

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Vectormune ND suspension and solvent for suspension for injection for chickens

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each dose of reconstituted vaccine (0.05 ml in-ovo or 0.2 ml subcutaneous) contains:

### **Active substance:**

Cell-associated live recombinant turkey herpes virus (rHVT/ND) expressing the fusion protein of Newcastle diseases virus D-26 lentogenic strain: 2,500 – 8,000 PFU\*

\* PFU: plaque forming units.

For the full list of excipients, see section 6.1.

## **3. PHARMACEUTICAL FORM**

Suspension and solvent for suspension for injection.  
Orange-yellowish semi-transparent frozen suspension.  
The solvent is a clear red solution.

## **4. CLINICAL PARTICULARS**

### **4.1 Target species**

Chickens and embryonated chicken eggs

### **4.2 Indications for use, specifying the target species**

For active immunisation of 18 day-old embryonated chicken eggs or one-day-old chicks to reduce mortality and clinical signs caused by Newcastle disease virus and to reduce mortality, clinical signs and lesions caused by Marek's disease virus.

Onset of immunity against Newcastle disease: 3 weeks of age.

Duration of immunity against Newcastle disease: 9 weeks of age.

Onset of immunity against Marek's disease: 1 week of age.

Duration of immunity: A single vaccination is sufficient to provide protection during the risk period of infection with Marek's disease.

### **4.3 Contraindications**

None.

### **4.4 Special warnings for each target species**

None.

## **4.5 Special precautions for use**

### Special precautions for use in animals

The vaccine strain was shown to be excreted by chickens and there was a slow spread to turkeys which was not detectable at 35 days but was detectable after 42 days of a contact study. Safety trials show the excreted vaccine strain is not harmful in turkeys; however, special precautions should be taken to avoid spreading of the vaccine strain to turkeys.

No spread was demonstrated between chickens.

It should be ensured that the vaccine suspension is mixed regularly in a gentle way during the vaccination session to guarantee that the vaccine suspension remains homogenous and that the correct vaccine virus titer is administered (e.g. when automatic in-ovo injection machines are used or during long vaccination sessions).

### Special precautions to be taken by the person administering the veterinary medicinal product to animals

Liquid nitrogen containers and vaccine ampoules should be handled by properly trained personnel only.

Personal protective equipment consisting of protective gloves, spectacles and boots should be worn when handling the veterinary medicinal product, before withdrawing from liquid nitrogen, during the ampoule thawing and opening operations.

Frozen glass ampoules may explode during sudden temperature changes. Store and use liquid nitrogen only in a dry and well-ventilated place. Inhalation of the liquid nitrogen is dangerous.

Personnel involved in the treatment of vaccinated birds should follow hygiene principles and take particular care in handling litter from vaccinated chickens.

## **4.6 Adverse reactions (frequency and seriousness)**

None known.

## **4.7 Use during pregnancy, lactation or lay**

Do not use in birds in lay and in future breeding birds.

## **4.8 Interaction with other medicinal products and other forms of interaction**

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

## **4.9 Amounts to be administered and administration route**

In-ovo and subcutaneous use.

### In-ovo:

One single dose of 0.05 ml is injected into each 18-day-old embryonated broiler chicken egg. For in-ovo application an automatic in-ovo egg injector can be used. In-ovo equipment should be calibrated to ensure that a 0.05 ml dose is applied to each egg.

### Subcutaneous use:

One single injection of 0.2 ml per chick is applied at one day of age. The vaccine may be injected by an automatic syringe.

Overview table for dilution possibilities of different presentations:

**For in-ovo administration:**

Vaccine ampoule presentation (No. of vaccine ampoules multiplied by doses needed)	Solvent presentation (ml)	Volume of one dose (ml)
2 x 2,000	200	0.05
1 x 4,000	200	0.05
2 x 4,000	400	0.05
4 x 4,000	800	0.05

The speed of automatic injection is at least 2,500 eggs per hour, therefore solvent presentation of at least or more than 400 ml is recommended to prime and inject for longer than 10 minutes. In-ovo equipment should be calibrated to ensure that a 0.05 ml dose is applied to each egg.

Solvent presentation smaller than 400 ml are not recommended to be used for in-ovo application by an automated machine as it may not be enough to prime the machine and to inject for longer than 10 minutes. The 200 ml presentation may be used for manual vaccination.

