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Patient Instructions for Sublingual /Oral Immunotherapy Staloral Liquid for Hay fever and Asthma 18 Oct 2013

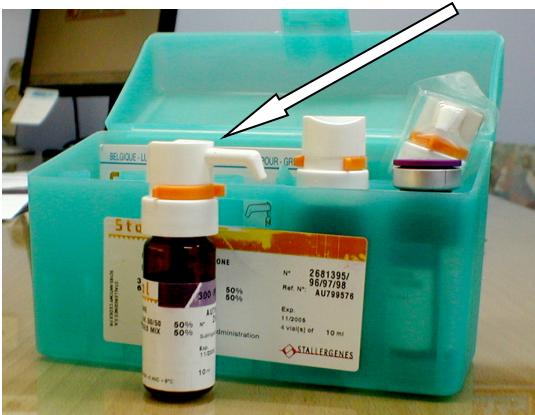
Allergen Extracts

The initial treatment kit comes in a blue plastic box with 3 colour-coded bottles of different strengths, with a “dispenser” on the top. The first bottle is colour-coded **blue** (10 IR/ml) and the remaining maintenance bottles will be colour coded **purple** (300 IR/ml) or **red** (100 IR/ml), depending on the allergen strength available for any one allergen. *Keep the 1st dilute bottle in case you need to go back to it.*

* These instructions apply to the NEW extracts available in Australia from October 2013 whereby 1 press of the NEW extract is equivalent to 2 does of the OLD extract. The new boxes will be labelled as being “NEW”. As of Oct 2013, the distributor will also be adding Goods and Services Tax, which increases the cost by 10%. Cost estimates listed below include the GST component.

Storage

Keep refrigerated; do NOT freeze as this can destroy the allergen. If travelling, carry in hand luggage (if flying) and keep upright, and refrigerate on arrival.



How to take the allergen extracts

- The bottles are like a miniature soap dispenser and each bottle needs to be “primed” when first used by pressing down completely a few times.
- Parents should administer doses to their children.
- The dose is measured in FULL PRESSES, not in drops.
- Take in the morning on an empty stomach

- Keep under tongue for at least 2 minutes, then swallow.
- The drops can have a salty/sweet oily or unpleasant taste. Children can suck a lollie/sweet at the same time
- Do NOT eat or drink anything for 15 minutes; the allergen is partially absorbed from under the tongue so if you eat/drink you may wash it away.
- Avoid crunchy cereals in the morning; they can cut the mouth lining & increase irritation. If you have had dental treatment or mouth ulcers, you may need to stop for a few days until it heals up, as broken mouth tissue may increase the risk of mouth irritation.
- If you forget to take them in the morning, take before bedtime instead.
- If you are taking 2 separate extracts, it is best to separate them by 5-15 minutes if possible. Or you can take one in the morning and one in the evening if there are no significant side-effects in the first 2-3 weeks. If not possible, you can take them at the same time.

If you stop treatment temporarily

- If there has been less than a 1-week gap, go back to your usual dose.
- If you have stopped for more than a week, go back to the beginning of the protocol and build up to the maintenance dose again.

Side-effects of oral immunotherapy:

- Irritation or itching or swelling inside the mouth (common).
- Stomach upset, stomach or chest pain (uncommon)
- Throat swelling, tight chest, asthma, rash (rare)

Controlling Side-effects

Mild side-effects can usually be controlled by temporarily reducing the dose **or** by taking an antihistamine the night before. The itchy mouth usually settles after 4-6 weeks so feel free to take a daily antihistamine the night before if needed. Local itch can also be controlled by directing the liquid to under the side of the tongue if under the front of the tongue causes

bad irritation. If more severe side-effects occur (e.g. throat swelling, difficulty breathing, bad stomach/chest pains), seek medical attention, stop treatment and contact Dr Mullins for further advice.

Ongoing bad side-effects

- Let Dr Mullins know.
- If local itch and swelling does not settle, change the location of administration to behind the lower lip in front of the teeth, hold 2 minutes, then swallow.
- If nausea/stomach upset is bad, then hold in the mouth for 2-3 minutes, then spit out the allergen into the sink (not swallow). This may reduce effectiveness but is better than not being able to tolerate the treatment at all.
- The above advice is based on theoretical aspects, the distribution of cells in the mouth that trigger side-effects compared to immunotherapy benefit, one small trial presented at a European meeting in 2012 and expert advice.

Delivery takes 2 months

Because of the way in which these are currently licensed in Australia, extracts are ordered on an individual patient basis from Europe and arrive in Australia ~ 6-8 weeks after a prescription is filled. This will require forward planning by patients and their doctors to ensure that there are no gaps in treatment schedules due to extracts “running out”. Make sure you order more allergen no later than when you are on the second-last bottle of your current supply. *Keep the 1st dilute bottle in case you need to go back to it.*

INITIAL PROTOCOL

The allergen is taken DAILY for the 1st 2 weeks (**blue** and **purple** bottles), until Maintenance dose reached.

		DAY →	1	2	3	4	5	6	7
Week 1	BOTTLE		10 IR/mL vial (blue cap)						
	Presses		1	2	3	4	5	5	5
Week 2 etc	Date								
	BOTTLE		Maintenance bottles (purple or red cap)						
	Presses		1	2	2	2	2	2	2
	Date								

Week 3 and Beyond: MAINTENANCE DOSES

2 presses/day, Mon-Fri. If no benefit after 4 months, increase dose to 2 presses/day, every day. (Note: this will increase cost and mean you will need to order allergen more often).

Important dates

Your initial allergen order will last ___ months
 Allergen will run out _____
 You should order more allergen _____
 Suggest review _____
 Your referral expires _____
 Planned treatment (if works) is 3-5 yrs.

If ineffective, options are those of:

- Medication;
- Higher oral doses; or
- Switching to immunotherapy injections

Estimated costs are provided as a guide

Estimates are **per** allergen extract. Estimates are approximate since technique may determine actual allergen volume dispensed, and cost estimates are based on calculations based on manufacturer and distributor costs that may change without notice. Other cost variables include the daily dose **and** the complexity of the actual extract used. Health Funds only occasionally gives rebates for oral liquid therapy and even then, only if you have ancillary/extras cover than covers medicines. Each bottle contains 50 doses but one loses some volume (~ 2 doses) when priming the device for initial use. Thus expect ~ 48 does/bottle. Off the shelf extracts cost ~ \$55 each and more complex ones made just for you ~ \$70 each.

Dose	1 bottle lasts	4 bottles last	5 bottles last	\$/year
1/day, every day	~6 wks	~ 6.4 months	~ 8 months	420-540
2/day, Mon-Fri only	~5 wks	~ 4.5 months	~ 5.5 months	600-760
2/day, every day	~3 wks	~ 3.2 months	~ 4 months	840 - 1070