftresistente Tabletten	40 mg	Gastro-resistant tablet	oral use	
Greece	Sanofi-Aventis Greece 348, Syngrou Avenue Building A 176 74 Kallithea Greece	Controloc 20 mg	20 mg	Gastro-resistant tablet	oral use	
Greece	Sanofi-Aventis Greece 348, Syngrou Avenue Building A 176 74 Kallithea Greece	Controloc	40 mg	Gastro-resistant tablet	oral use	
Greece	Sanofi-Aventis Greece 348, Syngrou Avenue Building A 176 74 Kallithea Greece	Controloc i.v.	40 mg	Powder for solution for injection	intravenous use	40 mg
Greece	Nycomed Hellas S.A. 196, Kifissias Ave. 152 31 Chalandri Athens Greece	Zurcazol 20 mg	20 mg	Gastro-resistant tablet	oral use	
Greece	Nycomed Hellas S.A. 196, Kifissias Ave. 152 31 Chalandri Athens Greece	Zurcazol	40 mg	Gastro-resistant tablet	oral use	
Greece	Nycomed Hellas S.A. 196, Kifissias Ave. 152 31 Chalandri Athens Greece	Zurcazol i.v.	40 mg	Powder for solution for injection	intravenous use	40 mg
Hungary	Nycomed GmbH Byk-Gulden-Str.2 78467 Konstanz Germany	Controloc 20 mg	20 mg	Gastro-resistant tablet	oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Hungary	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Controloc 40 mg	40 mg	Gastro-resistant tablet	oral use	
Hungary	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Controloc i.v.	40 mg	Powder for solution for injection	intravenous use	40 mg
Ireland	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Protium	40 mg	Gastro-resistant tablet	oral use	
Ireland	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Protium 20 mg	20 mg	Gastro-resistant tablet	oral use	
Ireland	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Protium i.v.	40 mg	Powder for solution for injection	intravenous use	40 mg
Italy	Nycomed Italia S.r.l via Libero Temolo 4 20126 Milan Italy	Pantecta	40 mg	Gastro-resistant tablet	oral use	
Italy	Nycomed Italia S.r.l via Libero Temolo 4 20126 Milan Italy	Pantecta	20 mg	Gastro-resistant tablet	oral use	
Italy	Almirall S.p.A via Messina, 38 Torre C 20154 Milan Italy	Pantopan	40 mg	Gastro-resistant tablet	oral use	
Italy	Almirall S.p.A via Messina, 38 Torre C 20154 Milan Italy	Pantopan	20 mg	Gastro-resistant tablet	oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Italy	Nycomed S.p.A. Via Temolo 4 20126 Milan Italy	Pantorc	40 mg	Gastro-resistant tablet	oral use	
Italy	Nycomed S.p.A. Via Temolo 4 20126 Milan Italy	Pantorc	20 mg	Gastro-resistant tablet	oral use	
Italy	Nycomed S.p.A. Via Temolo 4 20126 Milan Italy	Pantorc.	40 mg	Powder for solution for injection	intravenous use	40 mg
Italy	Recordati Industria Chimica e Farmaceutica S.p.A Via M. Civitali 1 20148 Milan Italy	Peptazol	40 mg	Gastro-resistant tablet	oral use	
Italy	Recordati Industria Chimica e Farmaceutica S.p.A Via M. Civitali 1 20148 Milan Italy	Peptazol	20 mg	Gastro-resistant tablet	oral use	
Latvia	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Controloc 20 mg	20 mg	Gastro-resistant tablet	oral use	
Latvia	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Controloc 40 mg	40 mg	Gastro-resistant tablet	oral use	
Lithuania	Nycomed GmbH Byk-Gulden-Str.2 78467 Konstanz Germany	Controloc	20 mg	Gastro-resistant tablet	oral use	
Lithuania	Nycomed GmbH Byk-Gulden-Str.2 78467 Konstanz Germany	Controloc	40 mg	Gastro-resistant tablet	oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Luxembourg	Nycomed Belgium SCA/CVA Gentsesteenweg 615 1080 Brussels Belgium	Panto-Byk-20	20 mg	Gastro-resistant tablet	oral use	
Luxembourg	Nycomed Belgium SCA/CVA Gentsesteenweg 615 1080 Brussels Belgium	Panto-Byk-40	40 mg	Gastro-resistant tablet	oral use	
Luxembourg	Nycomed Belgium SCA/CVA Gentsesteenweg 615 1080 Brussels Belgium	Panto-Byk-IV	40 mg	Powder for solution for injection	intravenous use	40 mg
Luxembourg	Nycomed Belgium SCA/CVA Gentsesteenweg 615 1080 Brussels Belgium	Pantozol-20	20 mg	Gastro-resistant tablet	oral use	
Luxembourg	Nycomed Belgium SCA/CVA Gentsesteenweg 615 1080 Brussels Belgium	Pantozol 40	40 mg	Gastro-resistant tablet	oral use	
Luxembourg	Nycomed Belgium SCA/CVA Gentsesteenweg 615 1080 Brussels Belgium	Pantozol-IV	40 mg	Powder for solution for injection	intravenous use	40 mg
Netherlands	Nycomed bv Jupiterstraat 250 2132 HK Hoofddorp Netherlands	Pantozol 20	20 mg	Gastro-resistant tablet	oral use	
Netherlands	Nycomed bv Jupiterstraat 250 2132 HK Hoofddorp Netherlands	Pantozol 40	40 mg	Gastro-resistant tablet	oral use	
Netherlands	Nycomed bv Jupiterstraat 250 2132 HK Hoofddorp Netherlands	Pantozol i.v.	40 mg	Powder for solution for injection	intravenous use	40 mg

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Netherlands	Nycomed bv Jupiterstraat 250 2132 HK Hoofddorp Netherlands	Pantoprazol Nycomed 40 mg	40 mg	Gastro-resistant tablet	oral use	
Norway	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Somac	20 mg	Gastro-resistant tablet	oral use	
Norway	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Somac	40 mg	Gastro-resistant tablet	oral use	
Norway	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Somac	40 mg	Powder for solution for injection	intravenous use	40 mg
Poland	Nycomed Pharma Sp.z o.o. Al. Jerozolimskie 146A 02-305 Warsaw Poland	Controloc 20	20 mg	Gastro-resistant tablet	oral use	
Poland	Nycomed Pharma Sp.z o.o. Al. Jerozolimskie 146A 02-305 Warsaw Poland	Controloc 40	40 mg	Gastro-resistant tablet	oral use	
Poland	Nycomed Pharma Sp.z o.o. Al. Jerozolimskie 146A 02-305 Warsaw Poland	Controloc	40 mg	Powder for solution for injection	intravenous use	40 mg
Portugal	Laboratórios Delta, Lda. Rua Direita, 148 Massamá 2745-751 QUELUZ Portugal	Apton 40 mg	40 mg	Gastro-resistant tablet	oral use	
Portugal	Laboratórios Delta, Lda. Rua Direita, 148 Massamá 2745-751 QUELUZ Portugal	Apton	20 mg	Gastro-resistant tablet	oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Portugal	Nycomed Portugal Produtos Farmaceuticos, Lda. Quinta da Fonte Edificio Gil Eanes Paço D'Arcos 2770-192 Paço D'Arcos Portugal	Pantoc 40 mg	40 mg	Gastro-resistant tablet	oral use	
Portugal	Nycomed Portugal - Produtos Farmacêuticos, Lda. Quinta da Fonte Edificio Gil Eanes Paço D'Arcos 2770-192 Paço D'Arcos Portugal	Pantoc	20 mg	Gastro-resistant tablet	oral use	
Portugal	Nycomed Portugal - Produtos Farmacêuticos, Lda. Quinta da Fonte Edificio Gil Eanes Paço D'Arcos 2770-192 Paço D'Arcos Portugal	Pantoc IV	40 mg	Powder for solution for injection	intravenous use	40 mg
Portugal	Nycomed Portugal - Produtos Farmacêuticos, Lda. Quinta da Fonte Edificio Gil Eanes Paço D'Arcos 2770-192 Paço D'Arcos Portugal	Zurcal	20 mg	Gastro-resistant tablet	oral use	
Portugal	Nycomed Portugal Produtos Farmaceuticos, Lda. Quinta da Fonte Edificio Gil Eanes Paço D'Arcos 2770-192 Paço D'Arcos Portugal	Zurcal 40 mg	40 mg	Gastro-resistant tablet	oral use	
Portugal	Nycomed Portugal - Produtos Farmacêuticos, Lda. Quinta da Fonte Edificio Gil Eanes Paço D'Arcos 2770-192 Paço D'Arcos Portugal	Pantoprazole ALTANA 20 mg	20 mg	Gastro-resistant tablet	oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Portugal	Nycomed Portugal - Produtos Farmacêuticos, Lda. Quinta da Fonte Edificio Gil Eanes Paço D'Arcos 2770-192 Paço D'Arcos Portugal	Pantoprazole ALTANA 40 mg	40 mg	Gastro-resistant tablet	oral use	
Romania	Nycomed GmbH Byk-Gulden-Str.2 78467 Konstanz Germany	Controloc 20 mg	20 mg	Gastro-resistant tablet	oral use	
Romania	Nycomed GmbH Byk-Gulden-Str.2 78467 Konstance Germany	Controloc 40 mg	40 mg	Gastro-resistant tablet	oral use	
Romania	Nycomed GmbH Byk-Gulden-Str.2 78467 Konstance Germany	Controloc i.v.	40 mg	Powder for solution for injection	intravenous use	40 mg
Slovak Republic	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Controloc 20 mg gastrorezistentné tablety	20 mg	Gastro-resistant tablet	oral use	
Slovak Republic	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Controloc 40 mg	40 mg	Gastro-resistant tablet	oral use	
Slovak Republic	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Controloc i.v.	40 mg	Powder for solution for injection	intravenous use	40 mg
Slovenia	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Controloc 20 mg gastrorezistentne tablete	20 mg	Gastro-resistant tablet	oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Slovenia	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Controloc 40 mg gastrorezistentne tablete	40 mg	Gastro-resistant tablet	oral use	
Slovenia	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Controloc 40 mg prašek za raztopino za injiciranje	40 mg	Powder for solution for injection	intravenous use	40 mg
Spain	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Anagastra 20 mg Blister	20 mg	Gastro-resistant tablet	oral use	
Spain	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Anagastra 40 mg blister	40 mg	Gastro-resistant tablet	oral use	
Spain	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Anagastra 40 mg polvo para solución inyectable I.V.	40 mg	Powder for solution for injection	intravenous use	40 mg
Spain	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Pantecta 20 mg comprimidos gastrorresistentes Blister	20 mg	Gastro-resistant tablet	oral use	
Spain	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Pantecta 40 mg Blister	40 mg	Gastro-resistant tablet	oral use	
Spain	Nycomed GmbH Byk-Gulden-Str.2 78467 Constance Germany	Ulcotenal 20 mg comprimidos gastrorresistentes Blister	20 mg	Gastro-resistant tablet	oral use	
Spain	Nycomed GmbH Byk-Gulden-Str.2 78467 Konstanz Germany	Ulcotenal 40 mg Blister	40 mg	Gastro-resistant tablet	oral use	

Member State EU/EEA	Marketing Authorisation Holder	(Invented) name	Strength	Pharmaceutical Form	Route of administration	Content (concentration)
Sweden	Nycomed AB Box 27264 102 53 Stockholm Sweden	Pantoloc	20 mg	Gastro-resistant tablet	oral use	
Sweden	Nycomed AB Box 27264 102 53 Stockholm Sweden	Pantoloc	40 mg	Gastro-resistant tablet	oral use	
Sweden	Nycomed AB Box 27264 102 53 Stockholm Sweden	Pantoloc	40 mg	Powder for solution for injection	intravenous use	40 mg
United Kingdom	Nycomed GmbH Byk-Gulden-Str.2 78467 Konstance Germany	Protium 20 mg	20 mg	Gastro-resistant tablet	oral use	
United Kingdom	Nycomed GmbH Byk-Gulden-Str.2 78467 Konstance Germany	Protium 40 mg	40 mg	Gastro-resistant tablet	oral use	
United Kingdom	Nycomed GmbH Byk-Gulden-Str.2 78467 Konstance Germany	Protium i.v.	40 mg	Powder for solution for injection	intravenous use	40 mg

ANNEX VIII

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE VETERINARY MEDICINAL PRODUCT, ANIMAL SPECIES, ROUTE OF ADMINISTRATION, APPLICANT/MARKETING AUTHORISATION HOLDER IN THE MEMBER STATES

Member State	Applicant/Marketing Authorisation Holder	Invented name	Pharmaceutical form	Strength	Animal species	Frequency and route of administration
Austria	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml, Suspension zum Eingeben für Ferkel	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0,4 ml oral suspension per kg body weight.
Belgium	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml, orale suspensie voor biggen	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0,4 ml oral suspension per kg body weight.
Bulgaria	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	СЕВАЗУРИЛ 50 мг/мл, суспензия за перорално прилагане при прасета	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0,4 ml oral suspension per kg body weight.
Cyprus	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml, πόσιμο εναιώρημα για χοιρίδια	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0,4 ml oral suspension per kg body weight.
Czech Republic	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml, Perorální suspense pro selata	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0,4 ml oral suspension per kg body weight.
Denmark	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	Cevazuril 50mg/ml, oral suspension til spædgrise	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0,4 ml oral suspension per kg body weight.

Member State	Applicant/Marketing Authorisation Holder	Invented name	Pharmaceutical form	Strength	Animal species	Frequency and route of administration
Estonia	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE Bristol UK	CEVAZURIL 50 mg/ml, Suukaudne suspension jaoks põrsad	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0,4 ml oral suspension per kg body weight.
France	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml, suspension buvable pour porcelets [1]	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0,4 ml oral suspension per kg body weight.
Germany	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml, Suspension zum Eingeben für Ferkel	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0,4 ml oral suspension per kg body weight.
Greece	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml, πόσιμο εναιώρημα για χοιρίδια	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0,4 ml oral suspension per kg body weight.
Hungary	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml, belsőleges szuszpenzió malacoknak	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0,4 ml oral suspension per kg body weight.
Ireland	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml, oral suspension for piglets	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0,4 ml oral suspension per kg body weight.

Member State	Applicant/Marketing Authorisation Holder	Invented name	Pharmaceutical form	Strength	Animal species	Frequency and route of administration
Italy	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml, sospensione orale per suinetti	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0,4 ml oral suspension per kg body weight.
Latvia	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml, Suspensija iekšķīgai lietošanai dzīļ sivēni	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0,4 ml oral suspension per kg body weight.
Lithuania	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml, Geriamoji suspensija dėl paršeliai	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0,4 ml oral suspension per kg body weight.
Luxembourg	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml, suspension buvable pour porcelets [1]	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0,4 ml oral suspension per kg body weight.
Malta	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml Suspensjoni orali għal ħnienes	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0,4 ml oral suspension per kg body weight.
The Netherlands	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml, orale suspensie voor biggen	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0,4 ml oral suspension per kg body weight.

Member State	Applicant/Marketing Authorisation Holder	Invented name	Pharmaceutical form	Strength	Animal species	Frequency and route of administration
Poland	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml, zawiesina doustna dla prosiąt	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0,4 ml oral suspension per kg body weight.
Portugal	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml, suspensão oral para leitões	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0,4 ml oral suspension per kg body weight.
Romania	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml, Suspensie orală pentru purceii	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0.4 ml oral suspension per kg body weight.
Slovakia	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml, Perorálna suspenzia pre prasiatka	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0.4 ml oral suspension per kg body weight.
Spain	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml, Suspensión Oral para lechones	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0.4 ml oral suspension per kg body weight.
United Kingdom	Ceva Santé Animale Z.I. La Ballastière 33500 Libourne FRANCE	CEVAZURIL 50 mg/ml, oral suspension for piglets	Oral suspension	50 mg toltrazuril/ml	Piglets	Individual animal treatment. Each piglet to be treated on day 3-5 of life with a single oral dose of 20 mg toltrazuril/kg body weight corresponding to 0.4 ml oral suspension per kg body weight.

(1) Marketing Authorisation granted

ANNEX IX

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, APPLICANTS IN THE MEMBER STATES

Member State EU/EEA	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Austria	Bluefish Pharmaceuticals AB Torsgatan 11 SE-111 23 Stockholm Sweden	Pantoprazol Bluefish 20 mg/40 mg magensaftresistente Tabletten	20 mg and 40 mg	Gastro-resistant tablet	Oral use
Denmark	Bluefish Pharmaceuticals AB Torsgatan 11 SE-111 23 Stockholm Sweden	Pantoprazole Bluefish	20 mg and 40 mg	Gastro-resistant tablet	Oral use
Finland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-111 23 Stockholm Sweden	Pantoprazole Bluefish 20 mg/40 mg enterotabletia/entero-tabletter	20 mg and 40 mg	Gastro-resistant tablet	Oral use
France	Bluefish Pharmaceuticals AB Torsgatan 11 SE-111 23 Stockholm Sweden	Pantoprazole Bluefish 20 mg/40 mg comprimé gastro-resistant	20 mg and 40 mg	Gastro-resistant tablet	Oral use
Germany	Bluefish Pharmaceuticals AB Torsgatan 11 SE-111 23 Stockholm Sweden	Pantoprazole Bluefish 20 mg/40 mg magensaftresistente tabletten	20 mg and 40 mg	Gastro-resistant tablet	Oral use
Hungary	Bluefish Pharmaceuticals AB Torsgatan 11 SE-111 23 Stockholm Sweden	Pantoprazole Bluefish 20 mg/40 mg bélben oldódó tabletta	20 mg and 40 mg	Gastro-resistant tablet	Oral use
Ireland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-111 23 Stockholm Sweden	Pantoprazole Bluefish 20 mg/40 mg gastro-resistant tablet	20 mg and 40 mg	Gastro-resistant tablet	Oral use
Italy	Bluefish Pharmaceuticals AB Torsgatan 11 SE-111 23 Stockholm Sweden	Pantoprazolo Bluefish	20 mg and 40 mg	Gastro-resistant tablet	Oral use
Netherlands	Bluefish Pharmaceuticals AB Torsgatan 11 SE-111 23 Stockholm Sweden	Pantoprazol Bluefish 20 mg/40 mg maagsapresistente-tabletten	20 mg and 40 mg	Gastro-resistant tablet	Oral use

Member State EU/EEA	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Norway	Bluefish Pharmaceuticals AB Torsgatan 11 SE-111 23 Stockholm Sweden	Pantoprazol Bluefish enterotabletter	20 mg and 40 mg	Gastro-resistant tablet	Oral use
Poland	Bluefish Pharmaceuticals AB Torsgatan 11 SE-111 23 Stockholm Sweden	Pantoprazole Bluefish	20 mg and 40 mg	Gastro-resistant tablet	Oral use
Portugal	Bluefish Pharmaceuticals AB Torsgatan 11 SE-111 23 Stockholm Sweden	Pantoprazole Bluefish	20 mg and 40 mg	Gastro-resistant tablet	Oral use
Spain	Bluefish Pharmaceuticals AB Torsgatan 11 SE-111 23 Stockholm Sweden	Pantoprazole Bluefish 20 mg/40 mg comprimidos gastro-resistentes	20 mg and 40 mg	Gastro-resistant tablet	Oral use
Sweden	Bluefish Pharmaceuticals AB Torsgatan 11 SE-111 23 Stockholm Sweden	Pantoprazole Bluefish	20 mg and 40 mg	Gastro-resistant tablet	Oral use

ANNEX X

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, APPLICANTS IN THE MEMBER STATES

Member State EU/EEA	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Czech Republic	Olinka (UK) Limited 38/40 Chamberlayne Road London, United Kingdom NW10 3JE	Pantoprazole 20 mg Gastro-resistant tablets	20 mg	Gastro-resistant tablet	Oral use
Czech Republic	Olinka (UK) Limited 38/40 Chamberlayne Road London, United Kingdom NW10 3JE	Pantoprazole 40 mg Gastro-resistant tablets	40 mg	Gastro-resistant tablet	Oral use
Germany	Olinka (UK) Limited 38/40 Chamberlayne Road London, United Kingdom NW10 3JE	Pantoprazole 20 mg Gastro-resistant tablets	20 mg	Gastro-resistant tablet	Oral use
Germany	Olinka (UK) Limited 38/40 Chamberlayne Road London, United Kingdom NW10 3JE	Pantoprazole 40 mg Gastro-resistant tablets	40 mg	Gastro-resistant tablet	Oral use
Poland	Olinka (UK) Limited 38/40 Chamberlayne Road London, United Kingdom NW10 3JE	Pantoprazole Olinka	20 mg	Gastro-resistant tablet	Oral use
Poland	Olinka (UK) Limited 38/40 Chamberlayne Road London, United Kingdom NW10 3JE	Pantoprazole Olinka	40 mg	Gastro-resistant tablet	Oral use
Slovak Republic	Olinka (UK) Limited 38/40 Chamberlayne Road London, United Kingdom NW10 3JE	Pantoprazole Olinka 20 mg Gastrorezistentne tablety	20 mg	Gastro-resistant tablet	Oral use
Slovak Republic	Olinka (UK) Limited 38/40 Chamberlayne Road London, United Kingdom NW10 3JE	Pantoprazole Olinka 40 mg Gastrorezistentne tablety	40 mg	Gastro-resistant tablet	Oral use

Member State EU/EEA	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
United Kingdom	Olinka (UK) Limited 38/40 Chamberlayne Road London, United Kingdom NW10 3JE	Pantoprazole 20 mg Gastro-resistant tablets	20 mg	Gastro-resistant tablet	Oral use
United Kingdom	Olinka (UK) Limited 38/40 Chamberlayne Road London, United Kingdom NW10 3JE	Pantoprazole 40 mg Gastro-resistant tablets	40 mg	Gastro-resistant tablet	Oral use

ANNEX XI

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, APPLICANTS IN THE MEMBER STATES

Member State EU/EEA	Applicant	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Germany	Olinka (UK) Limited 38/40 Chamberlayne Road London, United Kingdom NW10 3JE	Pantoprazole 20 mg Volkspharma Gastro-resistant tablets	20 mg	Gastro-resistant tablet	Oral use
Germany	Olinka (UK) Limited 38/40 Chamberlayne Road London, United Kingdom NW10 3JE	Pantoprazole 40 mg Volkspharma Gastro-resistant tablets	40 mg	Gastro-resistant tablet	Oral use
Poland	Olinka (UK) Limited 38/40 Chamberlayne Road London, United Kingdom NW10 3JE	Pantoprazole Phargem	20 mg	Gastro-resistant tablet	Oral use
Poland	Olinka (UK) Limited 38/40 Chamberlayne Road London, United Kingdom NW10 3JE	Pantoprazole Phargem	40 mg	Gastro-resistant tablet	Oral use
United Kingdom	Olinka (UK) Limited 38/40 Chamberlayne Road London, United Kingdom NW10 3JE	Pantoprazole 20 mg Gastro-resistant tablets	20 mg	Gastro-resistant tablet	Oral use
United Kingdom	Olinka (UK) Limited 38/40 Chamberlayne Road London, United Kingdom NW10 3JE	Pantoprazole 40 mg Gastro-resistant tablets	40 mg	Gastro-resistant tablet	Oral use

