PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

DYMISTA® NASAL SPRAY

Azelastine hydrochloride 137 micrograms and fluticasone propionate 50 micrograms per actuation

Nasal spray, suspension

Read all of this leaflet carefully because it contains important information for you

DYMISTA NASAL SPRAY is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use DYMISTA NASAL SPRAY carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share DYMISTA NASAL SPRAY with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What DYMISTA NASAL SPRAY is and what it is used for
2. What you need to know before you use DYMISTA NASAL SPRAY
3. How to use DYMISTA NASAL SPRAY
4. Possible side effects
5. How to store DYMISTA NASAL SPRAY
6. Contents of the pack and other information

1. What DYMISTA NASAL SPRAY is and what it is used for

DYMISTA NASAL SPRAY contains two active substances: 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 – thus reducing symptoms of allergic rhinitis.

- Fluticasone propionate belongs to a group of medicines called corticosteroids which reduces inflammation.

DYMISTA NASAL SPRAY is used for the treatment of seasonal and perennial allergic rhinitis (including hay fever) and rhino-conjunctivitis in adults if the use of either intranasal antihistamine or corticosteroid alone is not sufficient.

DYMISTA NASAL SPRAY is also used for short term treatment of seasonal allergic rhinitis in children above the age of 12 years if the use of either intranasal antihistamine or corticosteroid alone is not sufficient.

Seasonal and perennial allergic rhinitis are allergic reactions to substances such as pollen (hay fever), house mites, moulds, dust or pets.

DYMISTA NASAL SPRAY relieves the symptoms of allergies, for example: runny nose, postnasal drip, sneezing and itchy or blocked nose.

2. What you need to know before you use DYMISTA NASAL SPRAY

Do not use DYMISTA NASAL SPRAY

- If you are hypersensitive (allergic) to azelastine hydrochloride, fluticasone propionate, or any of the other ingredients of DYMISTA NASAL SPRAY (listed in section 6).

Warnings and precautions

Take special care with DYMISTA NASAL SPRAY:

- If you had a recent operation on your nose.
- If you have an infection in your nose. Infections of the nasal airways should be treated with antibacterial or antifungal medication. If you are given medication for *an* infection in your nose you can continue to use DYMISTA NASAL SPRAY to treat your allergies.
- If you have tuberculosis or an untreated infection.
- If you have a change in vision or a history of increased ocular pressure, glaucoma and/or cataracts.
- If you suffer from impaired adrenal function. Care must be taken when transferring from systemic steroid treatment to DYMISTA NASAL SPRAY.
- If you suffer from a severe liver disease. Your risk of suffering from systemic side effects is increased.

In these cases, your doctor will decide whether you can use DYMISTA NASAL SPRAY. It is important

that you take your dose as stated in section 3 below or as advised by your doctor. Treatment with higher than recommended doses of nasal corticosteroids may result in adrenal suppression, a condition that may produce weight loss, fatigue, muscle weakness, low blood sugar, salt cravings, joint pains, depression and darkening of the skin. If this happens your doctor may recommend another medicine during periods of stress or elective surgery.

To avoid adrenal suppression your doctor will advise you to take the lowest dose at which effective control of your symptoms of rhinitis is maintained.

Taking nasal corticosteroids (as contained in DYMISTA NASAL SPRAY) may, when taken for a long-time, cause children and adolescents to grow more slowly. The doctor will check your child's height regularly, and make sure he or she is taking the lowest possible effective dose.

Contact your doctor if you experience blurred vision or other visual disturbances.

If you are unsure whether the above applies to you, talk to your doctor or pharmacist before using DYMISTA NASAL SPRAY.

Children

This medicine is not recommended for children under 12 years of age.

Other medicines and DYMISTA NASAL SPRAY

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Some medicines may increase the effects of DYMISTA NASAL SPRAY, and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV infection (e.g. ritonavir, cobicistat) and medicines for the treatment of fungal infections (e.g. ketoconazole).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before you start taking this medicine.

Driving and using machines

DYMISTA NASAL SPRAY has minor influence on the ability to drive and use machines. You may experience fatigue, dizziness or blurred vision due to the disease itself or when using DYMISTA NASAL SPRAY. In these cases, do not drive or operate machinery. Please be aware that drinking alcohol may enhance these effects.

It is not always possible to predict to what extent DYMISTA NASAL SPRAY may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DYMISTA NASAL SPRAY affects them.

DYMISTA NASAL SPRAY contains benzalkonium chloride

Benzalkonium chloride may cause irritation or swelling of the nasal mucosa and bronchospasm, especially if used for a long time.

Tell your doctor or pharmacist if you feel discomfort when using the spray.

3. How to use DYMISTA NASAL SPRAY

Do not share medicines prescribed for you with any other person.

Always use DYMISTA NASAL SPRAY exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist, if you are not sure.

It is essential to use DYMISTA NASAL SPRAY regularly to gain the full therapeutic benefit.

Contact with the eyes should be avoided.

Adults and children (over 12 years of age)

The recommended dose is one spray into each nostril twice daily, in the morning and evening.

Use in children under 12 years of age

This medicine is not recommended for children under 12 years of age.

Use in renal and hepatic impairment

There are no data in patients with renal and hepatic impairment.

Method of administration

For nasal use only.

It is important that you take your dose as advised by your doctor. You should use only as much as your doctor recommends.