**For subcutaneous administration:**

Vaccine ampoule presentation (No. of vaccine ampoules multiplied by doses needed)	Solvent presentation (ml)	Volume of one dose (ml)
1 x 1,000	200	0.20
1 x 2,000	400	0.20
2 x 2,000	800	0.20
1 x 4,000	800	0.20

The usual aseptic precautions should be applied to all administration procedures.

Be familiar with all safety and precautionary measures for handling liquid nitrogen in order to prevent personal injury.

Preparation of vaccine suspension for injection:

1. After matching the dose size of the vaccine with the solvent size, quickly remove the exact number of ampoules needed from the liquid nitrogen container.
2. Draw up 2 ml of solvent into a 5 ml syringe.
3. Thaw rapidly the contents of the ampoules by gentle agitation in water at 27–39 °C.
4. As soon as they are completely thawed, open ampoules holding them at arms length in order to prevent any risk of injury should the ampoule break.
5. Once the ampoule is open, slowly draw up the content into the 5 ml sterile syringe already containing 2 ml of solvent with a needle of at least 18 gauge diameter.
6. Transfer the suspension into the solvent bag. The diluted vaccine prepared as described is mixed by gentle agitation.
7. Withdraw a portion of the diluted vaccine into the syringe to rinse the ampoule. Remove the washing from the ampoule and inject it gently into the solvent bag. Repeat one or two times.
8. The diluted vaccine prepared as described is mixed by gentle agitation so as to be ready for use.

Repeat the operations in point 2–7 for the appropriate number of ampoules to be thawed.

Use the vaccine immediately, slowly mix regularly to ensure uniform suspension of cells and use within a period not exceeding 2 hours.

**4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

No symptoms were observed after the administration of a 10-fold dose of vaccine.

**4.11 Withdrawal period(s)**

Zero days.

## **5. IMMUNOLOGICAL PROPERTIES**

Immunologicals for Aves, live viral vaccines for domestic fowls.  
ATCvet code: QI01AD.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

#### Suspension:

EMEM  
L-glutamine  
Sodium bicarbonate  
Hepes  
Bovine serum  
Dimethyl sulfoxide  
Water for injection

#### Solvent:

Sucrose  
Casein hydrolysate  
Sorbitol  
Dipotassium hydrogen phosphate  
Potassium dihydrogen phosphate  
Phenol red  
Water for injection

### **6.2 Incompatibilities**

Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the medicinal product.

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.  
Shelf life after reconstitution according to directions: 2 hours.

### **6.4. Special precautions for storage**

#### Suspension:

Store and transport frozen in liquid nitrogen (-196 °C).  
The liquid nitrogen containers must be checked regularly for liquid nitrogen level and must be refilled as needed.

#### Solvent:

Store below 25 °C. Do not freeze.

## **6.5 Nature and composition of immediate packaging**

### Suspension:

Type I glass ampoule containing 1,000, 2,000 or 4,000 doses of the vaccine. Five ampoules per cane. The canes with ampoules are stored in a liquid nitrogen container.

### Solvent:

Polyvinylchloride bag containing 200 ml, 400 ml or 800 ml in individual over-pouch.

Not all pack sizes may be marketed.

## **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Discard any ampoules that have been accidentally thawed. Do not re-freeze under any circumstances. Do not re-use opened containers of diluted vaccine.

## **7. MARKETING AUTHORISATION HOLDER**

CEVA-Phylaxia Co. Ltd.

Budapest

Szállás u. 5.

1107

HUNGARY

## **8. MARKETING AUTHORISATION NUMBER(S)**

EU/2/00/000/001–003

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: {DD/MM/YYYY}

## **10 DATE OF REVISION OF THE TEXT**

{MM/YYYY}

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

## **PROHIBITION OF SALE, SUPPLY AND/OR USE**

The manufacture, import, possession, sale, supply and/or use of Vectormune ND may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and use Vectormune ND must consult the relevant Member State's competent authority on the current vaccination policies prior to the manufacture, import, possession, sale, supply and/or use.

**ANNEX II**

- A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**

**A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND  
MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**

Name and address of the manufacturer of the biological active substance

CEVA-Phylaxia Co. Ltd.  
Szállás u. 5.  
1107 Budapest  
HUNGARY

Name and address of the manufacturer responsible for batch release

CEVA-Phylaxia Co. Ltd.  
Szállás u. 5.  
1107 Budapest  
HUNGARY

**B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

Veterinary medicinal product subject to prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

- a) the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.
- b) the disease to which the product is intended to confer immunity is largely absent from the territory in question.