ANNEX XII

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES (EU/EEA)

Member State (EU/EEA)	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
Czech Republic	Ratiopharm GmbH Graf Arco Strasse 3 89079 Ulm, Germany	Valproat-Ratiopharm Chrono 300 mg	300 mg	Prolonged-release tablet	Oral use
Czech Republic	Ratiopharm GmbH Graf Arco Strasse 3 89079 Ulm, Germany	Valproat-Ratiopharm Chrono 500 mg	500 mg	Prolonged-release tablet	Oral use
Germany	Ratiopharm GmbH Graf Arco Strasse 3 89079 Ulm, Germany	Valproinsäure-ratiopharm chrono 300 mg Retardtabletten	300 mg	Prolonged-release tablet	Oral use
Germany	Ratiopharm GmbH Graf Arco Strasse 3 89079 Ulm, Germany	Valproinsäure-ratiopharm chrono 500 mg Retardtabletten	500 mg	Prolonged-release tablet	Oral use
Italy	Ratiopharm GmbH Graf Arco Strasse 3 89079 Ulm, Germany	Acido valproico E sodio Valproato Ratiopharm	300 mg	Prolonged-release tablet	Oral use
Italy	Ratiopharm GmbH Graf Arco Strasse 3 89079 Ulm, Germany	Acido valproico E sodio Valproato Ratiopharm	500 mg	Prolonged-release tablet	Oral use
Luxembourg	Ratiopharm GmbH Postfach 3380 89070 Ulm, Germany	Valproinsäure Ratiopharm Chrono	300 mg	Prolonged-release tablet	Oral use
Luxembourg	Ratiopharm GmbH Postfach 3380 89070 Ulm Germany	Valproinsäure Ratiopharm Chrono	500 mg	Prolonged-release tablet	Oral use
The Netherlands	Ratiopharm Nederland B.V. Florapark 4 2012HK Haarlem The Netherlands	Natriumvalproaat ratiopharm chrono 300 mg	300 mg	Prolonged-release tablet	Oral use

Member State (EU/EEA)	Marketing Authorisation Holder	Product Name	Strength	Pharmaceutical Form	Route of administration
The Netherlands	Ratiopharm Nederland B.V. Florapark 4 2012HK Haarlem The Netherlands	Natriumvalproaat ratiopharm chrono 500 mg	500 mg	Prolonged-release tablet	Oral use
Poland	Ratiopharm GmbH Graf-Arco-Strasse 3 89079 Ulm Germany	Valpro-ratiopharm Chrono 300 mg	199,8 mg + 87 mg	Prolonged-release tablet	Oral use
Poland	Ratiopharm GmbH Graf-Arco-Strasse 3 89079 Ulm Germany	Valpro-ratiopharm Chrono 500 mg	333 mg + 145 mg	Prolonged-release tablet	Oral use
Portugal	Ratiopharm – Comércio e Indústria de Produtos Farmacêuticos, Lda. Rua Quinta do Pinheiro – Edifício Tejo 6° Piso Carnaxide P-2790-143	Ácido Valpróico Ratiopharm 300 mg Comprimidos de libertação prolongada	300 mg	Prolonged-release tablet	Oral use
Portugal	Ratiopharm – Comércio e Indústria de Produtos Farmacêuticos, Lda. Rua Quinta do Pinheiro – Edifício Tejo 6° Piso Carnaxide P-2790-143 Portugal	Ácido Valpróico Ratiopharm 500 mg Comprimidos de libertação prolongada	500 mg	Prolonged-release tablet	Oral use
Slovakia	Ratiopharm GmbH Graf-Arco-Strasse 3 89079 Ulm Germany	Valpro ratiopharm Chrono	500 mg	Prolonged-release tablet	Oral use
United Kingdom	Ratiopharm GmbH Graf-Arco-Strasse 3 89079 Ulm Germany	Valprotek CR 300 mg (prolonged release) tablets	300 mg	Prolonged-release tablet	Oral use
United Kingdom	Ratiopharm GmbH Graf-Arco-Strasse 3 89079 Ulm Germany	Valprotek CR 500 mg (prolonged release) tablets	500 mg	Prolonged-release tablet	Oral use

ANNEX XIII

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE MEDICINAL PRODUCT, ROUTE OF ADMINISTRATION, APPLICANT IN THE MEMBER STATES

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
Austria	TEVA Pharma B.V. Computerweg 10, 3542 DR Utrecht The Netherlands	Clopidogrel Teva 75 mg Filmtabletten	75 mg	Film-coated tablet	Oral Use
Belgium	TEVA Pharma B.V. Computerweg10, 3542DR Utrecht The Netherlands	Clopidogrel 75 mg film-coated tablets	75 mg	Film-coated tablet	Oral Use
Bulgaria	TEVA Pharma B.V., Computerweg 10 3542 DR Utrecht The Netherlands	Clopix 75 mg film-coated tablets	75 mg	Film-coated tablet	Oral Use
Cyprus	TEVA Pharma BV Computerweg 10, 3542 DR Utrecht The Netherlands	Clopidogrel 75 mg film-coated tablets	75 mg	Film-coated tablet	Oral Use
Czech Republic	Teva Pharmaceuticals CR, s.r.o., Radlická 3185/1c, 150 00 Praha 5, Czech Republic	Teclop 75 mg film-coated tablets	75 mg	Film-coated tablet	Oral Use
Denmark	Dr. Reddy's Laboratories (UK) Ltd. 6 Riverview Road, Beverley, East Yorkshire, HU17 0LD United Kingdom	Clopix	75 mg	Film-coated tablet	Oral Use
Estonia	Dr. Reddy's Laboratories (UK) Ltd. 6 Riverview Road, Beverley, East Yorkshire, HU17 0LD United Kingdom	Clopidogrel Dr. Reddy's 75 mg	75 mg	Film-coated tablet	Oral Use
Finland	Teva Sweden AB Jarnvägsgatan 11 Box 1070 25110 Helsingborg Sweden	Tevaplat 75 mg film-coated tablets	75 mg	Film-coated tablet	Oral Use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
France	TEVA Classics Immeuble Palatin 1 1 cours du Triangle 92836 PARISLA DEFENSE FRANCE	Clopidogrel TEVA CLASSICS 75 mg film-coated tablets	75 mg	Film-coated tablet	Oral Use
Germany	Dr. Reddy's Laboratories (UK) Ltd. 6 Riverview Road, Beverley, East Yorkshire, HU17 0LD United Kingdom	Clopidogrel 75 mg film-coated tablets	75 mg	Film-coated tablet	Oral Use
Greece	Dr. Reddy's Laboratories (UK) Ltd. 6 Riverview Road, Beverley, East Yorkshire, HU17 0LD United Kingdom	Clopidogrel 75 mg film-coated tablets	75 mg	Film-coated tablet	Oral Use
Hungary	Dr. Reddy's Laboratories (UK) Ltd. 6 Riverview Road, Beverley, East Yorkshire, HU17 0LD United Kingdom	ALVADAVIX 75 mg film-coated tablets	75 mg	Film-coated tablet	Oral Use
Ireland	TEVA Generics B.V. Computerweg 10, 3542DR Utrecht The Netherlands	Clopidogrel 75 mg film-coated tablets	75 mg	Film-coated tablet	Oral Use
Italy	Dr. Reddy's Laboratories (UK) Ltd. 6 Riverview Road, Beverley, East Yorkshire, HU17 0LD United Kingdom	Clopidogrel 75 mg film-coated tablets	75 mg	Film-coated tablet	Oral Use
Latvia	Dr. Reddy's Laboratories (UK) Ltd. 6 Riverview Road, Beverley, East Yorkshire, HU17 0LD United Kingdom	Clopidogrel Dr. Reddy's 75 mg film-coated tablets	75 mg	Film-coated tablet	Oral Use
Lithuania	Dr. Reddy's Laboratories (UK) Ltd. 6 Riverview Road, Beverley, East Yorkshire, HU17 0LD United Kingdom	Clopidogrel Dr. Reddy's 75 mg film-coated tablets	75 mg	Film-coated tablet	Oral Use
Luxembourg	Teva Pharma BV Computerweg 10 NL- 3542 DR Utrecht The Netherlands	Clopidophar	75 mg	Film-coated tablet	Oral Use

Member State EU/EEA	Applicant company name, address	(Invented) Name	Strength	Pharmaceutical Form	Route of administration
The Netherlands	Dr. Reddy's Laboratories (UK) Ltd. 6 Riverview Road, Beverley, East Yorkshire, HU17 0LD United Kingdom	Clopidogrel 75 mg filmomhulde tabletten	75 mg	Film-coated tablet	Oral Use
Norway	Teva Sweden AB Järnvägsgatan 11, Box 1070 251 10 Helsingborg	Tevaplat 75 mg film-coated tablets	75 mg	Film-coated tablet	Oral Use
Poland	Teva Pharma B.V. Computerweg 10, 3542 DR Utrecht The Netherlands	Clopidogrel Teva Pharma	75 mg	Film-coated tablet	Oral Use
Romania	Dr. Reddy's Laboratories (UK) Ltd. 6 Riverview Road, Beverley, East Yorkshire, HU17 0LD United Kingdom	XOVAL 75 mg comprimate filmate	75 mg	Film-coated tablet	Oral Use
Slovak Republic	Dr. Reddy's Laboratories (UK) Ltd. 6 Riverview Road, Beverley, East Yorkshire, HU17 0LD United Kingdom	Clopidogrel 75 mg film-coated tablets	75 mg	Film-coated tablet	Oral Use
Spain	TEVA GENERICOS ESPAÑOLA, S.L. Guzmán el Bueno 133, Edificio Britania 4ºIzq. 28003 MADRID, Spain	Clopidogrel TEVAGEN 75 mg film-coated tablets	75 mg	Film-coated tablet	Oral Use
Sweden	Dr. Reddy's Laboratories (UK) Ltd. 6 Riverview Road, Beverley, East Yorkshire, HU17 0LD United Kingdom	Clopidogrel Reddy's	75 mg	Film-coated tablet	Oral Use
United Kingdom	Teva Pharma BV. Computerweg 10, Utrecht NL–3542DR Netherlands	Clopidogrel 75 mg film-coated tablets	75 mg	Film-coated tablet	Oral Use

ANNEX XIV

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE VETERINARY MEDICINAL PRODUCTS, ANIMAL SPECIES, ROUTE OF ADMINISTRATION, INDICATIONS/WITHDRAWAL PERIODS AND APPLICANTS/MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Austria	Chevita Tierarzneimittel Gesellschaft m.b.H. Kaplanstraße 10 AT 4600 Wels AUSTRIA	Doxymax 500 mg/g - Pulver zur Herstellung einer Lösung zum Einnehmen für Schweine und Hühner	Doxycycline hyclate	500 mg/g	Oral powder	Pigs, Chicken (broiler)	Chicken: 3-5 days, oral via drinking water	Chicken: 25mg doxycyclin hyclat/kg BW/day = 1g powder/20 kg/day	Meat and offal: Chicken (Broiler) 5 days, Eggs: not for use in laying hen Indications: infection of respiratory tract caused by Mycoplasma spp. (M.gallisepticum, Escherichia coli, Septicamia caused by Pasteurella multocida
Belgium	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	Doxycycline 50 % Dopharma	Doxycycline hyclate	500 mg/g	Water soluble powder	Calves, porcine, poultry	Poultry: 50mg/kg/day	3-5 days 500 g/1 000 L drinking water	Meat and offal: 6 days Indications: infections by micro-organisms in respiratory or gastro-intestinal system
Belgium	VIRBAC S.A. 1ère avenue - 2065 m - L.I.D. 06516 CARROS FRANCE	Pulmodox 50 %	Doxycycline hyclate	500 mg/g	Water soluble powder	Calves, porcine, poultry	Poultry: 50 mg/kg/day	3-5 days 500 g/1 000 L drinking water	Meat and offal: 6 days Indications: infections by micro-organisms in respiratory or gastro-intestinal system
Belgium	Eurovet Animal Health B.V. Handelsveg 25 PO Box 179 5530 AD Bladel THE NETHERLANDS	Soludox 50 %	Doxycycline hyclate	500mg/g	Water soluble powder	Porcine, poultry	Poultry: 10-20mg/kg/day	3-4 days 100-200 g/1 000 L drinkwater	Meat and offal: 3 days/10mg/kg 12 days/20mg/kg Indications: respiratory diseases

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Belgium	Eurovet Animal Health B.V. Handelsveg 25 PO Box 179 5530 AD Bladel THE NETHERLANDS	Soludox 15 % ad. us. vet..	Doxycycline hyclate	150mg/g	Water soluble powder	Porcine, calves, poultry, fancy birds, pigeons	Poultry: 10-20mg/kg/day	3-5 days 500 g/1 000 L drinkwater	Meat and offal: 7 days Indications: respiratory diseases caused by germs
Belgium	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen BELGIUM	Hydrodoxx 500 mg/g water-soluble powder	Doxycycline hyclate	500mg/g doxycycline hyclate	Powder for oral solution	Chickens (broilers) & Pigs (fattening pigs)	Oral (drinking water)	20 mg doxycycline (hyclate)/kg x 3-5 days	Meat and offal: Chickens: 6 days Do not use in laying birds producing eggs for human consumption Indications: Chickens (broilers): Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum.
Bulgaria	Farma Sis OOD 4 San Stefano Str. Dobrich BULGARIA	Doxinyl 10 % Oral Suspension	Doxycycline hyclate	100mg/ml	Oral Suspension	Poultry	Via drinking water	50 -100 ml Doxinyl 10 % in 100 l drinking water per day (50-100 mg Doxycycline in 1 l drinking water) 3-5 days	Meat - 5 days
Bulgaria	Farma Sis OOD 4 San Stefano Str. Dobrich BULGARIA	Cyvadox 10 %	Doxycycline hyclate	100mg/ml	Oral Suspension	Poultry	Via drinking water	0,5-1 ml in 1 l drinking water per day \3-5 days\ 50-100 mg Doxycycline	Meat - 7 days
Bulgaria	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	Doxycycline 50 % w.s.p.	Doxycycline hyclate	500mg/g	Water soluble powder	Poultry	Via drinking water	500g Doxycycline 50 % w.s.p. in 100 l drinking water/3-5 days/	Meat - 4 days
Bulgaria	Farmavet OOD 40 Otec Paisij Str. Shumen BULGARIA	Doxycycline 20 % Pulvis solubilis	Doxycycline hyclate	200mg/g	Water soluble powder	Poultry	Via drinking water	50g Doxycycline 20 % in 100l drinking water/3-5 days/	Meat - 7 days

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Bulgaria	Interchemie Werken De Adelaar BV Hosterweg 26a 5811 Ccastenray THE NETHERLANDS	Doxy – WS	Doxycycline hyclate	200mg/g	Water soluble powder	Poultry	Via drinking water	1kg Doxy-WS in 2 000-4 000 l drinking water	Meat - 7 days
Bulgaria	Ceva Sante Animale France La Balastiere 33501 Libourne Cedex FRANCE	Doxyvit 50 % WSP	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry	Via drinking water	2-3g Doxyvit 50 % WSP in 10 l. Drinking water - 5 days/equivalent to 100-150 mg Doxycycline in 1l water	Meat - 7 days
Bulgaria	Ceva Sante Animale France La Balastiere 33501 Libourne Cedex FRANCE	Doxyvit 100	Doxycycline hyclate	100 mg/g	Water soluble powder	Poultry	Via drinking water	10 mg Doxyvit per kg body weight per day	Meat - 7 days
Bulgaria	Vetpartners OOD Ivan Asen Str. 4270 Parvomaj BULGARIA	Polidoxichem 500/WSP	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry	Via drinking water	50-100 mg Doxycycline in 1l drinking water/3-5 days/ equivalent to 0,1-0,2g Polidoxichem 500 WSP in 1l drinking water per day	Meat - 7 days
Bulgaria	Biovet AD 39 Petar Rakov Str. 4550 Peshtera BULGARIA	Vibravet 10 % Water soluble premix	Doxycycline hyclate	100 mg/g	Water soluble powder	Poultry	Via drinking water	1g Vibravet 10 % in 1l drinking water /=67-100 mg Doxycycline/per day. 5 days	Meat - 7 days

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Cyprus	PREMIER SHUKUROGLOU LTD	HIPRADOXI -S	Doxycycline hyclate	100 mg	Oral solution	Pigs, Chicken (broiler)	By oral route, via drinking water	Broilers: 50-100 mg doxycycline hyclaye/L water for 3-5 days	Broilers: meat: 5 days Pigs: meat:6 days
Czech republic	Industria Italiana Integratori TREI S.p.A. Viale Corassori 62 41100 Modena ITALY	DOXIPAN 20	Doxycycline hyclate	20 g/100 g	Powder for oral solution	Chicken-broiler, turkey	Administer orally via drinking water for 5 days.	Broiler: 5-7,5 g of product/10 l drinking water turkey: 10 – 20 mg doxycycline/kg bodyweight	Chicken broiler: Meat and offal: 5 days. Turkey: meat and offal: 10 days Indications: Chicken broilers: Chronic respiratory diseases and associated infections. Turkeys: Diseases caused G+ and G- microorganisms and mycoplasmas, especially respiratory and articular syndrome caused by mycoplasmas and/or staphylococcus.
Czech republic	Pharmagal s.r.o., Murgašova 5, 949 01 Nitra, SLOVAK REPUBLIC	DOXYGAL	Doxycycline hyclate	50 mg/1 g	Powder for oral solution	Poultry	Administer orally via drinking water for 3-5 days.	Therapeutically- preventive: 50 mg doxycycline/1 l drinking water Therapeutically: 100 mg doxycycline/1 l drinking water	Meat and offal: 7 days. Not permitted for use in laying hens from which eggs are produced for human consumption. Indications: Used for the treatment of the secondary bacterial infections following to viral origin diseases. Poultry: CRD (mycoplasmosis), colibacillosis

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Czech republic	Lavet Pharmaceuticals Ltd., 1161 Budapest Ottó u. 14, HUNGARY	DOXYVIT 40 %	Doxycicline hyclate	40g/100g	Powder for oral solution	Chicken-broiler, turkey	Administer orally via drinking water for 3-5 days.	1.Continuous therapy: 1,0g DOXYVIT 40 % per 3-6 L of drinking water 2.Pulse therapy: 10-20 mg doxycycline / kg b.w., intervals 4-8 hours.	Chicken broiler, turkey: Meat and offal: 4 days. Not permitted for use in laying hens from which eggs are produced for human consumption. Indications: Treatment and prevention of respiratory, intestinal and systemic infections caused by microorganisms susceptible to doxycycline in broilers and turkeys. Chronic respiratory disease (Mycoplasma gallisepticum, Escherichia coli) Aerosaculitis (Mycoplasma meleagridis) Infectious synovitis (Mycoplasma synoviae) Fowl cholera (Pasterella multocida) Bordetella turkey infections (Bordetella avium) Infectious coryza (Haemophilus paragallinarum) Colibacillosis (Eschrichia coli) Necrotic enteritidis (Clostridium perfringens) Chlamydiosis (Chlamydia psittaci)
Czech republic	Laboratorios Karizoo S.A Polígono Industrial La Borda Mas Pujades 11-12 08140 Caldes de Montbui Barcelona SPAIN	KARIDOX 100 mg/ml	Doxycycline hyclate	100 mg/1 ml	Oral solution	Chicken-broiler	Administer orally via drinking water for 3-5 days.	10-20 mg doxycycline/kg bodyweight/day (i.e.. 0,5-1,0 ml of product/l of drinking water/day).	Chickens(broilers): Meat and offal: 7 days. Not permitted for use in laying hens from which eggs are produced for human consumption Indications: Prevention and treatment of chronic respiratory disease (CRD) and mycoplasmosis caused by microorganisms susceptible to doxycycline.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Czech republic	Tekro, spol. s.r.o., Višňová 2/484, 140 00 Praha 4, CZECH REPUBLIC	MEDITEK DOX 100	Doxycycline hyclate	100g/kg	Powder for oral solution	Broiler	Administer orally via drinking water for 3-5 days.	10 mg Doxycycline hyclate/1kg body-weight (1,0 kg of product / 1 000 l drinking water)	Chickens (broilers): Meat and offal: 7 days Indications: Prevention and treatment of infection disease of the respiratory and gastrointestinal tract in pigs and broilers caused by the pathogens susceptible to doxycy-cline. It is efficient on the several bacteria resistant to first generation tetracy-clines.
Czech republic	CHEMO IBERICA, S.A. Gran Via Carlos III, 98 7[a] Edificio Trade 08028 Barcelona SPAIN	ORIDOX 100 mg/ml, per-orální roztok pro podání v pitné vodě pro brojlery a pra-sata	Doxycycline hyclate	100 mg/1ml	Oral solution	Chicken-broiler	Administer orally via drinking water for 3-5 days.	10-20 mg doxycycline/kg bodyweight/day (i.e.. 0,5-1,0 ml of product/ldrinking water/day	Chickens (broilers): Meat and offal: 7 days. Eggs: Not permitted for use in laying hens from which eggs are produced for human consumption Indications: Prevention and treatment of chronic respiratory disease (CRD) and mycoplasmosis caused by microorgan-isms susceptible to doxy-cycline.
Czech republic	VIRBAC S.A. 1ère avenue - 2065 m - L.I.D. 06516 CARROS FRANCE	Pulmodox O.S.P. 5 %	Doxycycline hyclate	0,05 g/1g	Powder for oral solution	Poultry	Administer orally via drinking water for 3-5 days.	Poultry till 2 weeks: 1 g of the product per L of drinking water and day Poultry over 2 weeks: 2 g of the product per L of drinking water and day Duration of the treatment: 3 - 5 days.	Chicken (broilers): Meat and offal: 4 days, Not permitted for use in lay-ing hens from which eggs are produced for human consumption. Indications: Treatment of respiratory infections caused by the pathogens susceptible to doxycycline and chickens (broilers).

