

## DYMISTA® 125/50 Nasal Spray

(Dye-mi'-sta)

Azelastine hydrochloride and fluticasone propionate; (azel-as-teen hydro-klor-ide) and (flu-tic-a-sone pro-pi-o-nate)

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about DYMISTA 125/50 Nasal Spray.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

**You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.**

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you using DYMISTA 125/50 Nasal Spray against the benefits they expect it will have for you.

**If you have any concerns about using this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

#### What DYMISTA 125/50 Nasal Spray is used for

DYMISTA 125/50 Nasal Spray is sprayed into the nose to treat allergic rhinitis (hayfever and other allergies) and rhinoconjunctivitis (allergy-induced symptoms in the nose and eyes) in adults and children 12 years and older where use of a combination (intranasal antihistamine and glucocorticoid) is appropriate.

DYMISTA 125/50 Nasal Spray relieves the symptoms of allergies, for example: symptoms relating to the nose - runny nose, sneezing, itchy or blocked nose and symptoms relating to the eyes - itchy, watery and red eyes.

Hayfever is an inflammation or swelling of the nose lining (which may cause blockage, runny nose, itching and/ or sneezing).

You may have symptoms only during spring or summer. This type of allergy is generally due to various pollens. Some people may experience symptoms all year round. This is usually caused by house dust mites, pets or moulds.

This medicine contains two active ingredients: azelastine hydrochloride and fluticasone propionate.

Azelastine hydrochloride belongs to a group of medicines called antihistamines. Antihistamines work by preventing the effects of substances such as histamine that the body produces as part of an allergic reaction. This reduces symptoms of an allergic rhinitis.

Fluticasone propionate belongs to a group of medicines called corticosteroids which are used to help reduce inflammation.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another purpose.

This medicine is only available with a doctor's prescription.

#### Before you use DYMISTA 125/50 Nasal Spray

##### *When you must not use it*

**Do not use the medicine if you have an allergy to azelastine hydrochloride or fluticasone propionate or any of the other ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction to a medicine may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**Do not give this medicine to a child under the age of 12 years.**

**Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

**If it has expired or is damaged, return it to your pharmacist for disposal.**

##### *Before you start to use it*

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- Recent injury or surgery to your nose or mouth
- Infection in your nose or sinus
- Ulcer or open sores in your nose
- Active or inactive tuberculosis
- Severe liver disease
- Increased/ high pressure in the eye (glaucoma) and/ or cataracts.

**Tell your doctor if you are pregnant or planning to become pregnant.**

Your doctor can discuss with you the risks and benefits involved.

**Tell your doctor if you are breast-feeding.**

It is not known if DYMISTA 125/50 Nasal Spray passes into the breast milk and could affect your baby. Your doctor can discuss with you the benefits and risks involved with using this medicine while you are breast-feeding.

**If you have not told your doctor about any of the above, tell them before you start using the medicine.**

##### *Taking other medicines*

**Tell your doctor if you are taking any other medicines, including medicines that you can buy without a prescription from a pharmacy, supermarket or health food shop.**

In particular, tell your doctor if you are taking:

- A medicine or medicines that depress the central nervous system. Concurrent use with DYMISTA 125/50 Nasal Spray may cause sleepiness or drowsiness.
- Ritonavir, an antiviral medicine
- Ketoconazole, an antifungal medicine
- Cimetidine, a medicine that inhibits stomach acid production.

These medicines may be affected by DYMISTA 125/50 Nasal Spray or may affect how well it works. You may need

different amounts of your medicine, or you may need to use a different medicine. Your doctor or pharmacist will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

#### How to use DYMISTA 125/50 Nasal Spray

##### *How to use it*

**Use only in your nose.**

**If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.**

##### *Preparing the spray*

- Gently blow your nose before using the medicine.
- Shake the bottle for 5 seconds and then remove the protective cap.
- The first time DYMISTA 125/50 Nasal Spray is used, prime the pump by squirting it into the air.
- Prime the pump by putting two fingers on either side of the spray pump and place your thumb on the bottom of the bottle.
- Press down and release the pump 6 times until a fine mist appears.
- The pump is now primed and ready to use.
- If the nasal spray has not been used for more than 7 days, you will need to prime the pump until a fine mist appears again.

##### *Using the spray*

- Blow your nose to clear your nostrils.
- Keep your head tilted downwards towards your toes. Do not tilt head backwards.
- Hold the bottle upright and carefully insert the spray tip into one nostril.
- Close other nostril with your finger, rapidly press down once and sniff gently at the same time.
- Breathe out through your mouth.
- Repeat in your other nostril.
- Breathe in gently, and do not tilt your head back after dosing. This will stop the medicine going into your throat and causing an unpleasant taste.
- After each use, wipe the spray tip with a clean tissue or cloth and then replace the protective cap.

##### *How much to use*

The recommended dose of DYMISTA 125/50 nasal spray is:

##### **Adults and children 12 years and older**

One spray into each nostril in the morning and evening.

##### **Children under 12 years**

This medicine is not recommended for children under 12 years.

**Do not exceed the recommended dose.**

**Always use DYMISTA 125/50 Nasal Spray exactly as your doctor has told you.**

The instructions given by your doctor may differ from the information contained in this leaflet.