Official control authority batch release is required for this product.

**C. STATEMENT OF THE MRLs**

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.



**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Ampoules of 1,000, 2,000 or 4,000 doses**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Vectormune ND

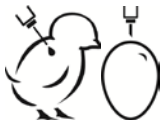
**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

rHVT/ND

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

1,000 doses  
2,000 doses  
4,000 doses

**4. ROUTE(S) OF ADMINISTRATION**



SC or in-ovo use.

**5. WITHDRAWAL PERIOD**

**6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**PARTICULARS TO APPEAR ON THE IMMEDIATE OR OUTER PACKAGES**

Solvent bags of 200 ml, 400 ml or 800 ml  
Over-pouches of 200 ml 400 ml or 800 ml

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Sterile solvent for cell-associated poultry vaccines

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

**3. PHARMACEUTICAL FORM**

Solvent for suspension for injection

**4. PACKAGE SIZE**

200 ml  
400 ml  
800 ml

**5. TARGET SPECIES**

Chickens and embryonated chicken eggs

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

**8. WITHDRAWAL PERIOD**

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP

**11. SPECIAL STORAGE CONDITIONS**

Store below 25 °C. Do not freeze.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

CEVA-Phylaxia Co. Ltd.  
Budapest  
Szállás u. 5.  
1107  
HUNGARY

**16. MARKETING AUTHORISATION NUMBER(S)**

**17. MANUFACTURER’S BATCH NUMBER**

Lot {number}

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET FOR:**  
**Vectormune ND suspension and solvent for suspension for injection for chickens**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder and manufacturer responsible for batch release:

CEVA-Phylaxia Co. Ltd.  
Budapest  
Szállás u. 5.  
1107  
HUNGARY

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Vectormune ND suspension and solvent for suspension for injection for chickens

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

Cell-associated live recombinant viral turkey herpes virus (rHVT/ND)  
expressing the fusion protein of Newcastle disease virus D-26 lentogenic strain: 2,500–8,000  
PFU\*/dose

\* PFU: plaque forming units

Orange-yellowish semi-transparent frozen suspension.  
The solvent is a clear red solution.

**4. INDICATION(S)**

For active immunisation of 18 day-old embryonated chicken eggs or one-day-old chicks to reduce mortality and clinical signs caused by Newcastle disease virus and to reduce mortality, clinical signs and lesions caused by Marek's disease virus.

Onset of immunity against Newcastle disease: 3 weeks of age.  
Duration of immunity against Newcastle disease: 9 week of age.

Onset of immunity against Marek's disease: 1 week of age.  
Duration of immunity: A single vaccination is sufficient to provide protection during the risk period of infection with Marek's disease.

**5. CONTRAINDICATIONS**

None.

**6. ADVERSE REACTIONS**

None known.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Chicken and embryonated chicken eggs.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

### In-ovo route:

One single injection of 0.05 ml is applied to each 18day-old embryonated broiler chicken egg. For in-ovo application an automatic in-ovo egg injector can be used.

### Subcutaneous use:

One single injection of 0.2 ml per chick is applied at one day of age. The vaccine may be applied by an automatic syringe.

Overview table for dilution possibilities of different presentations:

### **For in-ovo administration:**

Vaccine ampoule presentation (No. of vaccine ampoules multiplied by doses needed)	Solvent presentation (ml)	Volume of one dose (ml)
2x 2,000	200	0.05
1x 4,000	200	0.05
2x 4,000	400	0.05
4x 4,000	800	0.05

The speed of automatic injection is at least 2,500 eggs per hour, therefore solvent presentation of at least or more than 400 ml is recommended to prime and inject for longer than 10 minutes. In-ovo equipment should be calibrated to ensure that a 0.05 ml dose is applied to each egg.

Solvent presentation smaller than 400 ml is not recommended to be used for in-ovo application as it may not be enough to prime the machine and to inject longer than 10 minutes. The 200 ml presentation may be used for manual vaccination.