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Czech republic	KELA Laboratoria n.v. Industrial Zone De Kluis St. Lenaartseweg 48 2320 Hoogstraten BELGIUM	Respidox 5 %	Doxycycline hyclate	50 mg / 1 g	Powder for oral solution	Poultry	Administer orally via drinking water for 3 days.	2 g of product/l drinking water	Poultry: Meat and offal: 7 days Not permitted for use in laying hens from which eggs are produced for human consumption. Indications: Treatment of the infections caused by the microrganisms susceptible to doxycycline. Poultry: CRD, colibacillosis, inflammation of nasal mucosa, synovitis, salmonelosis, fowl cholera, chlamydiosis
Czech republic	COOPHAVET Saint Herblon 44150 Ancenis FRANCE	RONAXAN P.S. 5 %	Doxycycline hyclate	50 mg / 1 g	Powder for oral solution	Chickens	Administer orally via drinking water for 5 days.	10 mg doxycycline / kg bodyweight. / day (i.e.. 1 g of product/5 kg bodyweight.)	Chicken (broilers): Meat and offal: 4 days, Not permitted for use in laying hens from which eggs are produced for human consumption. Indications: Treatment of respiratory infections caused by the pathogens susceptible to doxycycline in chickens (broilers).
Czech republic	LABORATORIOS CALIER, S.A. BARCELONÉS, 26 08520 Les Franqueses del Valles SPAIN	Doxycycline Calier 500 mg/g	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry Pigs	Oral 3-5 days	20 mg/kg/day	6 days Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Czech republic	Ceva Animal Health Slovakia spol. s.r.o. Račianska 77 831 02 Bratislava SLOVENIA	DOXYVIT 100	Doxycycline hydrocloride	100 g/1 000 g	Powder for oral solution	Poultry (chicken, turkey, goose)	Administer orally via drinking water for 5 days.	10 mg doxycycline/kg bodyweight per day, i.e. 0,1 g DOXYVIT 100 / kg bodyweight	Meat and offal: 7 days. Not permitted for use in laying hens from which eggs are produced for human consumption. Indications: Treatment and prevention of respiratory, intestinal and systemic infections caused by micro-organisms susceptible to doxycycline in hens, turkeys and gouses: chronical respiratory disease (Mycoplasma gallisepticum, Escherichia coli), aerosaculitis (Mycoplasma meleagridis), synovitis (Mycoplasma synoviae), fowl cholera (Pasteurella mul tocida), bordetela turkey infections (Bordetella avium), infectious coryza (Haemophilus paragallinarum), colibacillosis (Esccherichia coli), necrotic enteritis (Clostridium perfringens), chlamydiosis (Chlamydia psittaci), prevention in stress conditions (vaccination, changes in housing, transportation)
Denmark	Laborartorios Karizoo S.A. Pol.Ind. La Borda c/Mas Pujades 11-12 Caldes de Montbui 08140 SPAIN	Karidox	Doxycycline hyclate	10 %	Oral solution	Chickens, swine	Orally (drinking water) for 3 to 5 days	In chickens: 10-20 mg doxycycline hyclate per kg bodyweight per day for 3 to 5 days (i.e. 0.5-1.0 ml product/litre water/day)	Chickens for slaughter: 7 days Eggs: May not be administered to egg laying poultry if the eggs are intended for human use. Indications:Prevention and treatment of CRD and mycoplasmosis caused by microorgansisms sensitive to doxycycline.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Denmark	CHEMO IBERICA, S.A. Gran Via Carlos III, 98 7[a] Edificio Trade 08028 Barcelona SPAIN	Oridox	Doxycycline hyclate	10 %	Oral solution	Chickens, swine	Orally (drinking water) for 3 to 5 days	In chickens: 10-20 mg doxycycline hyclate per kg bodyweight per day for 3 to 5 days (i.e. 0.5-1.0 ml product/litre water/day)	Chickens for slaughter: 7 days Eggs: May not be administered to egg laying poultry if the eggs are intended for human use. Indications: Prevention and treatment of CRD and mycoplasmosis caused by microorganisms sensitive to doxycycline.
Denmark	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen BELGIUM	HydroDoxx	Doxycycline hyclate	500 mg/g doxycycline hyclate	Powder for oral solution	Chickens (broilers) & Pigs (fattening pigs)	Oral (drinking water)	20 mg doxycycline (hyclate)/kg x 3-5 days	Meat and offal: Chickens: 6 days Do not use in laying birds producing eggs for human consumption Indications: Chickens (broilers): Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum.
Estonia	Laboratorios Hipra S.A. Avda La Selva 135 17170 Amer (Girona) SPAIN	Hipradoxi-S	Doxycycline hyclate	100 mg/ml	Concentrate for oral solution	chicken (broilers)	oral use via drinking water.	50 … 100 mg doxycycline/litre water	Meat and offal: 5 days. Not authorised for use in laying birds producing eggs for human consumption. Indications: Colibacillosis, C.R.D. and associated infections.
Estonia	Laboratorios Hipra S.A. Avda La Selva 135 17170 Amer (Girona) SPAIN	Hipradoxi-P	Doxycycline hyclate	100 mg/g	powder for oral solution	chicken (broilers)	oral use via drinking water.	20 mg doxycycline/kg bw/day	Meat and offal: 5 days. Not authorised for use in laying birds producing eggs for human consumption. Indications: Colibacillosis, C.R.D. and associated infections.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Estonia	Maxx Pharma OÜ Kaluri tee 5 Haabneeme 74001 Viimsi Harjumaa ESTONIA	Doxyprim 40 %	Doxycycline hyclate	400 mg/g	powder for oral solution	chicken, turkeys	oral use via drinking water.	10 … 20 mg/kg bw/day 5 days	Meat and offal: 4 days. Not authorised for use in laying birds producing eggs for human consumption. Indications: For the treatment of respiratory, intestinal and systemic infections caused by doxycycline-sensitive organisms.
Estonia	Zoovetvaru uusaru 5 76505 Saue Harjumaa ESTONIA	Doxycin	Doxycycline hyclate	200 mg/g	powder for oral solution	chicken (broilers)	for oral administaration, via drinking water.	10 mg doxycycline/kg bw/day 3-5 days	Meat and offal: 6 days. Do not use in laying birds producing eggs for human consumption. Indications: For the treatment of infections of the respiratory system and alimentary tract caused by microorganisms sensitive to doxycycline, including mycoplasmas, bordeteliosis, chlamydiosis, pasteurellosis anaerobic infections, salmonellosis, staphylococcosis, colibacillosis.
Estonia	Dutch Farm Veterinary Pharmaceuticals B.V. Veemweg 1 3771 MT Barnevald THE NETHERLANDS	Dutch Farm Doxycycline 20 % WSP	Doxycycline hyclate	200 mg/g	powder for oral solution	poultry	for oral administration, via drinking water.	15 mg Doxycycline hyclate/kg bw/day 3-5 days.	Meat and offal: 7 days. Do not use in laying birds producing eggs for human consumption. Indications: For the treatment of infections caused by microorganisms sensitive to doxycycline, especially respiratory infections.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Germany	LABORATORIOS CALIER, S.A. BARCELONÉS, 26 08520 Les Franqueses del Valles SPAIN	DOXYCYCLINE CALIER 500 mg/g, Pulver zum Eingeben über das Trinkwasser für Huhn und Schwein	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry Pigs	Oral 3-5 days	20 mg/kg/day	Meat and offal: 6 days Indications: Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum
Germany	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen BELGIUM	HydroDoxx 500 mg/g Pulver zum Eingeben über das Trinkwasser	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chickens (broilers) & Pigs (fattening pigs)	Oral (drinking water)	20 mg doxycycline (hyclate)/kg x 3-5 days	Meat and offal: Chickens: 6 days Do not use in laying birds producing eggs for human consumption Indications: Chickens (broilers): Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum.
Greece	Durden Trading Limited 12, Kennedy Av. Nicosia CYPRUS	Stardox	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chickens(broiler) Non –egg laying chickens Calves pigs	In drinking water	20 mg/kg X 4-7 days	Meat and offal: 14 days Indications: CRD caused by Mycoplasma gallisepticum colibacilosis
Greece	NEW VET A.E Fleming 15 15123 Marousi Attikis GREECE	Nexyclin	Doxycycline hyclate	400 mg/g	Powder for oral solution	Chickens(broiler) Turkeys pigs	In drinking water	20 mg/kg	Meat and offal: 4 days Indications: Respiratory infections caused by Mycoplasma gallisepticum, E.coli Pasteurella multocida, Chlamydia psittaci

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Greece	VIRBAC S.A. 1ère avenue - 2065 m - L.I.D. 06516 CARROS FRANCE	Pulmodox	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chickens(broiler) Non –egg laying chickens Calves pigs	In drinking water	10 mg/kg X 3-5 days	Meat and offal: 9 days Indications: Respiratory infections caused by Mycoplasma spp, E.coli, Haemophilus paragalinarum, Bordetella avium Enteritis caused by Clostridium perfringens and colinum
Greece	Nutri-Biomed Hellas LTD 1, V. Hugo & Chlois Metamorfosi Attikis 14452 Athens GREECE	Doxyveto	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chickens(broiler) Non –egg laying chickens Calves pigs	In drinking water	25 mg/kg X 3-5 days	Meat and offal: 9 days Indications: Respiratory infections caused by Mycoplasma spp, E.coli, Haemophilus paragalinarum, Bordetella avium Enteritis caused by Clostridium perfringens and colinum
Greece	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	Doxycyclin 50 Dopharma	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chickens(broiler) Calves pigs	In drinking water	25 mg/kg X 3-5 days	Meat and offal: 9 days Indications: Respiratory infections caused by Mycoplasma spp, E.coli, Haemophilus paragalinarum, Bordetella avium Enteritis caused by Clostridium perfringens and colinum
Greece	Durden Trading Limited 12, Kennedy Av. Nicosia CYPRUS	Doxycycline 150/Durden	Doxycycline hydrocloride	150 mg/g	Powder for oral solution	Chickens(broiler) Non –egg laying chickens Calves pigs	In drinking water	10 mg/kg X 3-5 days	Meat and offal: 4 days Indications: Respiratory infections caused by Mycoplasma gallisepticum, E.coli, Haemophilus paragalinarum

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Greece	AFOI TETOROU ABE 10 km National road Athens-Lamia 14451, Metamorfosi GREECE	Doxycycline 150/Afoi Tetorou	Doxycycline hydrocloride	150 mg/g	Powder for oral solution	Chickens(broiler) Non –egg laying chickens Calves pigs	In drinking water	10 mg/kg X 3-5 days	Meat and offal:4 days Indications: Respiratory infections caused by Mycoplasma gallisepti-cum, E.coli, Haemophilus paragalinarum
Spain	LAB. DR ESTEVE Avda Mare de Deu de Montserrat 221 08041 Barcelona SPAIN	DOX ESTEVE	Doxycycline hyclate	100 mg/g	Water soluble powder	Poultry Pigs Bovine	Oral 3-5 days	20 mg / Kg/day	Meat and offal: 9 days Indications: Infections caused by Mycoplasma spp (Micoplasmosis, CRD) or Pasteurella multocida (Pasteurellosis). Meat and offal: Poultry: 5 days Turkeys: 7 days colibacilosis, C.R.D., micoplasmosis.
Spain	S.P. Veterinaria SA Crta. Reus Vinyols Km 4.1 Apartado 60 Riudoms 43330 (Tarra-gona) SPAIN	DOXI 100 mg/ml POLVO ORAL	Doxycycline hyclate	10 g/100 g	Water soluble powder	Poultry Turkeys Pigs	Oral 3-5 days (Poul-try and turkeys) 5 days (Pigs)	50 – 100 mg/l drink-ing water/day (poul-try and turkey) 10 mg/kg/day (pigs)	Meat and offal: Broilers: 5 days Turkeys: 7 days Pigs: 4 days
Spain	FATRO URIACH VET-ERINARIA, S.L. Constitucion, 1 08960 Sant Just Desvern SPAIN	DOXIDOL	Doxycycline hyclate	10 g/100 g	Water soluble powder	Poultry Pigs	Oral 3-5 days	7.5 – 15 mg/kg/day	Meat and offal: 7 days Indications: Colibacilosis CRD
Spain	DIVASA-FARMAVIC, S.A. CTRA. SANT HIPOLIT, KM. 71 08503 GURB – VIC SPAIN	DOXIVET 20	Doxycycline hyclate	200 mg/ml	Oral solution	Poultry Pigs	Oral 3-5 days	10 - 20 mg/Kg/day	Meat and offal: 7 days Indications: Colibacilosis, CRD, Micoplasmosis

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Spain	MEVET, S. A. POLIGONO INDUSTRIAL EL SEGRE, PARCELA409-410 25191 Lérida SPAIN	DOXICIVALL POLVO	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry Pigs	Oral 3-5 days	20 mg/kg/day	Meat and offal: 4 days Indications: Colibacilosis, CRD, Micoplasmosis
Spain	Laboratorios Hipra S.A. Avda La Selva 135 17170 Amer (Girona) SPAIN	HIPRADOXI-S	Doxycycline hyclate	100 mg/ml	Oral solution	Poultry Pigs	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 5 days Indications: colibacilosis, C.R.D., micoplasmosis
Spain	LAMONS, S.A. POL.IND. MECANOVA, NAVES 27-28 25191 LLEIDA SPAIN	DOXICICLINA 10 % LAMONS	Doxycycline hyclate	100 mg/ml	Oral solution	Poultry Pigs	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 5 days Indications: colibacilosis, C.R.D., micoplasmosis
Spain	Laboratorios Hipra S.A. Avda La Selva 135 17170 Amer (Girona) SPAIN	HIPRADOXI-P	Doxycycline hyclate	100 mg/g	Water soluble powder	Poultry Pigs	Oral 3-5 days	20 mg/Kg/day	Meat and offal: 5 days Indications: colibacilosis, C.R.D., and associated infections
Spain	POLICHEM, S.A. Ctra. Reus-Cambrils, Km. 3 43206 Reus SPAIN	DOXICHEM	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days Indications: colibacilosis, C.R.D., micoplasmosis
Spain	SUPER'S DIANA, S.L Ctra. Barcelona - Ripoll, Km 17 08150 Parets del Valles SPAIN	DOXBRON	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days Indications: colibacilosis, C.R.D., micoplasmosis
Spain	COTECNICA -COOPERATIVA TECNICA AGROPECUARIA Ctra. N II KM 494,5 25250 Bellpuig (Lerida) SPAIN	DOXICICLINA 500 USO VETERINARIO COTECNICA	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days Indications: colibacilosis, C.R.D., micoplasmosis

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Spain	CENAVISA, S.A. Camí Pedra Estela S/N 43205 Reus SPAIN	LAFIDOX POLVO ORAL	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days Indications: colibacilosis, C.R.D., micoplasmosis
Spain	LABORATORIOS SYVA, S.A. PARROCO PABLO DIEZ, 49-57 24010 TROBAJO DEL CAMINO SPAIN	SYVADOX 10 %	Doxycycline hyclate	100 mg/ml	Oral solution	Poultry Pigs	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days Indications: colibacilosis, C.R.D., micoplasmosis
Spain	INVESA INTERNACIONAL, S.A. Esmeralda, 19 - 4º 08950 ESPLUGUES DE LLOBREGAT SPAIN	DX-10	Doxycycline hyclate	100 mg/ml	Oral solution	Poultry Pigs	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days Indications: colibacilosis, C.R.D., micoplasmosis
Spain	CENAVISA, S.A. Camí Pedra Estela S/N 43205 Reus SPAIN	DOXICICLINA 500 GANADEXIL	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry Turkeys	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days Indications: colibacilosis, C.R.D., micoplasmosis
Spain	DIVASA-FARMAVIC, S.A. CTRA. SANT HIPOLIT, KM. 71 08503 GURB – VIC SPAIN	DOXIVET 5	Doxycycline hyclate	50 mg/g	Water soluble powder	Poultry Turkeys	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days Indications: colibacilosis, C.R.D., micoplasmosis
Spain	INDUSTRIAL VETERINARIA S.A. Esmeralda, 19 - 4º 08950 ESPLUGUES DE LLOBREGAT SPAIN	DOXINYL	Doxycycline hyclate	100 mg/ml	Oral solution	Poultry Pigs	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days Indications: colibacilosis, C.R.D., micoplasmosis

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Spain	JAER, S.A. Barcelona, 411 08620 San Vicens del Horts SPAIN	MASTERMIX DOXICICLINA	Doxycycline hyclate	50 mg/g	Water soluble powder	Poultry Turkeys	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days Indications: colibacilosis, C.R.D., micoplasmosis
Spain	Laboratorios Karizoo S.A Polígono Industrial La Borda Mas Pujades 11-12 08140 Caldes de Montbui Barcelona SPAIN	KARIDOX	Doxycycline hyclate	100 mg/ml	Oral solution	Poultry Pig	Oral 3-5 days	10 - 20 mg/Kg/day	Meat and offal: 7 days Indications: C.R.D., micoplasmosis
Spain	CHEMO IBERICA, S.A. Gran Via Carlos III, 98 7ª Edificio Trade 08028 Barcelona SPAIN	SOLDOXIN	Doxycycline hyclate	100 mg/ml	Oral solution	Poultry Pig	Oral 3-5 days	10 - 20 mg/Kg/day	Meat and offal: 7 days Indications: C.R.D., micoplasmosis
Spain	LABORATORIOS CALIER, S.A. BARCELONÉS, 26 08520 Les Franqueses del Valles SPAIN	CALIERDOXINA 50 % P O	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry	Oral 5 days	20 mg/kg/day	Meat and offal: 7 days Indications: C.R.D., micoplasmosis
Spain	LABORATORIOS CALIER, S.A. BARCELONÉS, 26 08520 Les Franqueses del Valles SPAIN	GANAMIX DOXICICLINA 50 % P O	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry	Oral 5 days	20 mg/kg/day	Meat and offal: 7 days Indications: C.R.D., micoplasmosis
Spain	S.P. Veterinaria SA Crta. Reus Vinyols Km 4.1 Apartado 60 Riudoms 43330 (Tarragona) SPAIN	HIDRODOX 10 %	Doxycycline hyclate	100 mg/ml	Oral solution	Poultry Pigs	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days Indications: colibacilosis, C.R.D., micoplasmosis

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Spain	VIRBAC ESPAÑA, S.A. Angel Guimera, 179-181 08950 Esplugues de Llobregat SPAIN	PULMODOX P.O.S.	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days Indications: C.R.D., micoplasmosis
Spain	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen BELGIUM	DILUDOX	Doxycycline hyclate	500 mg/g doxycycline hyclate	Powder for oral solution	Chickens (broilers) & Pigs (fattening pigs)	Oral (drinking water)	20 mg doxycycline (hyclate)/kg x 3-5 days	Meat and offal: Chickens: 6 days Do not use in laying birds producing eggs for human consumption Indications: Chickens (broilers): Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum.
Spain	LABORATORIOS CALIER, S.A. BARCELONÉS, 26 08520 Les Franqueses del Valles SPAIN	DOXICICLINA CALIER 500 mg/g	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry Pigs	Oral 3-5 days	20 mg/kg/day	Meat and offal: 6 days Indications: Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum
Spain	LABORATORIOS MAYMO, S.A. Via Augusta, 302 08017 Barcelona SPAIN	MAYDOX PS	Doxycycline hydrocloride	50 mg/g	Water soluble powder	Poultry Turkeys	Oral 3-5 days	50 – 100 mg/l drinking water/day	Meat and offal: 7 days Indications: colibacilosis, C.R.D., micoplasmosis
France	COOPHAVET Saint Herblon 44150 Ancenis FRANCE	RONAXAN P.S. 5 %	Doxycycline hyclate	50 mg/g	Water soluble powder	Turkey Porcine Broilers Calves	Prevention 1 - 3 days Curative treatment: 3 - 5 days	10 mg/kg/day	Meat and offal: Turkey: 6 days Broilers: 4 days Indications: Broilers and turkey: Preventive and treatment of infections in respiratory system

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
France	FRANVET ZI d'Etriche-Route d'Avire BP 103 49500 Segré Cedex FRANCE	DOXY 5 FRANVET	Doxycycline hyclate	50 mg/g	Water soluble powder	Turkey, Porcine Hens Calves	Prevention 1 - 3 days Curative treatment: 3 - 5 days	10 mg/kg/day	Meat and offal: Turkey: 6 days Hens: 4 days Indications: Prevention and treatment of infections in respiratory system
France	VIRBAC S.A. 1ère avenue - 2065 m - L.I.D. 06516 CARROS FRANCE	PULMODOX P.O.S. 5 %	Doxycycline hyclate	50 mg/g	Water soluble powder	Porcine Calves Poultry	Prevention 1 - 3 days Curative treatment: 3 - 5 days	10 mg/kg/day	Meat and offal: Turkey: 6 days Hens: 4 days Indications: Prevention and treatment of infections in respiratory system
France	Sogeval Laboratoires 200 route De Mayenne 53022 Laval Cedex FRANCE	DOXYVAL 5 %	Doxycycline hyclate	50 mg/g	Water soluble powder	Turkey Porcine Broilers Calves	Prevention 1 - 3 days Curative treatment: 3 - 5 days	10 mg/kg/day	Meat and offal: Turkey: 6 days Hens: 4 days Indications: Prevention and treatment of infections in respiratory system
France	Laboratoires Biove 3 rue de Lorraine 62510 Arques FRANCE	ACTI DOXY 5	Doxycycline hyclate	50 mg/g	Water soluble powder	Dindon Porcine Broilers Calves	Prevention 1 - 3 days Curative treatment: 3 - 5 days	10 mg/kg/day	Meat and offal: Turkey: 6 days Hens: 4 days Indications: Prevention and treatment of infections in respiratory system
France	Ceva Sante Animale France La Balastiere 33501 Libourne Cedex FRANCE	DOXYVIT	Doxycycline hyclate	50 mg/g	Water soluble powder	Turkeys Porcine Broilers Calves	Prevention 1 - 3 days Curative treatment: 3 - 5 days	10 mg/kg/day	Meat and offal: Turkey: 6 days Hens: 4 days Indications: Prevention and treatment of infections in respiratory system