**If you are not sure of the correct dose or how to use this medicine, ask your doctor or pharmacist.**

#### *How long to use it*

DYMISTA 125/50 Nasal Spray is suitable for long term use.

**Continue using your medicine for as long as your doctor tells you to.**

#### *If you forget to use it*

**If you miss a dose, use DYMISTA 125/50 Nasal Spray when the next dose is due.**

**Do not use a double dose to make up for the dose that you missed.**

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering to use your medicine, ask your pharmacist for some hints.**

#### *If you have too much (overdose)*

If you or someone else accidentally uses too much DYMISTA 125/50 Nasal Spray on one occasion, there is nothing to worry about.

However, if you use too much of it over a long time (months or years), you may start to get unwanted side effects inside your nose and body.

**Discuss any worries you may have about this with your doctor or pharmacist.**

**Immediately telephone your doctor or the Poisons Information Centre (telephone 131 126) if you think you or anyone else may have taken too much DYMISTA 125/50 Nasal Spray. Do this even if there are no signs or symptoms of discomfort or poisoning.**

### While you are using DYMISTA 125/50 Nasal Spray

#### *Things you must do*

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using this medicine.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.**

**If you become pregnant while you are using this medicine, tell your doctor.** Your doctor can discuss with you the risks of using it while you are pregnant.

#### *Things you must not do*

**Do not give this medicine to anyone else, even if their symptoms seem to be the same as yours.**

**Do not use it to treat any other complaints unless your doctor tells you to.**

#### *Things to be careful of*

**Make sure you know how you react to DYMISTA 125/50 Nasal Spray before you drive, operate machinery, or do anything else that could be dangerous if you are tired, drowsy, dizzy or light-headed.** DYMISTA 125/50 Nasal Spray is unlikely to make you feel drowsy. However, if you are drowsy, do not drive a car or operate machinery.

### Side effects

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using DYMISTA 125/50 Nasal Spray.**

All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by this list of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- irritated nose. This can cause mild stinging, itching or sneezing
- a bitter or unpleasant taste in your mouth
- unpleasant smell
- cough, dry throat or throat irritation
- sore throat
- nose bleeds
- nausea
- headache.

**Tell your doctor or pharmacist as soon as possible if you notice any of the following:**

- sleepiness or drowsiness
- feeling weary, exhausted or weak
- damage of the skin and mucous membrane in the nose
- blurred vision or increased pressure in your eye.

**If any of the following happen, stop using DYMISTA 125/50 Nasal Spray and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:**

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

### After using DYMISTA 125/50 Nasal Spray

#### *Storage*

**Keep DYMISTA 125/50 Nasal Spray in a cool dry place where the temperature stays below 25°C.**

**Do not refrigerate or freeze this medicine.**

**Discard after 6 months of first opening the bottle.**

**Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep the medicine where young children cannot reach it.**

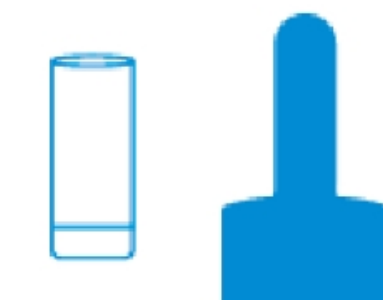
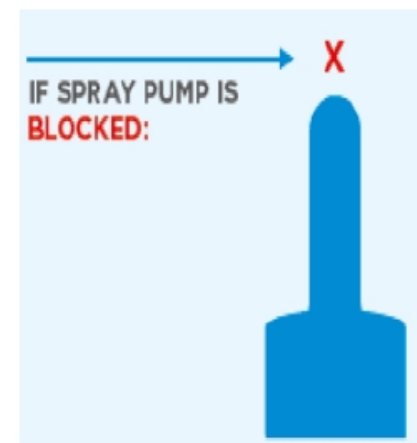
**A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.**

#### *Cleaning instructions*

- **Remove the clear dust cap. Gently grip the sides of the white plastic spray tip and pull upwards to lift the plastic spray away from the glass bottle.**



- **Allow to dry completely.**



**carefully place the spray tip back onto the DYMISTA 125/50 Nasal Spray bottle and press down firmly.**

- **Re-prime the pump before using DYMISTA 125/50 Nasal Spray again.**

#### *Disposal*

**If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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#### Product description

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##### *What it looks like*

DYMISTA 125/50 Nasal Spray is a white suspension.

This medicine comes in an amber coloured glass bottle fitted with a spray pump, applicator and a protective cap. Handle with care. The 4 mL bottle contains 28 sprays.

The 17 mL bottle contains 120 sprays.

##### *Ingredients*

DYMISTA 125/50 Nasal Spray is a novel formulation containing the following active ingredients: azelastine hydrochloride and fluticasone propionate. One spray (137 mg) contains 125 µg of azelastine (as the hydrochloride) and 50 µg of fluticasone propionate.

This medicine also contains the following inactive ingredients:

- glycerol
- microcrystalline cellulose
- carmellose sodium
- phenethyl alcohol
- disodium edetate
- benzalkonium chloride
- polysorbate 80
- purified water.

##### *Sponsor*

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