### **For subcutaneous administration:**

Vaccine ampoule presentation (No. of vaccine ampoules multiplied by doses needed)	Solvent presentation (ml)	Volume of one dose (ml)
1 x1,000	200	0.20
1 x 2,000	400	0.20
2 x 2,000	800	0.20
1x 4,000	800	0.20

## 9. ADVICE ON CORRECT ADMINISTRATION

The usual aseptic precautions should be applied to all administration methods.

Be familiar with all safety and precautionary measures for handling liquid nitrogen in order to prevent personal injury.

### Procedure for preparing vaccine suspension:

1. After matching the dose size of the vaccine with the solvent size, quickly remove the exact number of ampoules needed from the liquid nitrogen container.
2. Draw up 2 ml of solvent into a 5 ml syringe
3. Thaw rapidly the contents of the ampoules by gentle agitation in water at 27–39 °C.



4. As soon as they are completely thawed, open ampoules holding them at arms length in order to prevent any risk of injury should the ampoule break.
5. Once the ampoule is open slowly draw up the content into the 5 ml sterile syringe already containing 2 ml solvent with a needle of at least 18 gauge diameter.
6. Transfer the suspension into the solvent bag. The diluted vaccine prepared as described is mixed by gentle agitation.
7. Withdraw a portion of the diluted vaccine into the syringe to rinse ampoule. Remove the washing from the ampoule and inject it gently into the solvent bag. Repeat it one or two times.
8. The diluted vaccine prepared as described is mixed by gentle agitation so as to be ready for use.

Repeat the operations in point 2–7 for the appropriate number of ampoules to be thawed.

Use the vaccine immediately, slowly mix regularly to ensure uniform suspension of cells and use within a period not exceeding 2 hours. It should be ensured that the vaccine suspension is mixed regularly in a gentle way during the vaccination session to guarantee that the vaccine suspension remains homogenous and that the correct vaccine virus titer is administered (e.g. when automatic in-ovo injection machines are used or during long vaccination sessions).

Do not use Vectormune ND if you notice visible signs of unacceptable decolourisation in the vials. Discard any ampoules that have been accidentally thawed. Do not re-freeze under any circumstances. Do not re-use opened containers of diluted vaccine.

## **10. WITHDRAWAL PERIOD**

Zero days.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

### Suspension:

Store and transport frozen in liquid nitrogen (-196 °C).

The liquid nitrogen containers must be checked regularly for liquid nitrogen level and must be refilled as needed.

### Solvent:

Store below 25 °C. Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 2 hours.

## **12. SPECIAL WARNING(S)**

### Special warnings for each target species:

Vaccinate healthy broiler chicks only.

### Special precautions for use in animals:

Vaccinated chicks may excrete the vaccine strain. A slow spread to turkeys which was not detectable at 35 days but was detectable after 42 days of a contact study. Special precautions should be taken to avoid spreading of the vaccine strain to turkeys.

No spread was demonstrated between chickens.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Liquid nitrogen containers and vaccine ampoules should be handled only by properly trained personnel.

Personal protective equipment consisting of protective gloves, spectacles and boots should be worn when handling the veterinary medicinal product, before withdrawing from liquid nitrogen, during the ampoule thawing and opening operations.

Frozen glass ampoules may explode during sudden temperature changes. Store and use liquid nitrogen only in a dry and well-ventilated place. Inhalation of the liquid nitrogen is dangerous.

Personnel involved in the treatment of vaccinated birds should follow hygiene principles and take particular care in handling litter from vaccinated chickens.

Lay:

Do not use in birds in lay and in breeding birds.

Interaction with other medicinal products and other forms of interaction:

No information is available on the safety and efficacy of this immunological veterinary medicinal product when used with any other veterinary medicinal product.

Incompatibilities:

Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the medicinal product.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

Detailed information on this product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

**15. OTHER INFORMATION**

Glass ampoule of 1,000; 2,000 or 4,000 doses of the vaccine. Five ampoules per cane.  
The canes with ampoules are stored in a liquid nitrogen container.

Polyvinylchloride bag containing 200 ml of solvent in individual over-pouch.

Polyvinylchloride bag containing 400 ml of solvent in individual over-pouch.

Polyvinylchloride bag containing 800 ml of solvent in individual over-pouch.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

**België/Belgique/Belgien**

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Metrologielaan 6

1130 Brussel

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Szállás utca 5, 1107 BUDAPEST

HUNGARY

Tel : 36 1 261 26 03

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**Lietuva**

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