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
France	Noe 10 rue Clement Ader ZA Le Patis 78120 Rambouillet FRANCE	COMPOMIX V DOXYCYCLINE	Doxycycline hyclate	50 mg/g	Water soluble powder	Dindon Porcine Broilers Calves	Prevention 1 - 3 days Curative treatment: 3 - 5 days	10 mg/kg/day	Meat and offal: Turkey: 6 days Hens: 4 days Indications: Prevention and treatment of infections in respiratory system
France	CHEMO IBERICA, S.A. Gran Via Carlos III, 98 7ª Edificio Trade 08028 Barcelona SPAIN	SOLDOXIN 100 MG/ML SOLUTION BUVABLE POUR POULES POULETS ET PORCINES	Doxycycline hyclate	100 mg/ml	Oral solution	Porcine Hens Broilers	CHICKEN (broilers): 10 - 20 mg of doxycycline / kg bw / day	3 - 5 days	Indications: CHICKENS (BROILERS) Prevention and treatment of chronic respiratory disease (CRD) and mycoplasmosis caused by microorganisms sensitive to doxycycline.
France	Laborartorios Karizoo S.A. Pol.Ind. La Borda c/Mas Pujades 11-12 Caldes de Montbui 08140 SPAIN	DOXYSOL 10 %	Doxycycline hyclate	100 mg/ml	Oral solution	Porcine Hens Broilers	CHICKEN (broilers): 10 - 20 mg of doxycycline / kg bw / day	3 - 5 days	Indications: CHICKENS (BROILERS). Prevention and treatment of chronic respiratory disease (CRD) and mycoplasmosis caused by microorganisms sensitive to doxycycline.
France	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen BELGIUM	HYDRODOXX 500 MG/G poudre pour administration dans l'eau de boisson pour poulets et porcs	Doxycycline hyclate	500 mg/g doxycycline hyclate	Powder for oral solution	Chickens (broilers) & Pigs (fattening pigs)	Oral (drinking water)	20 mg doxycycline (hyclate)/kg x 3-5 days	Meat and offal: Chickens: 6 days Do not use in laying birds producing eggs for human consumption Indications: Chickens (broilers): Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
France	LABORATORIOS CALIER, S.A. BARCELONÉS, 26 08520 Les Franqueses del Valles SPAIN	DOXYCYCLINE CALIER 500 MG/G poudre pour administration dans l'eau de boisson pour poulets et porcins	Doxycycline hyclate	500 mg/g	Water soluble powder	Poultry Pigs	Oral 3-5 days	20 mg/kg/day	Meat and offal: 6 days Indications: Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum
Hungary	COOPHAVET Saint Herblon 44150 Ancenis FRANCE	Ronaxan P.S. 5 % oldható por	Doxycycline hyclate	5 g/100 g	Powder for oral solution	Chicken	Chicken younger than 2 weeks: 1 g powder/1 litre of drinking water/day. Chicken older than 2 weeks: 2 g powder/1 litre of drinking water.	10 mg doxycycline/kg bw/day, for 3-5 days.	Meat and offal: 4 days Indications: For the treatment of CRD and Mycoplasma diseases, and other infections
Hungary	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	Doxycycline 50 % WSP	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chicken	500 g product dissolved in 1 000 litre of drinking water.	25 mg doxycycline/kg bw/day, for 3-5 days.	Meat and offal: 4 days Indications: For the treatment and control of chicken respiratory diseases
Hungary	Kon-Pharma GmbH. 30625 Hannover GERMANY	Doxy 50 % por belsőleges oldathoz	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chicken, turkey	Chicken: 500 mg product dissolved in 1 litre of drinking water. Turkey: 400 mg product/1 litre of drinking water	30 mg doxycycline/kg bw/day, for 5 days.	Meat and offal: Chicken and turkey: 11 days.
Hungary	V.M.D. Állatgyógyászati Kft. 1093 Budapest HUNGARY	Doxyveto-50	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chicken	Continuous treatment: 0,2 g product/1 litre of drinking water. Pulse treatment: calculated amount of the product should be dissolved in the drinking water consumed during 8 hours.	10 mg doxycycline/kg bw/day, for 5 days.	Meat and offal: 10 days Indications: For the treatment of CRD and pasteurellosis; synovitis in turkey.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Hungary	Novartis Animal Health d.o.o. Verovskava 57 1000 Ljubljana SLOVENIA	Doxyril 50 % por belsőleges oldathoz	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chicken	5 g product/100 kg bw/day, dissolved in the drinking water.	25 mg doxycycline/kg bw/day, for 3-5 days.	Meat and offal: 6 days Indications: For the treatment of CRD, pasteurellosis, colibacillosis, Haemophilus and Clostridium infections
Hungary	Animal-Med Kft. 1029 Budapest HUNGARY	Anidox 10 % por belsőleges oldathoz	Doxycycline hyclate	100 mg/g	Powder for oral solution	Chicken	1 000 g product dissolved in 1 000 litre of drinking water.	10 mg doxycycline/kg bw/day, for 5 days.	Meat and offal: 12 days Indications: For the treatment of mycoplasmosis, pasteurellosis, colibacillosis.
Hungary	Animal-Med Kft. 1029 Budapest HUNGARY	Anidox 100 % por belsőleges oldathoz	Doxycycline hyclate	1 000 mg/g	Powder for oral solution	Chicken	100 g product dissolved in 1 000 litre of drinking water.	10 mg doxycycline/kg bw/day, for 5 days.	Meat and offal: 12 days Indications: For the treatment of infections caused by: Mycoplasma gallisepticum, E. coli, Bordetella avium, Haemophilus paragallinarum and Pasteurella multocida
Hungary	Lavet Pharmaceuticals Ltd., 1161 Budapest Ottó u. 14, HUNGARY	Doxyprim 40 % vízoldékony pulvis	Doxycycline hyclate	400 mg/g	Powder for oral solution	Chicken, turkey	Continuous treatment: 1 g product/3-6 litre of drinking water. Pulse treatment: calculated amount of the product should be dissolved in the drinking water consumed during 4-8 hours.	10-20 mg/ doxycycline/kg bw/day, for 3-5 days.	Meat and offal: 4 days Indications: For the treatment of infections caused by: Mycoplasma gallisepticum, E. coli, Bordetella avium, Haemophilus paragallinarum and Pasteurella multocida

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Hungary	CHEMIFARMA S.p.A Via Don Eugenio Servadei 16 47100 Forli ITALY	Doxifarm 50 % WSP	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chicken	40 g product/100 kg bw/100 litre of drinking water.	20 mg doxycycline/kg bw/day, for 5 days.	Meat and offal: 5 days Indications: For the treatment of CRD, mycoplasmosis, synovitis, colibacillosis, ileitis (necroric and ulcerosus), haemophilus-infection.
Hungary	VIRBAC S.A. 1ère avenue - 2065 m - L.I.D. 06516 CARROS FRANCE	Pulmodox 50 % WSP	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chicken	500 g product dissolved in 1 000 litre of drinking water.	25 mg doxycycline/kg bw/day, for 3-5 days.	Meat and offal: 4 days Indications: For the treatment of CRD and other respiratory diseases, caused by: Mycoplasma spp., Pasteurella spp., E. coli, and Chlamydia psittaci.
Hungary	Phylaxia Pharma Zrt. 8000 Székesfehérvár HUNGARY	Doxyphyl SP	Doxycycline hyclate	300 mg/g	Powder for oral solution	chicken, turkey	40 g product/1 200 kg bw/day, calculated amount of the product should be dissolved in the drinking water consumed during 3 hours.	10 mg doxycycline/kg bw/day, for 3-5 days.	Meat and offal: chicken: 7 days, turkey: 10 days. Indications: For the treatment of respiratory infections caused by Mycoplasma spp., E. coli, Haemophilus paragallinarum, Bordetella avium, and ileitis caused by Clostridium perfringens and Cl. colinum.
Hungary	Eurovet Animal Health B.V. Handelsveg 25 PO Box 179 5530 AD Bladel THE NETHERLANDS	Soludox 50 % pulvis	Doxycycline hyclate	500 mg/g	Powder for oral solution	Chicken	Dissolved in the drinking water.	10 mg/kg bw and 20 mg/kg bw/day, for 4 days.	Meat and offal: chicken treated with 10 mg/kg bw: 5 days, chicken treated with 20 mg/kg bw: 12 days. Indications: For the treatment of respiratory and other diseases caused by doxycycline-sensitive bacteria.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Hungary	CHEMO IBERICA, S.A. Gran Via Carlos III, 98 7[a] Edificio Trade 08028 Barcelona SPAIN	Oridox 100 mg/ml belsőleges oldat	Doxycycline hyclate	100 mg/ml	Concentrate for oral solution	Chicken	100 mg/ml oral concentrate dissolving in the drinking water.	10-20 mg/ doxycycline/kg bw/day, for 3-5 days.	Meat and offal: 7 days Indications: For the treatment of respiratory and other diseases caused by doxycycline-sensitive bacteria.
Hungary	Laboratorios Karizoo S.A Polígono Industrial La Borda Mas Pujades 11-12 08140 Caldes de Montbui Barcelona SPAIN	Karidox 100 mng/ml belsőleges oldat	Doxycycline hyclate	100 mg/ml	Concentrate for oral solution	Chicken	100 mg/ml oral concentrate dissolving in the drinking water.	10-20 mg/ doxycycline/kg bw/day, for 3-5 days.	Meat and offal: 7 days Indications: For the treatment and prevention of CRD or other Mycoplasma diseases
Hungary	CENAVISA, S.A. Camí Pedra Estela S/N 43205 Reus SPAIN	Doxycen belsőleges oldat	Doxycycline hyclate	200 mg/ml	Concentrate for oral solution	Chicken	1 ml/20 kg bw/day dissolved in the drinking water.	10 mg doxycycline/kg bw/day, for 5 days.	Meat and offal: 5 days Indications: For the treatment of CRD, mycoplasmosis and colibacillosis.
Hungary	Lavet Pharmaceuticals Ltd., 1161 Budapest Ottó u. 14, HUNGARY	Doxyvit 100 WSP	Doxycycline hydrocloride	100 mg/g	Powder for oral solution	Chicken, turkey, goose	Continuous treatment: 1 g product/1 litre of drinking water. Pulse treatment: calculated amount of the product should be dissolved in the drinking water consumed during 6-8 hours.	10 mg/ doxycycline/kg bw/day, for 3-5 days.	Meat and offal: Chicken, turkey, goose 7 days Indications: For the treatment of respiratory and enteric diseases in broiler chickens

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Hungary	Industria Italiana Integratori TREI S.p.A. Viale Corassori 62 41100 Modena ITALY	Doxipan 20 WSP	Doxycycline hydrocloride	200 mg/g	Powder for oral solution	Chicken	5-7.5 g product dissolving in 10 litre of drinking water.	10-15 mg/ doxycycline/kg bw/day, for 3-5 days.	Meat and offal: 5 days Indications: For the treatment of CRD, mycoplasmosis, synovitis, colibacillosis, ileitis (necroric and ulcerosus), haemophilus-infection.
Hungary	Laboratorios Hipra S.A. Avda La Selva 135 17170 Amer (Girona) SPAIN	Hipradoxi-S oral solutio	Doxycycline hydrocloride	100 mg/ml	Concentrate for oral solution	Chicken	100 mg/ml oral concentrate dissolving in 1 litre of drinking water.	10 mg doxycycline/kg bw/day, for 5 days.	Meat and offal: 5 days Indications: For the treatment and prevention of CRD or other Mycoplasma diseases
Ireland	S.P. Veterinaria SA Crta. Reus Vinyols Km 4.1 Apartado 60 Riudoms 43330 (Tarragona) SPAIN	DOXIVEX 10 % Concentrate for oral solution.	Doxycycline hyclate	100 mg/ml	Concentrate for oral solution	Chickens (broilers) and Pigs	For oral administration via the drinking water. for 3-5 days	Chickens (broilers): 50 - 100 mg Doxycycline / litre of drinking water / day (equivalent to 0.5 - 1.0 ml DOXIVEX 10 % / litre of drinking water / day) for 3-5 days	Meat & offal: 7 days. Not permitted for use in laying birds producing eggs for human consumption Indications: Treatment of colibacillosis, chronic respiratory disease (CRD) and mycoplasmosis caused by microorganisms sensitive to doxycycline
Ireland	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen BELGIUM	Aquadoxx 500 mg/g water-soluble powder	Doxycycline hyclate	500 mg/g doxycycline hyclate	Powder for oral solution	Chickens (broilers) & Pigs (fattening pigs)	Oral (drinking water)	20 mg doxycycline (hyclate)/kg x 3-5 days	Meat and offal: Chickens: 6 days Do not use in laying birds producing eggs for human consumption Indications: Chickens (broilers): Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Italy	CEVA VETEM S.P.A. Via Colleoni n.15 20041 Agrate Brianza (Milano) ITALY	DOXICICLINA 20 % CEVA VETEM	Doxycycline hyclate	Doxycycline 200 g. per 1 kg. of product	Water soluble powder	broiler, turkey	drinking water	Broiler, Turkey: 1 g / 10 kg b.w per 5 days.	Meat and offal: broiler: 7 days turkey: 8 days Indications: Broiler: Treatment of chronic respiratory disease Turkey: Treatment of infective synusitis
Italy	CHEMIFARMA S.p.A Via Don Eugenio Servadei 16 47100 Forli ITALY	DOXICICLINA 50 % CHEMIFARMA	Doxycycline hyclate	Doxycycline 500 g. per 1 kg. of product	Water soluble powder	broiler, swine	drinking water	Broiler: 20 mg of doxycycline / per 1 kg b.w.(per 3 - 5 days) Swine: 20 mg of doxycycline / per 1 kg b.w per 3 - 5 days	Meat and offal: broiler: 6 days Do not use in hens producing eggs for human consumption. swine: 5 days Indications: Broiler: Chronic respiratory disease caused by: Pasteurella soo, Mycoplasma spp, Haemophilus gallinarum, Bordetella avium, ans Clamidia psittaci.
Italy	SINTOFARM S.P.A. Via Togliatti n.5 42016 Guastalla (Reggio Emilia) ITALY	DOXIFARM 50 %	Doxycycline hyclate	Doxycycline hyclate 500 mg. (equivalent to 433,3 mg of Doxiclina) per 1 g. of product	Water soluble powder	broiler, swine	drinking water	Broiler: 25 mg of doxycycline hyclate/per 1 kg b.w.(per 3 - 5 days) Swine: 20 mg of doxycycline hyclate/per 1 kg b.w per 5 days	Meat and offal: broiler: 6 days Do not use in hens producing eggs for human consumption. swine: 4 days Indications: Broiler: Treatment and control of respiratory disease caused by Mycoplasma spp, Haemophilus paragallinarum, Escherichia coli. Enteritis caused by Clostridium perfringens and Clostridium colinum

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Italy	INDUSTRIA ITAILIANA INTEGRATORI TREI SpA Via Affarosa n.4 42010 Rio Saliceto (Reggio Emilia) ITALY	DOXIPAN 54	Doxycycline hyclate	Doxycycline 500 g. per 1 kg. of product	Water soluble powder	broiler, turkey, swine	drinking water	Broiler: 10 mg of doxycycline / 1 kg b.w. Turkey: 20 mg of doxycycline / 1 kg b.w. Swine: 10 mg of doxycycline / 1 kg b.w per 5 days	Meat and offal: broiler: 3 days Do not use in hens producing eggs for human consumption. turkey: 10 days swine: 4 days Indications: Broiler-:Chronic respiratory disease. Turkey:Respiratory and joints syndroms caused by Mycoplasms and/or Staphilococcus
Italy	INTERVET ITALIA S.R.L. Via W. Tobagi n.7 20068 Peschiera Borromeo (Milano) ITALY	NAXOCET	Doxycycline hyclate	Doxycycline hyclate 500 mg. per 1 g. of product	Water soluble powder	broiler	drinking water	Broiler: 20 mg of doxyclyne hyclate/1 kg b.w. per 5 days.	Meat and offal: broiler: 8 days Do not use in hens producing eggs for human consumption. Indications: Chronic respiratory disease caused by Mycoplasma spp.
Lithuania	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	DOXYCYCLINE 50 %, geriamieji milteliai	Doxycycline hyclate	500 mg/g	Oral powder	Calves, pigs and poultry.	4–7 days with drinking water	Poultry: 40 mg per 1 kg of body weight, or 200–400 g per 1 000 litres of drinking water, during 4–7 days.	Meat and offal: Poultry – 4 days. Do not use in animals producing eggs for human consumption. Indications: for the treatment of poultry: ornythosis, caused by Clamydia psittaci, colibacteriosis caused by E. coli, CRD caused by Mycoplasma gallisepticum

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Lithuania	Lavet Pharmaceuticals Ltd., 1161 Budapest Ottó u. 14, HUNGARY	DOXYPRIM 40 % geriamieji milteliai	Doxycycline hyclate	400 mg/g	Oral powder	Chickens, turkeys and pigs.	Should be administered for a period of 5 days in chicken and turkeys together with drinking water.	Chicken and turkeys: 10–20 mg doxycycline hyclate per 1 kg of body weight daily, administrated pulse dosed when the daily requirement is given in limited quantity of water to be consumed by the birds within 4–8 hours or supplied continuously as 67–133 mg ml Doxycycline hyclate per 1 litre of drinking water.	Meat and offal: Edible tissues of chickens and turkeys – 4 days. Indications: In chickens and turkeys indications include: chronicle respiratoric diseases (Mycoplasma gallisepticum, E. coli), airsacculitis (Mycoplasma meleagridis), infectious synovitis (Mycoplasma synoviae), colibacillosis (E. coli), fowl cholera (Pasteurella multocida), turkey bordetellosis (Bordetella avium), infectious coryza (Haemophilus paragallinarum), necrotic enteritis (Clostridium perfringens), chlamydiosis (Chlamydia psittaci).
Lithuania	Eurovet Animal Health B.V. Handelsveg 25 PO Box 179 5530 AD Bladel THE NETHERLANDS	SOLUDOX 50 %, geriamieji milteliai	Doxycycline hyclate	500 mg/g	Oral powder	Pigs and chickens.	Should be administered orally with drinking water for a period of 4 days.	Chickens: 10* mg doxycycline hyclate per 1 kg of body weight daily for 4 days; 20* mg doxycycline hyclate per 1 kg of body weight daily for 4 days. * The highest dose is recommended in case of infections caused by strains which are moderately susceptible (MIC up to 2 µg/ml), whilst the lowest dosage maybe used for (highly) susceptible strains (MIC up to 0.5–1.0 µg/ml)	Indications: For the treatment of infections caused by micro-organisms susceptible to doxycycline, such as Pasteurella multocida and Ornithobacterium rhinotracheale in chickens.

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The Netherlands	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	Doxycycline-hyclaat 50 %	Doxycycline hyclate	Per gram powder: 500 mg doxycycline hyclate.	Powder for oral solution	Calves, non-egg laying chickens and turkeys.	Non-egg laying chickens and turkeys: oral via drinking water. bodyweight per day for 4-7 days.	Non-egg laying chickens and turkeys: 20 mg doxycycline hyclate per kg	Turkeys - meat: 28 days. Non-egg laying chickens - meat: 14 days. Indications: Turkeys: — Ornithosis caused by Chlamydia psittaci — Colibacillosis caused by E. coli — CRD caused by Mycoplasma gallisepticum Non-egg laying chikens Colibacillosis caused by E. coli
The Netherlands	Dutch Farm Veterinary Pharmaceuticals B.V. Veemweg 1 3771 MT Barneveld THE NETHERLANDS	Doxycycline 20 % W.O.	Doxycycline hyclate	Per gram powder: 200 mg doxycycline hyclate	Powder for oral solution	Non-egg laying chickens	Oral via drinking water. for 3 days	10 mg doxycycline hyclate per kg bodyweight per day for 3 days	Meat: 7 days. Indication non-egg laying chickens: — Polyarthritis caused by Mycoplasma synoviae; — CRD, amongst others caused by Mycoplasma gallisepticum; — Colibacillosis caused by Escherichia coli
The Netherlands	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	Doxycycline-hyclaat 20 %	Doxycycline hyclate	Per gram powder: 200 mg doxycycline hyclate.	Powder for oral solution	Calves, pigs, chickens and turkeys.	Chickens and turkeys: oral via drinking water for 4-7 days.	Chickens and turkeys: 20 mg doxycycline hyclate per kg bodyweight	Turkeys - meat: 28 days. Chickens - meat: 14 days, eggs: 10 days. Indication turkeys: — Ornithosis caused by Chlamydia psittaci — Colibacillosis caused by E. coli — CRD caused by Mycoplasma gallisepticumIndication Indication chickens: — Colibacillosis caused by E. coli — CRD caused by Mycoplasma gallisepticum

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The netherlands	Dutch Farm International B.V. Nieuw Walden 112 1394 PE Nederhorst den Berg THE NETHERLANDS	Doxycycline 20 % W.O.	Doxycycline hyclate	Per gram powder: 200 mg doxycycline hyclate.	Powder for oral solution	Non-egg laying chickens (broilers).	Oral via drinking water.	10 mg doxycycline hyclate per kg bodyweight per day for 3 days.	Meat: 7 days. Do not administer to chickens producing eggs for human consumption. Indication non-egg laying chickens: — Polyarthritis caused by Mycoplasma synoviae; — CRD, amongst others caused by Mycoplasma gallisepticum; — Colibacillosis caused by Escherichia coli.
The Netherlands	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	Doxycycline-hyclaat 50 %	Doxycycline hyclate	Per gram powder: 500 mg doxycycline hyclate.	Powder for oral solution	Calves, pigs, non-egg laying chickens.	Non-egg laying chickens: oral via drinking water. for 4-5 days.	Non-egg laying chickens: 20 mg doxycycline hyclate per kg bodyweight per day for 4-5 days.	Non-egg laying chickens - meat: 14 days. Indication non-egg laying chickens: — Colibacillosis caused by E. coli — CRD caused by Mycoplasma gallisepticum
The Netherlands	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	Doxycycline 50 % WSP	Doxycycline hyclate	Per gram powder: 500 mg doxycycline hyclate.	Powder for oral solution	Non-egg laying chickens.	Non-egg laying chickens: oral via drinking water.	Non-egg laying chickens: 25 mg doxycycline hyclate per kg bodyweight per day for 3-5 days.	Non-egg laying chickens - meat: 6 days. Indication non-egg laying chickens: — Respiratory infections caused by Mycoplasma spp (M. gallisepticum, M.synoviae en M. meleagridis), E. coli and Haemophilus paragallinarum; — Enteritis caused by Clostridium perfringens en Clostridium colinum.

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The Netherlands	Interchemie Werken De Adelaar BV Hosterweg 26a 5811 Ccastenray THE NETHERLANDS	Doxy WS	Doxycycline hyclate	Per gram powder: 200 mg doxycycline hyclate.	Powder for oral solution	Non-egg laying chickens (broilers).	Oral via drinking water.	10 mg doxycycline hyclate per kg bodyweight per day for 3 days.	Meat: 7 days. Indication non-egg laying chickens: — Polyarthritis caused by Mycoplasma synoviae; — CRD, amongst others caused by Mycoplasma gallisepticum; — Colibacillosis caused by Escherichia coli.
The Netherlands	Eurovet Animal Health B.V. Handelsveg 25 PO Box 179 5530 AD Bladel THE NETHERLANDS	Soludox 50 %	Doxycycline hyclate	Per gram powder: 500 mg doxycycline hyclate.	Powder for oral solution	Pigs and non-egg laying chickens.	Non-egg laying chickens: oral via drinking water.	Non-egg laying chickens: - Pasteurellosis caused by Pasteurella multocida: 10 mg doxycycline hyclate per kg bodyweight per day for 3-4 days.infections caused by Ornithobacterium rhinotracheale (ORT): 20 mg doxycycline hyclate per kg bodyweight per day for 3-4 days	Non-egg laying chickens: - Pasteurellosis – meat: 5 days.- ORT – meat: 12 days. Do not administer to chickens producing eggs for human consumption
The Netherlands	Eurovet Animal Health B.V. Handelsveg 25 PO Box 179 5530 AD Bladel THE NETHERLANDS	Doxyfar 50 %	Doxycycline hyclate	Per gram powder: 500 mg doxycycline hyclate.	Powder for oral solution	Pigs and non-egg laying chickens.	Non-egg laying chickens: oral via drinking water.	Non-egg laying chickens: *Pasteurellosis* caused by *Pasteurella multocida*: 10 mg doxycycline hyclate per kg bodyweight per day for 3-4 - Respiratory infections caused by Ornithobacterium rhinotracheale (ORT): 20 mg doxycycline hyclate per kg bodyweight per day for 3-4 days	Non-egg laying chickens: — Pasteurellosis – meat: 5 days. — ORT – meat: 12 days. Do not administer to chickens producing eggs for human consumption.