Instruction for use

Preparing the spray

The bottle should be shaken gently before use for about 5 seconds by tilting it upwards and downwards and the protective cap be removed afterwards. Prior to first use DYMISTA NASAL SPRAY must be primed by pressing down and releasing the pump 6 times. If DYMISTA NASAL SPRAY has not been used for more than 7 days it must be reprimed once by pressing down and releasing the pump.

Using the spray

After blowing the nose, the suspension is to be sprayed once into each nostril keeping the head tilted downward (see figure). After use the spray tip is to be wiped and the protective cap to be replaced.



Duration of treatment

DYMISTA NASAL SPRAY is suitable for long-term use. The duration of treatment should correspond to the period of experiencing allergy symptoms.

If you use more DYMISTA NASAL SPRAY than you should

If you spray too much of this medicine into your nose you are unlikely to have any problems. If you are worried or if you have used doses higher than recommended over a long period, contact your doctor.

If anyone, especially a child, accidentally drinks DYMISTA NASAL SPRAY, contact your doctor or nearest hospital casualty department as soon as possible.

If you forget to use DYMISTA NASAL SPRAY

Use your nasal spray as soon as you remember, then take the next dose at the usual time. Do not use a double dose to make up for a forgotten individual dose.

If you stop using DYMISTA NASAL SPRAY

Do not stop using DYMISTA NASAL SPRAY without asking your doctor, because this puts the success of the treatment at risk.

4. Possible side effects

DYMISTA NASAL SPRAY can have side effects.

Not all side effects reported for DYMISTA NASAL SPRAY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DYMISTA NASAL SPRAY, please consult your health care provider for advice.

If any of the following happens, stop using DYMISTA NASAL SPRAY and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to DYMISTA NASAL SPRAY. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Side effects with unknown frequency (frequency cannot be estimated from the available data):

- Blurred vision.
- Sores in the nose.

Systemic side effects (side effects concerning the whole body) may occur when DYMISTA NASAL SPRAY is used at high doses for a long time. These effects are much less likely to occur if you use a corticosteroid nasal spray than if you take corticosteroids by mouth.

These effects may vary in individual patients and between different corticosteroid preparations (see section 2).

Nasal corticosteroids can affect the normal production of hormones in your body, particularly if you use high doses for a long time. In children and adolescents this side effect can cause them to grow more slowly than others.

In rare cases a reduction of the bone density (osteoporosis) was observed, if nasal corticosteroids were administered long-term.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Very common side effects (these may affect more than 1 in 10 people):

- Nosebleed.

Common side effects (these may affect up to 1 in 10 people):

- Headache.
- A bitter taste in your mouth, especially if you tilt your head backwards when you are using the nasal spray. This should go away if you have a soft drink a few minutes after using DYMISTA NASAL SPRAY.

- Unpleasant smell.

Uncommon side effects (these may affect up to 1 in 100 people):

- Irritation of the inside of the nose. This can cause mild stinging, itching or sneezing, nasal dryness, cough, dry throat or throat irritation.

Rare side effects (these may affect up to 1 in 1 000 people):

- Dry mouth.

Very rare side effects (these may affect up to 1 in 10 000 people):

- Dizziness or drowsiness.
- Cataract, glaucoma or increased pressure in your eye where you may have a loss of vision and/or red and painful eyes. These side effects have been reported following prolonged treatment with fluticasone propionate nasal sprays.
- Damage of the skin and mucous membrane in the nose.
- Feeling sick, weary, exhausted or weak.
- Rash, itchy skin or red, raised itchy bumps.
- Bronchospasm (the narrowing of the airways in the lungs).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of DYMISTA NASAL SPRAY.

5. How to store DYMISTA NASAL SPRAY

Store all medicines out of reach of children.

- Store at or below 30 °C.
- Do not refrigerate or freeze.
- Store in the original container until required for use.
- Keep the container in the outer carton.
- Protect from light/moisture.
- Do not store in a bathroom.

- Do not use after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DYMISTA NASAL SPRAY contains

- The active substances are azelastine hydrochloride and fluticasone propionate.

  Each g of suspension contains 1 mg azelastine hydrochloride and 0,365 mg fluticasone propionate.

  Each spray/ actuation (0,14 g) delivers 137 micrograms azelastine hydrochloride (= 125 micrograms azelastine) and 50 micrograms fluticasone propionate.
- The other ingredients are benzalkonium chloride, carmellose sodium, disodium edetate, glycerol, microcrystalline cellulose, phenylethyl alcohol, polysorbate 80 and purified water.

What DYMISTA NASAL SPRAY looks like and contents of the pack

DYMISTA NASAL SPRAY is a white, homogenous, redispersible suspension free from visible foreign matter.

The product is presented in the following marketable packs:

DYMISTA NASAL SPRAY is filled into Ph. Eur. Type I 10 mL amber glass bottle or a Ph. Eur. Type I 25 mL amber glass bottle.

Each bottle is fitted with a spray pump and a nasal applicator (actuator) assembled with a dust cap.

The spray pump is crimped to the glass bottle and cannot be taken apart.

Pack sizes of 4 mL or 17 mL.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Viatris Healthcare (Pty) Ltd

4 Brewery Street

Isando

Gauteng, 1609

Tel.: +27(0)11 451 1300

Manufacturer: Cipla Limited, Pithampur, India

This leaflet was last revised in

17 April 2026

Registration number

55/21.5.1/0573

ZIMBABWE: P.P.

Reg. No.: (To be allocated)