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The Netherlands	Kepro B.V. Maagdenburgstraat 38 7421 ZE Deventer THE NETHERLANDS	Doxy 200 W.S.P.	Doxycycline hyclate	Per gram powder: 200 mg doxycycline hyclate.	Powder for oral solution	Non-egg laying chickens (broilers).	Oral via drinking water.	10 mg doxycycline hyclate per kg bodyweight per day for 3 days.	Meat: 7 days. Do not administer to chickens producing eggs for human consumption. Indication: — Polyarthritis caused by Mycoplasma synoviae; — CRD, amongst others caused by Mycoplasma gallisepticum; — Colibacillosis caused by Escherichia coli.
The Netherlands	Eurovet Animal Health B.V. Handelsveg 25 PO Box 179 5530 AD Bladel THE NETHERLANDS	Soludox 50 %	Doxycycline hyclate	Per gram powder: 500 mg doxycycline hyclate.	Powder for oral solution	Pigs and non-egg laying chickens.	Non-egg laying chickens: oral via drinking water.	Non-egg laying chickens: 10 mg doxycycline hyclate per kg bodyweight per day for 3-4 days.	Non-egg laying chickens – meat: 5 days. Indication: Pasteurellosis caused by Pasteurella multocida
The Netherlands	Laboratorios Karizoo S.A Polígono Industrial La Borda Mas Pujades 11-12 08140 Caldes de Montbui Barcelona SPAIN	Karidox 10 % Oral Solution	Doxycycline hyclate	Per ml: 100 mg doxycycline (as hyclate).	Oral solution	Pigs and chickens (broilers).	Chickens (broilers): oral via drinking water.	Chickens (broilers): 10-20 mg doxycycline per kg bodyweight per day for 3-5 days	Chickens (broilers) - meat: 7 days. Indication: Prevention and treatment of CRD and mycoplasmosis caused by microorganisms sensitive to doxycycline.
The Netherlands	Huvepharma, Uitbreidingstraat 80 2600 Antwerpen BELGIUM	HydroDoxx 500 mg/g	Doxycycline hyclate	Per g: 500 mg doxycycline hyclate.	Powder for oral solution	Pigs and chickens (broilers).	Chickens (broilers): oral via drinking water.	Chickens (broilers): 20 mg doxycycline per kg bodyweight per day for 3-5 days	Chickens (broilers) - meat: 6 days. Do not administer to chickens producing eggs for human consumption.

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The Netherlands	CHEMO IBERICA, S.A. Gran Via Carlos III, 98 7[a] Edificio Trade 08028 Barcelona SPAIN	Soldoxin	Doxycycline hyclate	Per ml: 100 mg doxycycline (as hyclate).	Oral solution	Pigs and chickens (broilers).	Chickens (broilers): oral via drinking water.	Chickens (broilers): 10-20 mg doxycycline per kg bodyweight per day for 3-5 days	Chickens (broilers) - meat: 7 days. Do not administer to chickens producing eggs for human consumption. Indication: Prevention and treatment of CRD and mycoplasmosis caused by microorganisms sensitive to doxycycline.
Poland	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	Doxymed 50	Doxycycline hyclate	500 mg/g	powder for oral solution	chickens	250-500 ml product/1 000 liter of drinking water	25 mg doxycyclini hyclate / kg bw/day for 3-5 days	Meat and offal: 4 days. Not for use in laying hens.
Poland	Eurovet Animal Health B.V. Handelsveg 25 PO Box 179 5530 AD Bladel THE NETHERLANDS	Soludox 50 %	Doxycycline hyclate	500 mg/g	Oral powder	chickens	2 g product/100 kg bw/day in case of Pasteurellosis or 4 g product / 100 kg bw/day in case of *Ornithrobacterium rhinotracheale* infection.	10 mg doxycycliny hyclate/kg bw/day in case of Pasteurellosis or 20 mg doxycyclini hyclate/kg bw/day in case of *Ornithrobacterium rhinotracheale* infection for 3-4 days	Meat and offal: 5 days in case of Pasteurellosis. 12 days in case of *Ornithrobacterium rhinotracheale* infection. Not for use in laying hens.
Poland	Laboratorios Hipra S.A. Avda La Selva 135 17170 Amer (Girona) SPAIN	Hipradoxi-S	Doxycycline hyclate	100 mg/ml	Oral solution	chickens	0,5-1,0 ml product/1 liter of drinking water	50-100 mg doxycyclini hyclate/1 liter of drinking water for 3-5 days	Meat and offal: 5 days. Not for use in laying hens.
Poland	Oropharma n.v. Dijkstraat 30 9140 Temse BELGIUM	Ornicure	Doxycycline hyclate	300 mg/4 g	Oral powder	pigeon, parrot	pigeon: 4g prodyct/2 liters of drinking water, parrot: 4 g product/0,5 liter	15 mg/kg bw./ day for 5 days, in case of parrot desease or clinical ornitosis for 3-4 weeks	Not for use in pigeons for human consumption.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Poland	Novartis Animal Health d.o.o. Verovskava 57 1000 Ljubljana SLOVENIA	Doxiryl 50 %	Doxycycline hyclate	500 mg/g	powder for oral solution	chicken (broiler)	25 mg doxycyclini hyclate / kg bw/day	25 mg doxycyclini hyclate / kg bw/day for 3-5 days	Meat and offal: 4 days. Not for use in laying hens.
Poland	S.P. Veterinaria SA Crta. Reus Vinyols Km 4.1 Apartado 60 Riudoms 43330 (Tarragona) SPAIN	Doxivex 10 %	Doxycycline hyclate	100 mg/ml	Concentrate for oral solution	chicken (broiler)	05-1,0 ml product/1 liter of drinking water	50-100 mg doxycyclini hyclas/1 liter of drinking water/day for 3-5 days	Meat and offal: 7 days. Not for use in laying hens.
Poland	CHEMO IBERICA, S.A. Gran Via Carlos III, 98 7[a] Edificio Trade 08028 Barcelona SPAIN	Oridox	Doxycycline hyclate	100 mg/ml	Oral solution	chicken (broiler)	05-1,0 ml product/1 liter of drinking water	10-20 mg doxycyclini hyclas/kg bw/day for 3-5 days	Meat and offal: 7 days. Not for use in laying hens.
Poland	Laboratorios Karizoo S.A Polígono Industrial La Borda Mas Pujades 11-12 08140 Caldes de Montbui Barcelona SPAIN	Karidox	Doxycycline hyclate	100 mg/ml	Oral solution	chicken (broiler)	05-1,0 ml product/1 liter of drinking water	10 -20 mg doxycyclini hyclas/kg bw/day for 3-5 days	Meat and offal: 7 days. Not for use in laying hens.
Poland	Drwalewskie Zakłady Przemysłu Bioweterynaryjnego S.A. Grójecka 6 05-651 Drwalew POLAND	Doxymina 20 %	Doxycycline hyclate	200 mg/g	Oral powder	chicken	25-50 g product/1 liter of drinking water	10 mg doxycyclini hyclate/kg bw/day, for 3-5 days	Meat and offal: 7 days. Not for use in laying hens.

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Poland	V.M.D.n.v./ s.a. Hoge Muew 900 2370 Arendonk BELGIUM	Doxycycline hyclate 50 %	Doxycycline hyclate	500 mg	powder for oral solution	chicken	25 mg doxycyclini hyclate / kg bw/day	25 mg doxycyclini hyclate / kg bw/day for 3-5 days	Meat and offal: 5 days. Not for use in laying hens.
Poland	INDUSTRIAL VETERINARIA S.A. Esmeralda, 19 - 4º 08950 ESPLUGUES DE LLOBREGAT SPAIN	Doxinyl	Doxycycline hyclate	100 mg/ml	Oral solution	chicken (broiler)	0,5-1,0 ml product/1 liter of drinking water/day	50-100 mg doxycyclini hyclate/1 liter of drinking water for 3-5 days	Meat and offal: 7 days. Not for use in laying hens.
Poland	Biofaktor Sp. z o.o.(Skierniewice) Czysta 4 96-100 Skierniewice POLAND	Doxycyclinum 20 %	Doxycycline hyclate	200 mg/ml	powder for oral solution	chicken, turkey	25-50 g product/1 liter of drinking water	10 mg doxycyclini hyclate/kg bw/day, for 3-5 days	1 Meat and offal: 4 days. Not for use in laying hens.
Poland	Tarchomińskie Zakłady Farmaceutyczne Polfa S.A. Fleminga 2 03-176 Warszawa POLAND	Doxycyclinum wet proszek	Doxycycline hyclate	200 mg/g	powder for oral solution	chicken, turkey,	25-50 g powder/1 liter of drinking water	10 mg doxycyclini hyclate/kg bw/day, for 3-5 days	Meat and offal: 7 days. Not for use in laying hens.
Poland	Sogeval Laboratoires 200 route De Mayenne 53022 Laval Cedex FRANCE	DOXYVAL 20 %	Doxycycline hyclate	20 g/100 g	Oral powder	chicken (broiler)	5 g produkt/100 kg bw/day or 0,5 g/1 liter of drinking water	10 mg doxycyclini hyclate/kg bw/day, for 3-5 days	Meat and offal: 4 days. Not for use in laying hens.
Poland	Eurovet Animal Health B.V. Handelsveg 25 PO Box 179 5530 AD Bladel THE NETHERLANDS	Soludox 15 %	Doxycycline hyclate	150 mg/g	Oral powder	chicken, turkey, pigeon, cage bird	10-20 mg doxycyclini hyclas/kg bw/day	10-20 mg/ kg bw/day for 3-5 days. In case of *Chlamydia psittaci* infection for 30-45 days.	Meat and offal: 7 days. Not for use in laying hens or in pigeons for human consumption.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Portugal	CEVA Saúde Animal –Produtos farmacêuticos e Imunológicos Lda. Ceva Saúde Animal Lda. Rua Doutor António Loureiro Borges 9/9ª 9º A Miraflores 1495-131 Algés PORTUGAL	DOXYPRIM 400 mg / g Pó para Solução Oral para Suínos, Frangos e Perus.	Doxycycline hyclate	Doxycycline hyclate 400 mg / g	Powder for oral solution	Swine, Chicken, Turkey	For oral administration in drinking water	Broilers and Turkeys: 20 mg Doxycycline hyclate/kg bw, for 5 days.	Chicken (Broilers) meat and offal: 5 days; Tukeys meat and offal:6 days; Not permitted for use in laying birds producing eggs for human consumption
Portugal	DIVASA FARMAVIC DE PORTUGAL Produtos e Equipamentos Veterinários Lda. Parque Empresarial de Vialonga Armazém nº 21 Casal do Bagulho Granja de Alpriate 2625-607 Vialonga PORTUGAL	DOXYVET-10	Doxycycline hyclate	Doxycycline hyclate 10g; Bromexin Cloridrate 1g	Oral solution	Bovine (Calves), Swine, Broilers, Turkeys, Ovine, Goat (Kid)	For oral administration in drinking water	Broilers and Turkeys: 50-100 mg/liter of water/day, for 3-5 days (Equivalent to 0,5-1 ml of DOXIVET-10 / liter of water/day	Meat and offal: 5 days
Portugal	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonksveer THE NETHERLANDS	VETADOXI 50	Doxycycline hyclate	Doxycycline hyclate 500 mg/g	Oral powder	Bovine (Calves), Swine and Birds	For oral administration in drinking water, milk or feed	25 mg/Kg bw in birds; 200 g/1 000 L water/day 3-5 days; 500 g/1 000 L drinking water birds	Meat and offal: 5 days; Not permitted for use in laying birds producing eggs for human consumption
Portugal	S.P. Veterinaria SA Crta. Reus Vinyols Km 4.1 Apartado 60 Riudoms 43330 (Tarragona) SPAIN	Hidrodox 10 % Concentrado para solução oral para aves (frangos de carne) e suínos	Doxycycline hyclate	Doxycycline (as hyclate) 100 mg	Concentrate for Oral Solution	Chickens (broilers) and swine	For oral administration in drinking water	Broilers: 50 – 100 mg Doxycycline hyclate/L drinking water/day (0,5-1,0 ml of VMP/drinking water/day) 3-5 days.	Birds (Broilers) meat and offal: 7 days. Not permitted for use in laying birds producing eggs for human consumption

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Portugal	Univete SA Rua D. Jerónimo Osório, 5 B 1400-119 Lisboa PORTUGAL	UNIDOXINA 200 mg/ml solução oral para suínos e aves	Doxycycline hyclate	Doxycycline (as hyclate) 200 mg	Oral solution	Chickens (broilers) and swine	For oral administration in drinking water	Broilers and Turkeys: 20 mg Doxycycline hyclate/kg bw, for 5 days.	Chicken (Broilers) meat and offal: 7 days. Not permitted for use in laying birds producing eggs for human consumption
Romania	DELOS IMPEX' 96 SRL 17, Pictor Ştefan Luchian sector 2 Bucharest ROMANIA	Doxidem 20	Doxycycline hyclate	200 mg/ml doxycycline hyclate	Oral solution	Poultry (not for use in animals from which eggs are produced for human consumption)	Oral	— 75 ml of product/100 litres drinking water/day for 3-5 consecutive days in young poultry up to 4 weeks — 150 ml of product/100 litres drinking water/day for 3-5 consecutive days in adult poultry	Meat and offal: 28 days Indications: Poultry For the treatment of mycoplasmosis, pasteurellosis, colibacillosis, staphylococcosis. Chronic respiratory disease, infections caused by Pasteurella spp., Mycoplasma spp., Salmonella spp., E. coli., Haemophillus paragallinarium, Staphylococcus, hepatitis caused by Campylobacter and dermatitis.
Romania	DELOS IMPEX' 96 SRL 17, Pictor Ştefan Luchian sector 2 Bucharest ROMANIA	Doxidem 50	Doxycycline hyclate	500 mg/g doxycycline hyclate	Water soluble powder	Poultry (not for use in animals from which eggs are produced for human consumption) Pigs	Oral (drinking water)	— 20-40 mg of product/kg body weight/day for 5 consecutive days, per os; — 200-300 g of product/1 000 litres of drinking water for 5 consecutive days	Meat and offal: 28 days Indications: Chronic respiratory disease, infections caused by Pasteurella spp., Mycoplasma spp., Salmonella spp., E. coli., Haemophillus paragallinarium, Staphylococcus, hepatitis caused by Campylobacter, dermatitis and other diseases caused by microorganisms sensitives to doxycycline.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Romania	DOPHARMA B.V. Zalmweg 24, P.O. BOX 205 4940 AE Raamsdonks-veer THE NETHERLANDS	Doxycycline 50 % WSP	Doxycycline hyclate	500 mg/g doxycycline hyclate	Water soluble powder	Poultry (not for use in animals from which eggs are produced for human consumption) Calves Pig	Oral (drinking water)	40 mg/kg of body weight or 200-400 g/1 000 litres of drinking water for 4-7 days	Meat and offal: Poultry 4 days Indications: — Ornithosis caused by Chlamydia psittaci in turkeys; — Colibacillosis caused by E. coli in chickens and turkeys; — CRD caused by Mycoplasma gallisepticum in chickens and turkeys;
Romania	FRANVET ZI d'Etriche-Route d'Avire BP 103 49500 Segré Cedex FRANCE	Doxy 5 Franvet	Doxycycline hyclate	50 mg/g doxycycline (as hyclate)	Water soluble powder	Poultry (not for use in animals from which eggs are produced for human consumption) Calves Pig	Oral (drinking water or liquid feed)	— 1 g of product/1 litre drinking water/day for 3-5 days in poultry up to 2 weeks — 2 g of product/1 litre drinking water/day for 3-5 days in poultry over 2 weeks	Meat and offal: Poultry 4 days Indications: For the prevention and treatment of respiratory infections caused by doxycycline sensitive microorganisms.
Romania	INDUSTRIA ITAILIANA INTEGRATORI TREI SpA Via Affarosa n.4 42010 Rio Saliceto (Reggio Emilia) ITALY	Doxipan 20	Doxycycline hyclate	200 mg/g doxycycline hyclate	Water soluble powder	Poultry pig	Oral (drinking water)	5-7,5 g of product for every 10 litres of drinking water	Meat and offal: Poultry 5 days Indications: Chronic respiratory disease and associated complications.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Romania	PHYLAXIA PHARMA LTD 1103 Budapest Gergely u.79 HUNGARY	Doxyphyl SP A.U.V.	Doxycycline hyclate	300 mg/g doxycycline hyclate	Water soluble powder	Poultry (chicken, hens, turkeys) v	Oral (drinking water)	10 mg/kg b.w. for 3-5 days or 100 mg of product/1 litre of drinking water	Chickens, hens: 7 days Turkey: 7 days (not for use in animals from which eggs are produced for human consumption) Indications: For the prevention and treatment of several bacterial infections.
Romania	LABORATORIOS SYVA S.A. Avda. Parroco Pablo Diez, 49-57 24010 Leon SPAIN	Syvadox 10 %	Doxycycline hyclate	100 mg/1 ml doxycycline (as hyclate)	Oral solution	Chickens (not for use in animals from which eggs are produced for human consumption)	Oral (drinking water)	50-100 mg doxycycline/1 litre of drinking water/day (equivalent to 0,5-1,0 ml of product/1litre of drinking water/day for 3-5 days	Chickens 7 days (not for use in animals from which eggs are produced for human consumption) Indications: Colibacillosis, CRD, mycoplasmosis – caused by previously mentioned germs sensitive to doxycycline.
Romania	VMD Berendonk 74 2370 Arendonk BELGIUM	Doxyveto 50S	Doxycycline hyclate	500 mg/g doxycycline (as hyclate)	Water soluble powder	Poultry Swine calves lambs	Oral (drinking water or feed)	20 mg doxycycline/kg b.w. /day in drinking water or 300 g of product/1 000 litres of drinking water or 600 g/1 000 kg of feed for 3-5 days	Poultry 8 days Indications: CRD (Mycoplasma gallisepticum), Ornithosis (Chlamidia psittaci), Infectious synovitis (Mycoplasma synoviae), Fowl cholera (Pasteurella multocida).

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Romania	CHEMIFARMA S.p.A Via Don Eugenio Servadei 16 47100 Forli ITALY	Doxiciclina 50 %	Doxycycline hyclate	500 mg/g doxycycline	Water soluble powder	Broiler chickens swine	Oral (per os, drinking water or liquid feed)	40 g of product/100 kg b.w. (20 mg of doxycycline/kg b.w) corresponding to about 15-30 g of product/100 litres of water for 3-5 days.	Broiler chickens 5 days Indications: Chronic respiratory disease and other respiratory illnesses, specially produced by Pasteurella spp., Mycoplasma spp., Haemophilus gallinarium, Bordetella avium and Chlamidia psittaci.
Romania	Lavet Pharmaceuticals Ltd., 1161 Budapest Ottó u. 14, HUNGARY	Doxiprim 40 % Soluble Powder	Doxycycline hyclate	400 mg/g doxycycline hyclate	Water soluble powder	Chickens turkeys (not for use in animals from which eggs are produced for human consumption) pigs	Oral (drinking water)	20 mg doxycycline hyclate/kg b.w.	Chickens and turkeys 4 days (not for use in animals from which eggs are produced for human consumption) Indications: treatment of respiratory, intestinal and systemic infections caused by doxycycline sensitive organisms: CRD (Mycoplasma gallisepticum, E. Coli), airsaculitis (Mycoplasma maleagridis), infectious synovitis (Mycoplasma synoviae), fowl cholera (Pasteurella multocida), infectious coryza (Haemophylus paragallinarum), colibacillosis (E. Coli), turkeys bordetellosis (Bordetella avium), necrotic enteritidis (Clostridium perfringens), chlamydiosis (Chlamidia psittaci). Prevention of secundary becterial infections due to stress conditions, vaccination, change of housing, transport.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Romania	Novartis Animal Health d.o.o. Verovskava 57 1000 Ljubljana SLOVENIA	Doxyril 50 %	Doxycycline hyclate	500 mg/g doxycycline hyclate	Water soluble powder	Poultry (not for use in animals from which eggs are produced for human consumption) pigs	Oral (drinking water)	25 mg doxycycline hyclate/kg b.w. during 3 to 5 consecutive days	Poultry 4 days (not for use in animals from which eggs are produced for human consumption) Indication: Respiratory tract Infections caused by Mycoplasma spp. (M. gallisepticum, M. synoviae and M. melagridis), E. coli, Haemophylus paragallinarium and Ornithobacterium rhinotracheale. Enteritidis caused by Clostridium perfringens and Clostridium colinum. Septicemia caused by Pasteurella multocida.
Romania	CEVA SANTE ANIMALE ROMANIA SRL 5 Chindiei, sector 4, Bucharest ROMANIA	Doxyvit 50 % WSP	Doxycycline hyclate	500 mg/g doxycycline hyclate	Water soluble powder	Poultry (chickens and turkeys) (not for use in animals from which eggs are produced for human consumption) pigs	Oral (drinking water)	15 mg doxycycline/kg b.w. for 5 consecutive days or 2 g of product/10 litres drinking water and equivalent to 100 mg of doxycycline/litre of drinking water	Poultry (chickens and turkeys) 7 days (not for use in animals from which eggs are produced for human consumption) Indications: Colibacillosis, CRD and mycoplasmosis, Clostridium perfringens, chlamydiosis, infectious coryza caused by Bordetella avium.
Romania	Laboratorios Karizoo S.A Polígono Industrial La Borda Mas Pujades 11-12 08140 Caldes de Montbui Barcelona SPAIN	Karidox 100 mg/ml oral solution for use in drinking water for chickens and pigs	Doxycycline hyclate	100 mg/ml doxycycline (as hyclate)	Oral solution	Poultry (chickens) (not for use in animals from which eggs are produced for human consumption) pigs	Oral (drinking water)	10-20 mg doxycycline/kg b.w. for 3 - 5 days.	Poultry (chickens) t days (not for use in animals from which eggs are produced for human consumption) Indications: Prevention and treatment of CRD and mycoplasmosis caused by microorganisms sensitive to doxycycline.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Romania	S.C. VIM SPECTRUM SRL 409 Sighisoarei Targu Mures ROMANIA	Vidoxim 10 % powder for oral solution for pigs and poultry	Doxycycline hyclate	100 mg/g doxycycline hyclate	Water soluble powder	Poultry (not for use in animals from which eggs are produced for human consumption) pigs	Oral (drinking water)	1 000 g of product/1 000 litres drinking water for 5 days	Poultry 10 days (not for use in animals from which eggs are produced for human consumption) Indications: Infections caused by Mycoplasma gallisepticum, E. coli, Bordetella avium, Haemophylus paragallinarium and Pasteurela multocida.
Romania	S.C. VIM SPECTRUM SRL 409 Sighisoarei Targu Mures ROMANIA	Vidoxim 100 % powder for oral solution for pigs and poultry	Doxycycline hyclate	1 000 mg/g doxycycline hyclate	Water soluble powder	Poultry (not for use in animals from which eggs are produced for human consumption) pigs	Oral (drinking water)	100 g of product/1 000 litres drinking water for 5 days	Poultry 10 days (not for use in animals from which eggs are produced for human consumption) Indications: Infections caused by M. gallisepticum, E. coli, Bordetella avium, Haemophylus paragallinarium and P. multocida.
Romania	CHEMO IBERICA, S.A. Gran Via Carlos III, 98 7ª Edificio Trade 08028 Barcelona SPAIN	Oridox (Soldoxin) 100 mg/ml oral solution for use in drinking water for chickens and pigs	Doxycycline hyclate	100 mg/ml doxycycline (as hyclate)	Oral solution	Chickens (broilers) (not for use in animals from which eggs are produced for human consumption) pigs	Oral (drinking water)	10-20 mg doxycycline/kg b.w. for 3 - 5 days.	Poultry (chickens) 7 days (not for use in animals from which eggs are produced for human consumption) Prevention and treatment of CRD and mycoplasmosis caused by microorganisms sensitive to doxycycline.
Romania	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen BELGIUM	HydroDoxx 500 mg/g Water Soluble Powder	Doxycycline hyclate	500 mg/g doxycycline hyclate	Powder for oral solution	Chickens (broilers) & Pigs (fattening pigs)	Oral (drinking water)	20 mg doxycycline (hyclate)/kg x 3-5 days	Meat and offal: Chickens: 6 days Do not use in laying birds producing eggs for human consumption Indications: Chickens (broilers): Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Romania	CEVA PHYLAXIA VETERINARY BIOLOGICALS CO. LTD. 1107 Budapesta Szallas u.5 HUNGARY	Doxivit 100	Doxycycline hydrocloride	100 mg/g doxycycline hydrochloride	Water soluble powder	Poultry (chickens, turkeys and goose) pigs	Oral (drinking water)	10 mg doxycycline hydrochloride/kg b.w. daily for 5 days	Poultry) 7 days (not for use in animals from which eggs are produced for human consumption) Indications: CRD (Mycoplasma gallisepticum, E. Coli), infectious coryza (Haemophylus paragallinarum), fowl cholera (Pasteurella multocida), colibacillosis (E. Coli), airsaculitis (Mycoplasma maleagridis), chlamydiosis (Chlamidia psittaci), necrotic enteritis (Clostridium perfringens).
Romania	PHARMATEKA BT 1046 Budapest Szigyarto u. 10 / 20 Kossuth Str. Pusztaberki, 2658 HUNGARY	DOXY H 10 %	Doxycycline hydrocloride	100 mg/g doxycycline hydrochloride	Water soluble powder	Poultry	Oral (drinking water)	1 g of product/1 litre of drinking water for 3-5 days	Poultry 10 days (not for use in animals from which eggs are produced for human consumption)
Romania	s.c. romvac company s.a.Şos. Centurii, nr. 7 Voluntari ROMANIA	Doxiciclina 10 %	Doxycycline hydrocloride	100 mg/g doxycycline hydrochloride	Water soluble powder	Poultry, including pigeons pigs bovine (calves)	Oral (drinking water)	2 g of product/10 kg b.w./day for 5-8 days	Poultry (chickens) 5 days (not for use in animals from which eggs are produced for human consumption)
Romania	S.C. Crida pharm s.r.l 2 Intrarea Vagonetului Bl. 101, Ap. 47, sector 6 Bucharest ROMANIA	Doxicol 60 %	Doxycycline hydrocloride	600 mg/g doxycycline hydrochloride	Water soluble powder	Poultry pigs	Oral (drinking water or feed)	broiler 0-14 days: 50g/1 000 litres of water; broiler 15 -28 days: 100g/1 000 litres of water;broiler 29 -35 days: 120g/1 000 litres of water;	Poultry 5 days (not for use in animals from which eggs are produced for human consumption) Indications: prevention and treatment of colibacillosis, respiratory diseases, mycoplasmosis.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Slovenia	Novartis Veterina d.o.o. Verovškova 57 1000 Ljubljana SLOVENIA	DOXYRIL 50 %	Doxycycline hyclate	50 % (500 mg/g)	powder for oral solution	pigs, poultry	Pigs and poultry: once a day, three to five days consecutively in drinking water	Pigs: 20 mg of doxycycline hycate per 1 kg of BW; Poultry 25 mg of doxycycline hycate per 1 kg of BW	Meat and offal: poultry: 4 days; Indications: respiratory infections (M gallisepticum, M, synoviae in M, melagridis), Escherichia coli, Haemophilus paragallinarum, Ornithobacterium rhinotracheale; Enteritis (Clostridium perfringens and Clostridium colinum; Septicemia (Pasteurella multocida)
Slovak republic	Trei Bio pharmaceutical division, Industria Italiana Integratori Trei Via Affarosa n.4 42010 Rio Saliceto (Reggio Emilia) ITALY	DOXIPAN 20 plv-.sol. ad us.vet.	Doxycycline hyclate	20 g/100 g	Water soluble powder	Calves, pigs, poultry-broilers, turkey	for 5 days in drinking water	Poultry-broilers: 5-7,5 g product/10 litre of drinking water Turkey:10-20 mg active substance/b. w. corresponding to 50-100 g product/100 liter d.w. Calves, pigs: 10 mg active substance/b.w./day corresponding to 0,5 g product/10 kg b.w.	Meat: Broilers 5 days, turkeys 10 days, Indications: Broilers: chronic respiratory disease and assotiated complications Turkeys: infections caused by G-positive and G-negative germs, mycoplasmas sensitive to doxycycline especially respiratory and articular syndrom caused by mycoplasma and/or staphylococcus
Slovak republic	DIVASA-FARMAVIC, S.A. CTRA. SANT HIPOLIT, KM. 71 08503 GURB – VIC SPAIN	DOXIVET 10 % plv-.sol. a.u.v.	Doxycycline hyclate	100 mg/ml	Water soluble powder	Poultry: (chickens and turkeys), bovine and swine	for 4 - 5 days in drinking water	0,5 ml of product/litre of drinking water	Meat: 5 days Indications: Treatment of CRD, mycoplasmosis, porcine enzootic pneumonia, bronchopneumonias, chlamidiasis, unspecific diarheas.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Slovak republic	Novartis Animal Health d.o.o. Verovskava 57 1000 Ljubljana SLOVENIA	DOXYRIL 500 mg/g prášok na perorálny roztok ad us.vet.	Doxycycline hyclate	500 mg/g	Water soluble powder	Pigs, broilers	during 3 to 5 consecutive days in drinking water	Pigs: 20 mg doxycycline hyclate/kg b.w. Broilers: 25 mg doxycycline hyclate/kg b.w.	Eddible tissues: broilers 4 days. Indications: Treatment of infections caused by microorganisms susceptible to doxycycline, particularly: Broilers: respiratory tract infections caused by Mycoplasma spp. (M.gallisepticum, M.synoviae and M.meleagridis), Escherichia coli, Haemophilus paragallinarum and Ornithobacterium rhinotracheale, enteritis caused by Clostridium perfringens and Clostridium colinum, septicemia caused by Pasteurella multocida
Slovak republic	Lavet Pharmaceuticals Ltd., 1161 Budapest Ottó u. 14, HUNGARY	DOXYVIT 40 % plv-.sol.	Doxycycline hyclate	40 g/100 g	Water soluble powder	Poultry: (chickens and turkeys) and swine	3-5 days in drinking water, poutry in drinking water, pigs: in drinking water, in feed	Chickens and turkeys:10-20 mg active doxycyclini hyclate/kg b.w.)/day, continual treatment: 1 g product/3-6 litre of drinking water, repeated treatment: 25-50 mg product/kg b.w.(10-20 mg doxycycline hyclate/kg b.w.) in drinking water	Meat of chickens and turkey: 4 days, Indications: Treatment and prophylaxis of respiratory, intestinal and systematic infections caused by doxycycline sensitive organism: Chickens, turkeys: chronic respiratory disease (Mycoplasma gallisepticum, E.coli), airsacculitis (M.meleagridis), infectious synovitis (M.synoviae), fowl cholera (P. multocida), turkey bordetellosis (Bordetella avium), infectious coryza (Haemophilus paragallinarum), collibacilosis (E.coli), necrotic enteritis (Clostridium prefringens), chlamydiiosis (CH. psittaci),

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Slovak republic	Tekro, spol. s.r.o., Višňová 2/484, 140 00 Praha 4, CZECH REPUBLIC	Meditek DOX 100 plv.sol. ad us.vet.	Doxycycline hyclate	100 g/1 000 g	Water soluble powder	Broilers, pigs	3-5 days in drinking water	Broilers: 10 mg doxycyclini hyclate/kg b.w (corresponding to 1 kg product/1 000 litre of drinking water)	Meat of broilers and pigs: 7 days. Indications: Treatment and prevention of respiratory and gastrointestinal diseases caused by organism sensitive to doxycycline: broilers: CRD, mycoplasmosis, aerosacculitis, synovitis, pasteurellosis, infectious cholera, colibacillosis, chlamidiosis, necrotic enteritis
Slovak republic	Pharmagal s.r.o., Murgašova 5, 949 01 Nitra, SLOVAK REPUBLIC	DOXYGAL plv.sol. ad us.vet.	Doxycycline hyclate	5 g/100 g	Water soluble powder	Pigs, poultry, calves, rabbits	Poultry: prevention 5 days, treatment 3 days, in drinking water Pigs, calves, rabbits: 5 days, in drinking water, in feed	Poultry: prevention: 50 mg active substance/1 litre of drinking water (1 g product/1 litre water), treatment: 100 mg active substance/1 litre water (2 g product/1 litre water)	Meat of poultry and rabbits: 7 days Indications: Poultry: CRD (mycoplasmosis), colibacillosis.
Slovak republic	COOPHAVET Saint Herblon 44150 Ancenis FRANCE	RONAXAN 5 % plv-.sol. ad us.vet.	Doxycycline hyclate	5 g/100 g	Water soluble powder	Pigs, poultry, calves	Prevention: 1-3 days, treatment: 3-5 days, in drinking, in feed	10 mg active substance/kg b.w./day (1 g product/5 kg b.w./day) Polutry: — less than 2 weeks old: 1 g product/litre of drinking water/day, — more than 2 weeks old: 2 g/litre water/day	Meat of poultry 4 days Indications: Poultry: preventive and curative treatment of respiratory infections,

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
Slovak republic	Laboratorios Karizoo S.A Polígono Industrial La Borda Mas Pujades 11-12 08140 Caldes de Montbui Barcelona SPAIN	KARIDOX 100 mg/ml roztok pre podávanie hydine a ošípaným perorálne v pitnej vode	Doxycycline hyclate	100 mg/ml	Water soluble powder	Chicken (broilers), pigs	Broilers: 3-5 days, Pigs: 5 days, in drinking water	Broilers: 10 -20 mg of doxycycline/kg b.w./day, (0,5-1,0 ml of product/litre of drinking water),	Meat and offals: chicken (broilers) 7 days Indications: Chicken (broilers): prevention and treatment of chronic respiratory disease (CRD) and mycoplasmosis caused by microorganism sensitive to doxycycline.
Slovak republic	CHEMO IBERICA, S.A. Gran Via Carlos III, 98 7[a] Edificio Trade 08028 Barcelona SPAIN	ORIDOX 100 mg/ml roztok pre podávanie hydine a ošípaným perorálne v pitnej vode	Doxycycline hyclate	100 mg/ml	Water soluble powder	Chicken (broilers), pigs	Broilers: 3-5 days, Pigs. 5 days, in drinking water	Broilers: 10 -20 mg of doxycycline/kg b.w./day, (0,5-1,0 ml of product/litre of drinking water),	Meat and offals: chicken (broilers) 7 days, Indications: Chicken (broilers): prevention and treatment of chronic respiratory disease (CRD) and mycoplasmosis caused by microorganism sensitive to doxycycline.
United kingdom	Laboratorios Karizoo S.A Polígono Industrial La Borda Mas Pujades 11-12 08140 Caldes de Montbui Barcelona SPAIN	Karidox 100 mg/ml Oral Solution for use in drinking water for Chickens and Pigs	Doxycycline hyclate	100 mg/ml doxycycline (as doxycycline hyclate)	Oral solution	Chickens (broilers) & Pigs	Oral (drinking water)	10-20 mg doxycycline/kg x 3-5 days	Meat & offal: Chickens (broilers): 7 days Indications: CHICKENS (BROILERS): Prevention and treatment of chronic respiratory disease (CRD) and mycoplasmosis caused by microorganisms sensitive to doxycycline.
United kingdom	CHEMO IBERICA, S.A. Gran Via Carlos III, 98 7[a] Edificio Trade 08028 Barcelona SPAIN	Soldoxin 100 mg/ml Oral Solution for use in drinking water for chickens and pigs	Doxycycline hyclate	100 mg/ml doxycycline (as doxycycline hyclate)	Oral solution	Chickens (broilers) & Pigs	Oral (drinking water)	10-20 mg doxycycline/kg x 3-5 days	Meat & offal: Chickens (broilers): 7 days Indications: CHICKENS (BROILERS): Prevention and treatment of chronic respiratory disease (CRD) and mycoplasmosis caused by microorganisms sensitive to doxycycline.

Member state/EEA	Applicant/Marketing Authorisation Holder	Product name	INN	Strength	Pharmaceutical form	Animal species	Frequency and route of administration	Recommended dose	Withdrawal period(s)/Indications
United kingdom	Huvepharma N.V. Uitbreidingstraat 80 2600 Antwerpen BELGIUM	HydroDoxx 500 mg/g Water Soluble Powder	Doxycycline hyclate	500 mg/g doxycycline hyclate	Powder for oral solution	Chickens (broilers) & Pigs (fattening pigs)	Oral (drinking water)	20 mg doxycycline (hyclate)/kg x 3-5 days	Meat and offal: Chickens: 6 days Indications: Chickens (broilers): Prevention and treatment of Chronic Respiratory Disease (CRD) caused by Mycoplasma gallisepticum.
UNITED KINGDOM	VMD NV, HOGE MAUW 900-2370 Arendonk BELGIUM	Doxyveto 50 s plus	Doxycycline hyclate	50 % w/w doxycycline hyclate	Powder for oral administration	Non-egg laying chickens	Oral (drinking water)	25 mg doxycycline (hyclate)/kg x 3-5 days	Meat and offal:6 days Indications: Respiratory infections caused by Mycoplasma spp., E. coli and Haemophilus paragallinarum. Enteritis caused by Clostridium perfringens and Clostridium colinum

ANNEX XV

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTHS OF THE VETERINARY MEDICINAL PRODUCTS, ANIMAL SPECIES, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION Holder IN THE MEMBER STATES

Member State / EEA	Marketing Authorisation Holder	Invented name	Pharmaceutical form	Strength	Animal species	Frequency and route of administration	Recommended dose
Austria	Intervet International B.V. P.O. Box 31 5830 AA Boxmeer The Netherlands	Vasotop P 0,625 mg; Vasotop P 1,25 mg; Vasotop P 2,5 mg, tablet for dogs	Tablet	0,625; 1,25 or 2,5 mg of ramipril	Dogs	Daily, oral	0,125 mg/kg; 0,25 mg/kg if the animal does not respond after 2 weeks of treatment
Belgium	Intervet International B.V. P.O. Box 31 5830 AA Boxmeer The Netherlands	Vasotop P 0,625 mg; Vasotop P 1,25 mg; Vasotop P 2,5 mg, tablet for dogs	Tablet	0,625; 1,25 or 2,5 mg of ramipril	Dogs	Daily, oral	0,125 mg/kg; 0,25 mg/kg if the animal does not respond after 2 weeks of treatment
Denmark	Intervet International B.V. P.O. Box 31 5830 AA Boxmeer The Netherlands	Vasotop P 0,625 mg; Vasotop P 1,25 mg; Vasotop P 2,5 mg, tablet	Tablet	0,625; 1,25 or 2,5 mg of ramipril	Dogs	Daily, oral	0,125 mg/kg; 0,25 mg/kg if the animal does not respond after 2 weeks of treatment
Germany	Intervet International B.V. P.O. Box 31 5830 AA Boxmeer The Netherlands	Vasotop P 0,625 mg; Vasotop P 1,25 mg; Vasotop P 2,5 mg, tablet for dogs	Tablet	0,625; 1,25 or 2,5 mg of ramipril	Dogs	Daily, oral	0,125 mg/kg; 0,25 mg/kg if the animal does not respond after 2 weeks of treatment
Greece	Intervet International B.V. P.O. Box 31 5830 AA Boxmeer The Netherlands	Vasotop P 0,625 mg; Vasotop P 1,25 mg; Vasotop P 2,5 mg, tablet for dogs	Tablet	0,625; 1,25 or 2,5 mg of ramipril	Dogs	Daily, oral	0,125 mg/kg; 0,25 mg/kg if the animal does not respond after 2 weeks of treatment
Spain	Intervet International B.V. P.O. Box 31 5830 AA Boxmeer The Netherlands	Vasotop P 0,625 mg; Vasotop P 1,25 mg; Vasotop P 2,5 mg, tablet for dogs	Tablet	0,625; 1,25 or 2,5 mg of ramipril	Dogs	Daily, oral	0,125 mg/kg; 0,25 mg/kg if the animal does not respond after 2 weeks of treatment
Finland	Intervet International B.V. P.O. Box 31 5830 AA Boxmeer The Netherlands	Vasotop P 0,625 mg; Vasotop P 1,25 mg; Vasotop P 2,5 mg, tablet for dogs	Tablet	0,625; 1,25 or 2,5 mg of ramipril	Dogs	Daily, oral	0,125 mg/kg; 0,25 mg/kg if the animal does not respond after 2 weeks of treatment
Ireland	Intervet International B.V. P.O. Box 31 5830 AA Boxmeer The Netherlands	Vasotop P 0,625 mg; Vasotop P 1,25 mg; Vasotop P 2,5 mg, tablet	Tablet	0,625; 1,25 or 2,5 mg of ramipril	Dogs	Daily, oral	0,125 mg/kg; 0,25 mg/kg if the animal does not respond after 2 weeks of treatment

Member State / EEA	Marketing Authorisation Holder	Invented name	Pharmaceutical form	Strength	Animal species	Frequency and route of administration	Recommended dose
Luxemburg	Intervet International B.V. P.O. Box 31 5830 AA Boxmeer The Netherlands	Vasotop P 0,625 mg; Vasotop P 1,25 mg; Vasotop P 2,5 mg, tablet for dogs	Tablet	0,625; 1,25 or 2,5 mg of ramipril	Dogs	Daily, oral	0,125 mg/kg; 0,25 mg/kg if the animal does not respond after 2 weeks of treatment
The Netherlands	Intervet International B.V. P.O. Box 31 5830 AA Boxmeer The Netherlands	Vasotop P 0,625 mg; Vasotop P 1,25 mg; Vasotop P 2,5 mg, tablet for dogs	Tablet	0,625; 1,25 or 2,5 mg of ramipril	Dogs	Daily, oral	0,125 mg/kg; 0,25 mg/kg if the animal does not respond after 2 weeks of treatment
Norway	Intervet International B.V. P.O. Box 31 5830 AA Boxmeer The Netherlands	Vasotop P 0,625 mg; Vasotop P 1,25 mg; Vasotop P 2,5 mg, tablet	Tablet	0,625; 1,25 or 2,5 mg of ramipril	Dogs	Daily, oral	0,125 mg/kg; 0,25 mg/kg if the animal does not respond after 2 weeks of treatment
Portugal	Intervet International B.V. P.O. Box 31 5830 AA Boxmeer The Netherlands	Vasotop P 0,625 mg; Vasotop P 1,25 mg; Vasotop P 2,5 mg, tablet for dogs	Tablet	0,625; 1,25 or 2,5 mg of ramipril	Dogs	Daily, oral	0,125 mg/kg; 0,25 mg/kg if the animal does not respond after 2 weeks of treatment

ANNEX XVI

LIST OF THE INVENTED NAME, PHARMACEUTICAL FORM, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION AND MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES (EU/EEA)

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Austria	Abbott GmbH Perfektastraße 84A A–1230 Wien Austria	Reductil 10 mg - Hartkapseln	10 mg	Capsule, hard	oral use
Austria	Abott GmbH Perfektastraße 84A A–1230 Wien Austria	Reductil 15 mg - Hartkapseln	15 mg	Capsule, hard	oral use
Austria	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	Sibutramin Teva 10 mg Kapseln	10 mg	Capsule, hard	oral use
Austria	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	Sibutramin Teva 15 mg Kapseln	15 mg	Capsule, hard	oral use
Belgium	Abbott SA rue du Bosquet 2 1348 Ottignies/LLN Belgium	Reductil 10 mg	10 mg	Capsule, hard	oral use
Belgium	Abbott SA rue du Bosquet 2 1348 Ottignies/LLN Belgium	Reductil 15 mg	15 mg	Capsule, hard	oral use
Belgium	SandozNV TelecomGardens Medialaan 40 1800 Vilvoorde Belgium	Sibutramin Sandoz 10 mg	10 mg	Capsule, hard	oral use
Belgium	SandozNV TelecomGardens Medialaan 40 1800 Vilvoorde Belgium	Sibutramin Sandoz 15 mg	15 mg	Capsule, hard	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Belgium	Teva pharma belgium Laarstraat 16 2610 Wilrijk Belgium	Sibutramin Teva 10 mg	10 mg	Capsule, hard	oral use
Belgium	Teva pharma belgium Laarstraat 16 2610 Wilrijk Belgium	Sibutramin Teva 15 mg	15 mg	Capsule, hard	oral use
Bulgaria	Abbott GmbH & Co KG Max-Planck-Ring 2 65205 Wiesbaden Germany	Reductil	10 mg	Capsule, hard	oral use
Bulgaria	Abbott GmbH & Co KG Max-Planck-Ring 2 65205 Wiesbaden Germany	Reductil	15 mg	Capsule, hard	oral use
Bulgaria	Sandoz d.d., Verovskova 57 SI - 1000 Ljubljana Slovenia	Sibutramin Sandoz	10 mg	Capsule, hard	oral use
Bulgaria	Sandoz d.d. Verovskova 57 SI-1000 Ljubljana Slovenia	Sibutramin Sandoz	15 mg	Capsule, hard	oral use
Bulgaria	Zentiva k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Lindaxa	10 mg	Capsule, hard	oral use
Bulgaria	Zentiva k.s. U kabelovny 130 102 37 Prague 10 Czech Republic	Lindaxa	15 mg	Capsule, hard	oral use
Bulgaria	Teva Pharmaceuticals Bulgaria EOOD 15 N.V. Gogol str. Sredetz district 1124 Sofia Bulgaria	Meissa	10 mg	Capsule, hard	oral use
Bulgaria	Teva Pharmaceuticals Bulgaria EOOD 15 N.V. Gogol str. Sredetz district 1124 Sofia Bulgaria	Meissa	15 mg	Capsule, hard	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Czech Republic	Abbott GmbH & Co.KG Max-Planck-Ring-2 65202 Wiesbaden Germany	MERIDIA 10 MG	10 mg	Capsule, hard	oral use
Czech Republic	Abbott GmbH & Co.KG Max-Planck-Ring-2 65202 Wiesbaden Germany	MERIDIA 15 MG	15 mg	Capsule, hard	oral use
Czech Republic	Zentiva, k.s. U kabelovny 130, 102 37 Prague 10 Czech Republic	LINDAXA 10	10 mg	Capsule, hard	oral use
Czech Republic	Zentiva, k.s. U kabelovny 130, 102 37 Prague 10 Czech Republic	LINDAXA 15	15 mg	Capsule, hard	oral use
Czech Republic	TEVA Pharmaceuticals ČR, s.r.o. Radlická 3185/Ic 150 00 Prague 5 Czech Republic	SIBUTRAMIN-TEVA 10 MG TOBOLKY	10 mg	Capsule, hard	oral use
Czech Republic	TEVA Pharmaceuticals ČR, s.r.o. Radlická 3185/Ic 150 00 Prague 5 Czech Republic	SIBUTRAMIN-TEVA 15 MG TOBOLKY	15 mg	Capsule, hard	oral use
Denmark	Abbott Scandinavia AB Postboks 509 SE-169 29, Solna Sweden	Reductil	10 mg	Capsule, hard	oral use
Denmark	Abbott Scandinavia AB Postboks 509 SE-169 29, Solna Sweden	Reductil	15 mg	Capsule, hard	oral use
Denmark	1A Farma A/S Herstedøstervej 27-29 DK–2620 Albertslund Denmark	Sibutramin "1A Farma"	10 mg	Capsule, hard	oral use
Denmark	1A Farma A/S Herstedøstervej 27-29 DK–2620 Albertslund Denmark	Sibutramin "1A Farma"	15 mg	Capsule, hard	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Denmark	Sandoz A/S C. F. Tietgens Boulevard 40 DK–5220 Odense SØ Denmark	Sibutramin "Sandoz"	10 mg	Capsule, hard	oral use
Denmark	Sandoz A/S C. F. Tietgens Boulevard 40 DK–5220 Odense SØ Denmark	Sibutramin "Sandoz"	15 mg	Capsule, hard	oral use
Denmark	Teva Danmark A/S Østergade 38 DK–1100 København K Denmark	Sibutramin "Teva"	10 mg	Capsule, hard	oral use
Denmark	Teva Danmark A/S Østergade 38 DK–1100 København K Denmark	Sibutramin "Teva"	15 mg	Capsule, hard	oral use
Estonia	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany	REDUCTIL	10mg	Capsule, hard	oral use
Estonia	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany	REDUCTIL	15mg	Capsule, hard	oral use
Estonia	Sandoz d.d. Verovskova 57 1000 Ljubljana Slovenia	SIBUTRIL	10mg	Capsule, hard	oral use
Estonia	Sandoz d.d. Verovskova 57 1000 Ljubljana Slovenia	SIBUTRIL	15mg	Capsule, hard	oral use
Estonia	Zentiva, k.s. U Kabelovny 130 Dolni Mecholupy 102 37 Prague 10 Czech Republic	LINDAXA 10	10mg	Capsule, hard	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Estonia	Zentiva, k.s. U Kabelovny 130 Dolni Mecholupy 102 37 Prague 10 Czech Republic	LINDAXA 15	15mg	Capsule, hard	oral use
Estonia	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	SIBUTRAMINE TEVA	10mg	Capsule, hard	oral use
Estonia	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	SIBUTRAMINE TEVA	15mg	Capsule, hard	oral use
Finland	Abbott ScandinaviaAB P.O. Box 509 16929 Solna Sweden	Reductil	10 mg, 15 mg	Capsule, hard	oral use
Finland	Sandoz A/S C.F. Tietgens Boulevard 40 5220 Odense SØ Denmark	Sibutramin Sandoz	10 mg, 15 mg	Capsule, hard	oral use
Finland	Teva Sweden AB Järnvägsgatan 11 Box 1070 25110 Helsingborg Sweden	Sibutramine Teva	10 mg, 15 mg	Capsule, hard	oral use
France	ABBOT France 10, RUE D'ARCUEIL SILIC 233 94528 RUNGIS CEDEX FRANCE	SIBUTRAL 10 mg, gélule	10 mg	capsule	oral use
France	ABBOT France 10, RUE D'ARCUEIL SILIC 233 94528 RUNGIS CEDEX FRANCE	SIBUTRAL 15 mg, gélule	15 mg	capsule	oral use
Germany	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany	Reductil 10 mg Hartkapseln	10 mg	Capsule, hard	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Germany	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany	Reductil 15 mg Hartkapseln	15 mg	Capsule, hard	oral use
Germany	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany	Zelium 10 mg Hartkapseln	10 mg	Capsule, hard	oral use
Germany	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany	Zelium 15 mg Hartkapseln	15 mg	Capsule, hard	oral use
Germany	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany	Reduxade 10 mg Hartkapseln	10 mg	Capsule, hard	oral use
Germany	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany	Reduxade 15 mg Hartkapseln	15 mg	Capsule, hard	oral use
Germany	1 A Pharma GmbH Keltenring 1 + 3 82041 Oberhaching Germany	Sibutramin - 1A Pharma 10 mg Hartkapseln	10 mg	Capsule, hard	oral use
Germany	1 A Pharma GmbH Keltenring 1 + 3 82041 Oberhaching Germany	Sibutramin - 1A Pharma 15 mg Hartkapseln	15 mg	Capsule, hard	oral use
Germany	HEXAL AG Postfach 1263 83602 Holzkirchen Germany	Sibutramin-HEXAL 10 mg Hartkapseln	10 mg	Capsule, hard	oral use
Germany	HEXAL AG Postfach 1263 83602 Holzkirchen Germany	Sibutramin-HEXAL 15 mg Hartkapseln	15 mg	Capsule, hard	oral use
Greece	Abbott Laboratories (Hellas) S.A. 512, Vouliagmenis Avenue GR 17456, Alimos Athens Greece	Reductil	10 mg	Capsule, hard	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Greece	Abbott Laboratories (Hellas) S.A. 512, Vouliagmenis Avenue GR 17456, Alimos Athens Greece	Reductil	15 mg	Capsule, hard	oral use
Greece	Teva Pharmaceuticals Europe B.V. European Headquarters Computerweg 10 3542 DR Utrecht The Netherlands	Sibutramine/Teva	10mg	Capsule, hard	oral use
Greece	Teva Pharmaceuticals Europe B.V. European Headquarters Computerweg 10 3542 DR Utrecht The Netherlands	Sibutramine/Teva	15 mg	Capsule, hard	oral use
Hungary	Zentiva k. s. U Kabelovny 130 102 37 Praha 10 Czech Republic	LINDAXA	10mg	Capsule, hard	oral use
Hungary	Zentiva k. s. U Kabelovny 130 102 37 Praha 10 Czech Republic	LINDAXA	15mg	Capsule, hard	oral use
Hungary	Teva Magyarország zrt. Rákóczi út 70-72. 1074 Budapest Hungary	MINIMECTIL	10mg	Capsule, hard	oral use
Hungary	Teva Magyarország zrt. Rákóczi út 70-72. 1074 Budapest Hungary	MINIMECTIL	15mg	Capsule, hard	oral use
Hungary	Abbott Laboratories Kft. Teve u. 1/a-c 1139 Budapest Hungary	REDUCTIL	10mg	Capsule, hard	oral use
Hungary	Abbott Laboratories Kft. Teve u. 1/a-c 1139 Budapest Hungary	REDUCTIL	15mg	Capsule, hard	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Iceland	Abbott Scandinavia Gårdsvägen 8 Box 5091 SE-169 29 Solna Sweden	Reductil	10 mg	Capsule, hard	oral use
Iceland	Abbott Scandinavia Gårdsvägen 8 Box 5091 SE-169 29 Solna Sweden	Reductil	15 mg	Capsule, hard	oral use
Ireland	Teva Pharma B.V. Computerweg 10 3542 Dr Utrecht Netherlands	Sibutramine Teva 10 mg Capsules	10 mg	Capsule, hard	oral use
Ireland	Teva Pharma B.V. Computerweg 10 3542 Dr Utrecht Netherlands	Sibutramine Teva 15 mg Capsules	15 mg	Capsule, hard	oral use
Ireland	Abbot Laboratories Ireland Ltd 4051 Kingswood Drive Citywest Business Campus Dublin 24 Ireland	Reductil 10 mg capsules, hard	10 mg	Capsule, hard	oral use
Ireland	Abbot Laboratories Ireland Ltd 4051 Kingswood Drive Citywest Business Campus Dublin 24 Ireland	Reductil 15 mg capsules, hard	15 mg	Capsule, hard	oral use
Ireland	Rowex Ltd Bantry Co.Cork Ireland	Sitrane 10 mg hard capsules	10 mg	Capsule, hard	oral use
Ireland	Rowex Ltd Bantry Co.Cork Ireland	Sitrane 15 mg hard capsules	15 mg	Capsule, hard	oral use
Italy	ABBOTT srl Via Pontina Km 52 04010 Campoverde di Aprilia Italy	REDUXATE	10 mg	capsule	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Italy	ABBOTT srl Via Pontina Km 52 04010 Campoverde di Aprilia Italy	REDUXATE	15 mg	capsule	oral use
Italy	ABBOTT srl Via Pontina Km 52 04010 Campoverde di Aprilia Italy	ECTIVA	10 mg	capsule	oral use
Italy	ABBOTT srl Via Pontina Km 52 04010 Campoverde di Aprilia Italy	ECTIVA	15 mg	capsule	oral use
Italy	ABBOTT srl Via Pontina Km 52 04010 Campoverde di Aprilia Italy	REDUCTIL	10 mg	capsule	oral use
Italy	ABBOTT srl Via Pontina Km 52 04010 Campoverde di Aprilia Italy	REDUCTIL	15 mg	capsule	oral use
Latvia	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany	Reductil 15 mg hard capsules	15 mg	Capsule, hard	oral use
Latvia	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany	Reductil 10 mg hard capsules	10 mg	Capsule, hard	oral use
Latvia	Sandoz d.d. Verovškova 57 1000 Ljubljana Slovenia	Sibutril 15 mg capsules, hard	15 mg	Capsule, hard	oral
Latvia	Sandoz d.d. Verovškova 57 1000 Ljubljana Slovenia	Sibutril 10 mg capsules, hard	10 mg	Capsule, hard	oral
Lithuania	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany	Reductil	10 mg	Capsule, hard	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Lithuania	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden Germany	Reductil	15 mg	Capsule, hard	oral use
Lithuania	Zentiva k. s. U kabelovny 130 10237 Prague 10 Dolni Mecholupy Czech Republic	Lindaxa	10 mg	Capsule, hard	oral use
Lithuania	Zentiva k. s. U kabelovny 130 10237 Prague 10 Dolni Mecholupy Czech Republic	Lindaxa	15 mg	Capsule, hard	oral use
Lithuania	Sandoz d.d. Verovskova 57 1000 Ljubljana Slovenia	Sibutril	10 mg	Capsule, hard	oral use
Lithuania	Sandoz d.d. Verovskova 57 1000 Ljubljana Slovenia	Sibutril	15 mg	Capsule, hard	oral use
Lithuania	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	Sibutramine Teva	10 mg	Capsule, hard	oral use
Lithuania	Teva Pharma B.V. Computerweg 10 3542 DR Utrecht The Netherlands	Sibutramine Teva	15 mg	Capsule, hard	oral use
Luxembourg	Abbott Laboratoires 2, rue du Bosquet B-1348 Ottignies L.L.N. Belgium	Reductil	10mg	capsule	oral use
Luxembourg	Abbott Laboratoires 2, rue du Bosquet B-1348 Ottignies L.L.N. Belgium	Reductil	15mg	capsules	oral use
Malta	Abbott Laboratories Limited Queenborough Kent ME11 5EL United Kingdom	Reductil	10mg	Capsule, hard	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Malta	Abbott Laboratories Limited Queenborough Kent ME11 5EL United Kingdom	Reductil	15mg	Capsule, hard	oral use
Netherlands	Abbott B.V. Siriusdreef 51 2132 WT, Hoofddorp Netherlands	Reductil 10 mg, capsules, hard	10 mg	Capsule, hard	oral use
Netherlands	Abbott B.V. Siriusdreef 51 2132 WT, Hoofddorp Netherlands	Reductil 15 mg, capsules, hard	15 mg	Capsule, hard	oral use
Netherlands	Sandoz B.V. Veluwezoom 22 1327 AH, Almere Netherlands	Sibutramine HCL monohydraat Sandoz 10 mg, harde capsules	10 mg	Capsule, hard	oral use
Netherlands	Sandoz B.V. Veluwezoom 22 1327 AH, Almere Netherlands	Sibutramine HCL monohydraat Sandoz 15 mg, harde capsules	15 mg	Capsule, hard	oral use
Netherlands	Medcor Pharmaceuticals B.V. Ketelmeerstraat 142-144 8226 JX, Lelystad Netherlands	Reductil 15 mg, capsules	15 mg	Capsule, hard	oral use
Netherlands	Medcor Pharmaceuticals B.V. Ketelmeerstraat 142-144 8226 JX, Lelystad Netherlands	Reductil 10 mg, capsules	10 mg	Capsule, hard	oral use
Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA, Haarlem Netherlands	Sibutramine HCL- monohydraat 10 mg PCH, capsules	10 mg	Capsule, hard	oral use
Netherlands	Pharmachemie B.V. Swensweg 5 2031 GA, Haarlem Netherlands	Sibutramine HCL- monohydraat 15 mg PCH, capsules	15 mg	Capsule, hard	oral use
Norway	Abbot Scandinavia AB Box 509 169 29 Solna Sweden	REDUCTIL	10 mg	Capsule, hard	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Norway	Abbot Scandinavia AB Box 509 169 29 Solna Sweden	REDUCTIL	15 mg	Capsule, hard	oral use
Norway	Euromedica NorgeAS Jerikoveien 28 C 1067 Oslo Norway	REDUCTIL	10 mg	Capsule, hard	oral use
Norway	Euromedica NorgeAS Jerikoveien 28 C 1067 Oslo Norway	REDUCTIL	15 mg	Capsule, hard	oral use
Norway	Sandoz A/ Edvard Thomsens Vej 14 2300 København S Danmark	SIBUTRAMIN SANDOZ	10 mg	Capsule, hard	oral use
Norway	Sandoz A/ Edvard Thomsens Vej 14 2300 København S Danmark	SIBUTRAMIN SANDOZ	15 mg	Capsule, hard	oral use
Poland	Teva Pharmaceuticals Polska Sp. z o.o. 53 Emilii Plater St. 00-113 Warsaw Poland	Afibron	10 mg	Capsule, hard	oral use
Poland	Teva Pharmaceuticals Polska Sp. z o.o. 53 Emilii Plater St. 00-113 Warsaw Poland	Afibron	15 mg	Capsule, hard	oral use
Poland	Zentiva a.s. U Kabelovny 130 Dolni Mecholupy 102 37 Praha 10 Czech Republic	Lindaxa 10	10 mg	Capsule, hard	oral use
Poland	Zentiva a.s. U Kabelovny 130 Dolni Mecholupy 102 37 Praha 10 Czech Republic	Lindaxa 15	15 mg	Capsule, hard	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Poland	Abbott Laboratories Poland Sp. z o. o. ul. Postępu 18A 02-676 Warsaw Poland	Meridia 10	10 mg	Capsule, hard	oral use
Poland	Abbott Laboratories Poland Sp. z o. o. ul. Postępu 18A 02-676 Warsaw Poland	Meridia 15	15 mg	Capsule, hard	oral use
Poland	Sandoz GmbH Biochemiestrasse 10 A–6250 Kundl Austria	Obesan	10 mg	Capsule, hard	oral use
Poland	Sandoz GmbH Biochemiestrasse 10 A–6250 Kundl Austria	Obesan	15 mg	Capsule, hard	oral use
Poland	1A Pharma GmbH Keltenring 1 + 3 82041 Oberhaching	Sibutramine-1A Pharma	10 mg	Capsule, hard	oral use
Poland	1A Pharma GmbH Keltenring 1 + 3 82041 Oberhaching Germany	Sibutramine-1A Pharma	15 mg	Capsule, hard	oral use
Poland	Biofarm Sp. z o.o. Wałbrzyska 13, 60-198 Poznan Poland	Zelixa	10 mg	Film-coated tablet	oral use
Poland	Biofarm Sp. z o.o. Wałbrzyska 13, 60-198 Poznan Poland	Zelixa	15 mg	Film-coated tablet	oral use
Portugal	ABBOTT LABORATORIOS, LDA Estrada Alfragide 67-AlfraparK-Edifício D, 2610-008 AMADORA Portugal	Zelium	10 mg	Capsule, hard	oral use
Portugal	ABBOTT LABORATORIOS, LDA Estrada Alfragide 67-AlfraparK-Edifício D, 2610-008 AMADORA Portugal	Zelium	15 mg	Capsule, hard	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Portugal	ABBOTT LABORATORIOS, LDA Estrada Alfragide 67-AlfraparK-Edifício D, 2610-008 AMADORA Portugal	Reductil	10 mg	Capsule, hard	oral use
Portugal	ABBOTT LABORATORIOS, LDA Estrada Alfragide 67-AlfraparK-Edifício D, 2610-008 AMADORA Portugal	Reductil	15 mg	Capsule, hard	oral use
Portugal	Teva Pharma – Produtos Farmacêuticos, Lda. EmpreendimentoLagoasPark Edifício 1 - 3 2740-264 Porto Salvo Portugal	Sibutramina Teva	10 mg	Capsule, hard	oral use
Portugal	Teva Pharma – Produtos Farmacêuticos, Lda. EmpreendimentoLagoasPark Edifício 1 - 3 2740-264 Porto Salvo Portugal	Sibutramina Teva	15 mg	Capsule, hard	oral use
Portugal	Solufarma - Produtos Farmacêuticos Unipessoal, Lda. Rua do Tejo, 56 - 9º A Esq 2775-325 Parede Portugal	Sibutramina Sibulaite	10 mg	Capsule, hard	oral use
Portugal	Solufarma - Produtos Farmacêuticos Unipessoal, Lda Rua do Tejo, 56 - 9º A Esq 2775-325 Parede Portugal	Sibutramina Sibulaite	15 mg	Capsule, hard	oral use
Portugal	Solufarma - Produtos Farmacêuticos Unipessoal, Lda Rua do Tejo, 56 - 9º A Esq 2775-325 Parede Portugal	Sibutramina Solufarma	10 mg	Capsule, hard	oral use
Portugal	Solufarma - Produtos Farmacêuticos Unipessoal, Lda Rua do Tejo, 56 - 9º A Esq 2775-325 Parede Portugal	Sibutramina Solufarma	15 mg	Capsule, hard	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Portugal	Farmoz - Sociedade Técnico Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Farmoz	10 mg	Capsule, hard	oral use
Portugal	Farmoz - Sociedade Técnico Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Farmoz	15 mg	Capsule, hard	oral use
Portugal	Pentafarma - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, nº 2 -Abrunheira 2710-089 Sintra Portugal	Sibutramina Egostar	10 mg	Capsule, hard	oral use
Portugal	Pentafarma - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, nº 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Egostar	15 mg	Capsule, hard	oral use
Portugal	Pentafarma - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, nº 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Blixie	10 mg	Capsule, hard	oral use
Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Blixie	15 mg	Capsule, hard	oral use
Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Atrolex	10 mg	Capsule, hard	oral use
Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Atrolex	15 mg	Capsule, hard	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Argam	10 mg	Capsule, hard	oral use
Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Argam	15 mg	Capsule, hard	oral use
Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Orexinib	10 mg	Capsule, hard	oral use
Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Orexinib	15 mg	Capsule, hard	oral use
Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Snomas	10 mg	Capsule, hard	oral use
Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Snomas	15 mg	Capsule, hard	oral use
Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Arpedex	10 mg	Capsule, hard	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Arpedex	15 mg	Capsule, hard	oral use
Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Marcoliz	10 mg	Capsule, hard	oral use
Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Marcoliz	15 mg	Capsule, hard	oral use
Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Ocram	10 mg	Capsule, hard	oral use
Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Ocram	15 mg	Capsule, hard	oral use
Portugal	Verum Pharma - Produtos Farmacêuticos - Unipessoal, Lda Av. Sidónio Pais, n.º 24, rés-do-chão esq São Sebastião da Pedreira 1000 Lisboa Portugal	Sibutramina Strami	10 mg	Capsule, hard	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Portugal	Verum Pharma - Produtos Farmacêuticos - Unipessoal, Lda Av. Sidónio Pais, n.º 24, rés-do-chão esq, São Sebastião da Pedreira 1000 Lisboa Portugal	Sibutramina Strami	15 mg	Capsule, hard	oral use
Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Fililex	10 mg	Capsule, hard	oral use
Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina Fililex	15 mg	Capsule, hard	oral use
Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina West Pharma	10 mg	Capsule, hard	oral use
Portugal	Tecnimede - Sociedade Técnico-Medicinal, S.A. Rua da Tapada Grande, 2 Abrunheira 2710-089 Sintra Portugal	Sibutramina West Pharma	15 mg	Capsule, hard	oral use
Portugal	Generis Farmacêutica, S.A. Office Park da Beloura, Edifício 4, Quinta da Beloura 2710-444 Sintra Portugal	Sibutramina Generis	8,37 mg	Capsule, hard	oral use
Portugal	Generis Farmacêutica, S.A. Office Park da Beloura, Edifício 4, Quinta da Beloura 2710-444 Sintra Portugal	Sibutramina Generis	12 556 mg	Capsule, hard	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Portugal	Sandoz Farmacêutica, Lda. Alameda da Beloura, Edifício 1, 2º - Escritório 15 2710-693 Sintra Portugal	Sibutramina Sandoz	10 mg	Capsule, hard	oral use
Portugal	Sandoz Farmacêutica, Lda. Alameda da Beloura, Edifício 1, 2º - Escritório 15 2710-693 Sintra Portugal	Sibutramina Sandoz	15 mg	Capsule, hard	oral use
Romania	Abbott GmbH & Co.KG Max-Planck-Ring 2 65205 Wiesbaden Germany	REDUCTIL 10 mg, capsule	10 mg	Capsule, hard	oral use
Romania	Abbott GmbH & Co.KG Max-Planck-Ring 2 65205 Wiesbaden Germany	REDUCTIL 15 mg, capsule	15 mg	Capsule, hard	oral use
Romania	SANDOZ S.R.L. ROMÂNIA Str. Livezeni nr. 7A, Târgu Mureş, Romania	MINIMACIN 10 mg, capsule	10 mg	Capsule, hard	oral use
Romania	SANDOZ S.R.L. ROMÂNIA Str. Livezeni nr. 7A, Târgu Mureş, Romania	MINIMACIN 15 mg, capsule	15 mg	Capsule, hard	oral use
Romania	S.C. TERAPIA S.A. Str. Fabricii, nr. 124, Cluj-Napoca, Romania	SILUTON 10 mg, capsule	10 mg	Capsule, hard	oral use
Romania	S.C. TERAPIA S.A. Str. Fabricii, nr. 124, Cluj-Napoca, Romania	SILUTON 15 mg, capsule	15 mg	Capsule, hard	oral use
Romania	TEVA PHARMACEUTICALS S.R.L. Str. Domniţa Ruxandra nr 12, parter, Sector 2, Bucureşti Romania	SIBUTRAMINĂ TEVA 10 mg, capsule	10 mg	Capsule, hard	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Romania	TEVA PHARMACEUTICALS S.R.L. Str. Domniţa Ruxandra nr 12, parter, Sector 2, Bucureşti Romania	SIBUTRAMINĂ TEVA 15 mg, capsule	15 mg	Capsule, hard	oral use
Romania	ZENTIVA a.s., U kabelovny 130, 102 37 Praga-10 Dolní Měcholupy, Czech Republic	LINDAXA 10 mg, capsule	10 mg	Capsule, hard	oral use
Romania	ZENTIVA a.s., U kabelovny 130, 102 37 Praga-10 Dolní Měcholupy Czech Republic	LINDAXA 15 mg, capsule	15 mg	Capsule, hard	oral use
Slovakia	Zentiva, k.s. Evropská 846/176a 160 00 Praha 6 Czech Republic	LINDAXA 10	10 mg	Capsule, hard	oral use
Slovakia	Zentiva, k.s. Evropská 846/176a 160 00 Praha 6 Czech Republic	LINDAXA 15	15 mg	Capsule, hard	oral use
Slovakia	TEVA Pharmaceuticals Slovakia s.r.o. Teslova 26, 821 02, Bratislava Slovak Republic	Sibutramin - Teva 10 mg kapsuly	10 mg	Capsule, hard	oral use
Slovakia	TEVA Pharmaceuticals Slovakia s.r.o. Teslova 26, 821 02 Bratislava Slovak Republic	Sibutramin - Teva 15 mg kapsuly	15 mg	Capsule, hard	oral use
Slovakia	Abbott Laboratories Slovakia s.r.o. Karadžicova 10 821 08 Bratislava Slovak Republic	Reductil 10 mg	10 mg	capsule	oral use
Slovakia	Abbott Laboratories Slovakia s.r.o. Karadžicova 10 821 08 Bratislava Slovak Republic	Reductil 15 mg	15 mg	capsule	oral use
Slovenia	Abbott Laboratories d.o.o. Dolenjska c. 242c SI–1000 Ljubljana Slovenia	Reductil 10 mg trde kapsule	10 mg	Capsule, hard	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Slovenia	Abbott Laboratories d.o.o. Dolenjska c. 242c SI–1000 Ljubljana Slovenia	Reductil 15 mg trde kapsule	15 mg	Capsule, hard	oral use
Slovenia	Lek farmacevtska družba d.d., Verovškova c. 57 SI–1000 Ljubljana Slovenia	Sibutramin Lek 10 mg trde kapsule	10 mg	Capsule, hard	oral use
Slovenia	Lek farmacevtska družba d.d., Verovškova c. 57 SI–1000 Ljubljana Slovenia	Sibutramin Lek 15 mg trde kapsule	15 mg	Capsule, hard	oral use
Spain	ABBOTT LABORATORIES, S.A. Avda. de Burgos 28050 Madrid Spain	REDUCTIL	10mg	Capsule, hard	oral use
Spain	ABBOTT LABORATORIES, S.A. Avda. de Burgos 28050 Madrid Spain	REDUCTIL	15 mg	Capsule, hard	oral use
Spain	TEVA GENERICOS ESPAÑOLA, S.L. Guzmán el Bueno 133 Edificio Britania 4ºIzq. 28003 MADRID Spain	SIBUTRAMINA TEVA	10mg	Capsule, hard	oral use
Spain	TEVA GENERICOS ESPAÑOLA, S.L. Guzmán el Bueno 133 Edificio Britania 4ºIzq. 28003 MADRID Spain	SIBUTRAMINA TEVA	15 mg	Capsule, hard	oral use
Spain	IDIFARMA, DESARROLLO FARMACEUTICO Polígono Mocholí. Plaza CEIN 5, Nave B-14Noain (Navarra) Spain	SIBUTRAMINA IDIFARMA	10 mg	Capsule, hard	oral use
Spain	IDIFARMA, DESARROLLO FARMACEU-TICO. Polígono Mocholí. Plaza CEIN 5, Nave B-14Noain (Navarra) Spain	SIBUTRAMINA IDIFARMA	15 mg	Capsule, hard	oral use
Sweden	Abbott ScandinaviaAB Box 509169 29 Solna Sweden	Reductil	10 mg	Capsule, hard	oral use

Member State EU/EEA	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
Sweden	Abbott ScandinaviaAB Box 509169 29 Solna Sweden	Reductil	15 mg	Capsule, hard	oral use
Sweden	Sandoz A/S, C.F. Tietgens Boulevard 40 DK–5220 Odense SØ Danmark	Sibutramin Sandoz	10 mg	Capsule, hard	oral use
Sweden	Sandoz A/S, C.F. Tietgens Boulevard 40 DK–5220 Odense SØ Danmark	Sibutramin Sandoz	15 mg	Capsule, hard	oral use
Sweden	Teva Sweden AB Box 1070 251 10 Helsingborg Sweden	Sibutramine Teva	10 mg	Capsule, hard	Oral use
Sweden	Teva Sweden AB Box 1070 251 10 Helsingborg Sweden	Sibutramine Teva	15 mg	Capsule, hard	Oral use
United Kingdom	Abbott Laboratories Limited Queenborough Kent ME11 5EL United Kingdom	Reductil 10mg	10mg	Capsule, hard	oral use
United Kingdom	Abbott Laboratories Limited Queenborough Kent ME11 5EL United Kingdom	Reductil 15mg	15mg	Capsule, hard	oral use
United Kingdom	Teva UK Limited Brampton Road HampdenPark Eastbourne, East Sussex BN22 9AG United Kingdom	Sibutramine Hydrochloride 15mg Capsules	10mg	Capsule, hard	oral use
United Kingdom	Teva UK Limited Brampton Road HampdenPark Eastbourne, East Sussex BN22 9AG United Kingdom	Sibutramine Hydrochloride 15mg Capsules	15mg	Capsule, hard	oral use

ANNEX XVII

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATIONS AND MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State	Marketing Authorisation Holder	Product Name	Strength/ dextropropoxyphene/ paracetamol/caffeine	Pharmaceutical Form	Route of Administration
Greece	Stargen Ltd Favierou 48 Athens 10438 Greece	Romidon	75mg/2ml	Solution for injection	Intramuscular, intravenous use
Greece	Norma Hellas S.A. Menandrou 54 Athens 10431 Greece	Zideron	75mg/2ml	Solution for injection	Intramuscular, intravenous use

ANNEX XVIII

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATIONS AND MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES

Member State	Marketing Authorisation Holder	Invented Name	Strength/ dextropropoxyphene/ paracetamol/caffeine	Pharmaceutical Form	Route of Administration
Belgium	Laboratories SMB s.a. 26-28 Rue de la Pastorale B–1080 Bruxelles Belgium	Algophene smb	30 mg/400 mg	Capsule, hard	Oral use
Cyprus	Remedica LTD PO Box 51706 3508 Lemesos Cyprus	Destirol	32,5 mg/325 mg	Tablet	Oral use
Cyprus	Interpak LTD PO Box 51166 3502 Lemesos Cyprus	Dologesic	32,5 mg/325 mg	Tablet	Oral use
Cyprus	Medochemie LTD MedochemieBuilding 1-10 Constantinoupoleos Str., 3011 Limassol, Cyprus	Medonol	32,5 mg/325 mg	Tablet	Oral use
Cyprus	Phadisco LTD PO Box 22173 1518 Lefkosia Cyprus	Distalgesic	32,5 mg/325 mg	Tablet	Oral use
France	Arrow Generiques 26, avenue Tony Garnier 69007 Lyon France	Dextropropoxyphene Paracetamol almus	30 mg/400 mg	Capsule, hard	Oral use
France	Arrow Generiques 26, avenue Tony Garnier 69007 Lyon France	Dextropropoxyphene Paracetamol arrow	30 mg/400 mg	Capsule, hard	Oral use
France	Sanofi-aventis France 1-13 Bd Romain Rolland 75014 Paris France	Dextropropoxyphene Paracetamol Biogalenique	30 mg/400 mg	Capsule, hard	Oral use

Member State	Marketing Authorisation Holder	Invented Name	Strength/ dextropropoxyphene/ paracetamol/caffeine	Pharmaceutical Form	Route of Administration
France	Sanofi- aventis France 1-13, boulevard Romain Rolland 75014 Paris France	Di-antalvic	30 mg/400 mg	Suppository	Rectal use
France	Biogaran 15, boulevard Charles de Gaulle 92700 Colombes France	Dextropropoxyphene Paracetamol biogaran	30 mg/400 mg	Capsule, hard	Oral use
France	Bouchara Recordati 68, rue Marjolin, BP 67 92302 Levallois-Perret Cedex France	Dioalgo	30 mg/400 mg	Capsule, hard	Oral use
France	Chemical Farma 3 quai Louis Blériot 75016 PARIS France	Dextroref	30 mg/400 mg	Capsule, hard	Oral use
France	Dci Pharma 180, rue Eugène Avinée 59120 Loos France	Dextropropoxyphene Paracetamol dci Pharma	30 mg/400 mg	Capsule, hard	Oral use
France	EG Labo - Laboratoires EuroGenerics 'Le Quintet' bâtiment A 12, rue Danjou 92517 Boulogne Billancourt Cedex France	Dextropropoxyphene Paracetamol eg	30 mg/400 mg	Capsule, hard	Oral use
France	Expanpharm International 6, rue de la Rochefoucauld 16000 Angoulême France	Dextropropoxyphene Paracetamol Expanpharm	30 mg/400 mg	Capsule, hard	Oral use
France	Substipharm 8 Rue Bellini 75116 Paris France	Dextropropoxyphene Paracetamol hexal	30 mg/400 mg	Capsule, hard	Oral use
France	Teva Santé Le Palatin 1 1, cours du Triangle 92936 Paris La Défense Cedex France	Dextropropoxyphene Paracetamol ivax	30 mg/400 mg	Capsule, hard	Oral use

Member State	Marketing Authorisation Holder	Invented Name	Strength/ dextropropoxyphene/ paracetamol/caffeine	Pharmaceutical Form	Route of Administration
France	Labo Concept Pharm 26, boulevard Paul Vaillant Couturier 94200 Ivry Sur Seine France	Dextropropoxyphene Paracetamol isomed	30 mg/400 mg	Capsule, hard	Oral use
France	Qualimed 117 Allée des Parcs 69800 Saint Priest France	Dextropropoxyphene Paracetamol qualimed	30 mg/400 mg	Capsule, hard	Oral use
France	Ranbaxy Pharmacie Generiques 11-15 Quai de Dion Bouton 92800 Puteaux France	Dextropropoxyphene Paracetamol rpg	30 mg/400 mg	Capsule, hard	Oral use
France	Laboratoires Alter 3, avenue de la Baltique ZI de Courtaboeuf 91140 Villebon Sur Yvette France	Dextropropoxyphene Paracetamol alter	30 mg/400 mg	Capsule, hard	Oral use
France	Sanofi-aventis France 1-13, boulevard Romain Rolland 75014 Paris France	Di-antalvic	30 mg/400 mg	Capsule, hard	Oral use
France	Laboratoires Therabel Lucien Pharma 19 Rue Alphone de Neuville 75017 Paris France	Di dolko	30 mg/400 mg	Capsule, hard	Oral use
France	Leurquin Mediolanum 68-88, rue Louis Ampère 93330 Neuilly-sur-Marne France	Talvidol	30 mg/400 mg	Capsule, hard	Oral use
France	Mylan SAS 117 Allée des Parcs 69800 Saint Priest France	Dextropropoxyphene Paracetamol Mylan	30 mg/400 mg	Capsule, hard	Oral use
France	Ratiopharm GmbH Graf Arco Strasse 3 89079 Ulm Germany	Dextropropoxyphene Paracetamol Ratiopharm	30 mg/400 mg	Capsule, hard	Oral use
France	Sandoz 49, avenue Georges Pompidou 92300 Levallois-Perret France	Dextropropoxyphene Paracetamol G Gam	30 mg/400 mg	Capsule, hard	Oral use

Member State	Marketing Authorisation Holder	Invented Name	Strength/ dextropropoxyphene/ paracetamol/caffeine	Pharmaceutical Form	Route of Administration
France	Sandoz 49, avenue Georges Pompidou 92300 Levallois-Perret France	Dextropropoxyphene Paracetamol Sandoz	30 mg/400 mg	Capsule, hard	Oral use
France	Teva Santé Le Palatin 1 1, cours du Triangle 92936 Paris la Défense Cedex France	Dextropropoxyphene Paracetamol Teva	30 mg/400 mg	Capsule, hard	Oral use
France	Sodephar 176, rue de l'Arbrisseau 59000 Lille France	Dextropropoxyphene Paracetamol Sodephar	30 mg/400 mg	Capsule, hard	Oral use
France	Actavis France Centre d'Affaires la Boursidière 92357 le Plessis-Robinson France	Dextropropoxyphene Paracetamol Actavis	30 mg/400 mg	Capsule, hard	Oral use
France	Actavis France Centre d'Affaires la Boursidière 92357 le Plessis-Robinson France	Dexap	30 mg/400 mg	Capsule, hard	Oral use
France	Sanofi-aventis France 1-13 Bd Romain Rolland 75014 Paris France	Dialgirex	30 mg/400 mg	Capsule, hard	Oral use
France	Sanofi-aventis France 1-13 Bd Romain Rolland 75014 Paris France	Dextropropoxyphene/Paracetamol Theraplix	30 mg/400 mg	Capsule, hard	Oral use
France	Zydus France 25, rue des Peupliers ZAC Les Hautes Pâtures Parc d'Activités des Peupliers 92000 Nanterre France	Dextropropoxyphene Paracetamol Zydus	30 mg/400 mg	Capsule, hard	Oral use
France	Alter 3, avenue de la Baltique 91140 Villebon Sur Yvette France	Dextropropoxyphene/Paracetamol/ Cafeine Alter	27 mg/400 mg/30 mg	Tablet	Oral use

Member State	Marketing Authorisation Holder	Invented Name	Strength/ dextropropoxyphene/ paracetamol/caffeine	Pharmaceutical Form	Route of Administration
France	Arrow Generiques 26, avenue Tony Garnier 69007 Lyon France	Dextropropoxyphene/Paracetamol/ Cafeine Almus	27 mg/400 mg/30 mg	Tablet	Oral use
France	Arrow Generiques 26, avenue Tony Garnier 69007 Lyon France	Dextropropoxyphene/Paracetamol/ Cafeine Arrow	27 mg/400 mg/30 mg	Tablet	Oral use
France	Arrow Generiques 26, avenue Tony Garnier 69007 Lyon France	Dextropropoxyphene/Paracetamol/ Cafeine Offilink	27 mg/400 mg/30 mg	Tablet	Oral use
France	Plus Pharmacie 26, boulevard Paul Vaillant-Couturier 94200 Ivry-sur-Seine France	Dextropropoxyphene / Paracetamol / Cafeine Isomed	27 mg/400 mg/30 mg	Tablet	Oral use
France	Biogaran 15, boulevard Charles de Gaulle 92700 Colombes France	Dextropropoxyphene/Paracetamol/ Cafeine Biogaran	27 mg/400 mg/30 mg	Tablet	Oral use
France	Eg Labo - Laboratoires EUROGENERICS 'Le Quintet' - bâtiment A 92517 Boulogne Billancourt Cedex France	Dextropropoxyphene/Paracetamol/ Cafeine Eg	27 mg/400 mg/30 mg	Tablet	Oral use
France	Ranbaxy Pharmacie Generiques 1115 Quai de Dion Bouton Immeuble Avant Seine 92816 Puteaux Cédex France	Dextropropoxyphene/Paracetamol/ Cafeine Rpg	27 mg/400 mg/30 mg	Tablet	Oral use
France	Mylan SAS 117 Allée des Parcs 69800 Saint Priest France	Dextropropoxyphene/Paracetamol/ Cafeine Mylan	27 mg/400 mg/30 mg	Tablet	Oral use
France	Mylan SAS 117 Allée des Parcs 69800 Saint Priest France	Dextropropoxyphene/Paracetamol/ Cafeine Mylan Pharma	27 mg/400 mg/30 mg	Tablet	Oral use

Member State	Marketing Authorisation Holder	Invented Name	Strength/ dextropropoxyphene/ paracetamol/caffeine	Pharmaceutical Form	Route of Administration
France	Qualimed (Lyon) 117 Allée des Parcs 69800 Saint Priest France	Dextropropoxyphene/Paracetamol/ Cafeine Qualimed	27 mg/400 mg/30 mg	Tablet	Oral use
France	Laboratoire Ratiopharm 19, boulevard Paul Vaillant Couturier 94200 Ivry sur Seine France	Dextropropoxyphene/Paracetamol/ Cafeine Ratiopharm	27 mg/400 mg/30 mg	Tablet	Oral use
France	Sandoz 49, avenue Georges Pompidou 92593 Levallois-Perret France	Dextropropoxyphene/Paracetamol/ Cafeine G Gam	27 mg/400 mg/30 mg	Tablet	Oral use
France	Sandoz 49, avenue Georges Pompidou 92300 Levallois-Perret France	Dextropropoxyphene/Paracetamol/ Cafeine Sandoz	27 mg/400 mg/30 mg	Tablet	Oral use
France	TEVA Santé Le Palatin 1 1, cours du Triangle 92936 Paris la Défense Cedex France	Dextropropoxyphene/Paracetamol/ Cafeine Teva	27 mg/400 mg/30 mg	Tablet	Oral use
France	Zydus France 25, rue des Peupliers ZAC Les Hautes Pâtures Parc d'Activités des Peupliers 92000 Nanterre France	Dextropropoxyphene/Paracetamol/ Cafeine Zydus	27 mg/400 mg/30 mg	Tablet	Oral use
France	Sanofi-aventis France 1-13 Bd Romain Rolland 75014 Paris France	Propofan	27 mg/400 mg/30 mg	Tablet	Oral use
France	Sanofi-aventis France 1-13 Bd Romain Rolland 75014 Paris France	Dextropropoxyphene/Paracetamol/ Cafeine Winthrop	27 mg/400 mg/30 mg	Tablet	Oral use
Luxembourg	S.M.B 26-28 rue de la Pastorale B–1080 Bruxelles Belgium	Algophene	30 mg/400 mg	Capsule	Oral use

Member State	Marketing Authorisation Holder	Invented Name	Strength/ dextropropoxyphene/ paracetamol/caffeine	Pharmaceutical Form	Route of Administration
Malta	Medochemie LTD MedochemieBuilding 1-10 Constantinoupoleos Str., 3011 Limassol, Cyprus	Medonol	32,5 mg/325 mg	Tablet	Oral use
Malta	Phadisco Ltd 185 Giannou Kranidioti Avenue CY–2235 Latsia Cyprus	Distalgesic	32,5 mg/325 mg	Tablet	Oral use
Norway	Actavis group hf Dalshraun 1 220 Hafnafjordur Iceland	Aporex	70 mg/400 mg	Tablet	Oral use
Portugal	Ferraz Lynce S.A Rua Consiglieri Pedroso 123 Queluz de Baixo Apartado 1001 2731901 Barcarena Portugal	Algifene	25 mg/300 mg	Coated tablet	Oral use

Member State	Marketing Authorisation Holder	Product Name	Strength/ dextropropoxyphene/ paracetamol/caffeine	Pharmaceutical Form	Route of Administration
Belgium	Pfizer s-a. Boulevard de la Plaine 111050 Bruxelles Belgium	Depronal	150 mg	Prolonged-release capsule, hard	Oral use
Denmark	Dansk Lægemiddelforsyning DLF ApS, Lodshusvej 11, DK–4230 Skælskør Denmark	Abalgin	65 mg	Capsule, hard	Oral use
Denmark	Dansk Lægemiddelforsyning DLF ApS, Lodshusvej 11, DK–4230 Skælskør Denmark	Abalgin	65 mg	Film-coated tablet	Oral use
Denmark	Dansk Lægemiddelforsyning DLF ApS, Lodshusvej 11, DK–4230 Skælskør Denmark	Abalgin retard	150 mg	Prolonged-release capsule	Oral use
Denmark	NordMedica A/S, Bredgade 41, DK–1260 Copenhagen K Denmark	Doloxene	100 mg	Capsule, hard	Oral use
Finland	Alternova A/S, Lodshusvej 11 4230 Skaelskoer Denmark	Abalgin	65 mg	Capsule, hard	Oral use
Finland	Alternova A/S, Lodshusvej 11 4230 Skaelskoer Denmark	Abalgin retard	150 mg	Prolonged-release capsule, hard	Oral use
France	Sanofi Aventis France 1-13 boulevard Romain Rolland 75014 Paris France	Antalvic adultes	65mg	Tablet	Oral use
Greece	Stargen Ltd Favierou 48 Athens 10439 Greece	Romidon	65 mg	Capsule, hard	Oral use
Luxembourg	PFIZER s-a. Boulevard de la Plaine 11 1050 Bruxelles Belgium	Depronal	150 mg	Prolonged-release capsule	Oral use
Netherlands	Pfizer B.V. Rivium Westlaan 142 2909 LD Capelle a/d Ijssel Nederlands	Depronal	150 mg	Modified release capsule	Oral use

Member State	Marketing Authorisation Holder	Product Name	Strength/ dextropropoxyphene/ paracetamol/caffeine	Pharmaceutical Form	Route of Administration
Spain	Parke Davis, S.L. Avda. de Europa, 20 B. Parque Empresarial La Moraleja; Alcobendas; 28108 Madrid España	Deprancol a.s.	150 mg	Prolonged-release capsule, hard	Oral use
Sweden	Meda AB, Box 906 170 09 Solna Sweden	Doloxene	50 mg	Capsule, hard	Oral use
Sweden	Meda AB, Box 906 170 09 Solna Sweden	Doloxene	100 mg	Capsule, hard	Oral use
Sweden	BioPhausiaAB, Blasieholmsgatan 2111 48 Stockholm Sweden	Dexofen	50 mg	Tablet	Oral use
Sweden	BioPhausiaAB, Blasieholmsgatan 2111 48 Stockholm Sweden	Dexofen	100 mg	Tablet	Oral use

ANNEX XIX

LIST OF THE INVENTED NAMES, PHARMACEUTICAL FORMS, STRENGTH OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION AND MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES (EEA)

Member State (EEA)	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical Form	Route of administration
CY - Cyprus	Les Laboratoires Servier 22, rue Garnier F- 92200 Neuilly-sur-Seine France	Lipophoral Tablets 150mg	150 mg	tablet	oral
FR - France	Les laboratoires Servier 22 rue Garnier F-92200 Neuilly-sur-Seine France	Mediator	150 mg	tablet	oral
FR - France	Mylan SAS 117 allée des Parcs 69800 Saint-Priest France	Benfluorex Mylan	150 mg	tablet	oral
FR - France	Qualimed 117 allée des Parcs 69800 Saint-Priest France	Benfluorex Qualimed	150 mg	tablet	oral
LU - Luxembourg	Les Laboratoires Servier 22, rue Garnier F- 92200 Neuilly-sur-Seine France	Mediator	150 mg	tablet	oral
PT - Portugal	Servier Portugal - Especialidades Farmacêuticas, Lda. Av. António Augusto de Aguiar 128, 1069-133 Lisboa Portugal	Mediator	150 mg	coated tablet	oral

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