DYMISTA® ALLERGY Nasal Spray

Active ingredient(s): *azelastine (as hydrochloride)/fluticasone propionate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DYMISTA ALLERGY. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DYMISTA ALLERGY.**

Where to find information in this leaflet:

1. Why am I using DYMISTA ALLERGY Nasal Spray?
2. What should I know before I use DYMISTA ALLERGY Nasal Spray?
3. What if I am taking other medicines?
4. How do I use DYMISTA ALLERGY Nasal Spray?
5. What should I know while using DYMISTA ALLERGY Nasal Spray?
6. Are there any side effects?
7. Product details

1. Why am I using DYMISTA ALLERGY?

DYMISTA ALLERGY Nasal Spray is sprayed into the nose to treat moderate to severe allergic rhinitis and rhino-conjunctivitis (hayfever and other allergies affecting the nose and eyes) for up to 6 months in adults and children 12 years and older. It relieves sneezing and runny, itchy, or blocked nose, and itchy, red or water 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 allergic rhinitis.

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

DYMISTA ALLERGY provides rapid nasal symptom relief from 5 minutes and eye symptom relief from 10 minutes.

2. What should I know before I use DYMISTA ALLERGY Nasal Spray?

Warnings

Do not use DYMISTA ALLERGY Nasal Spray if:

- you are allergic to azelastine hydrochloride or fluticasone propionate, or any of the ingredients listed at the end of this leaflet.
- this medicine has expired or if the packaging is torn or shows signs of tampering.

Check with your doctor or pharmacist if you:

- have any other 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.
- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

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

DYMISTA ALLERGY Nasal Spray contains benzalkonium chloride

DYMISTA ALLERGY Nasal Spray contains 14 micrograms (equiv. to 0.014 mg or 0.14 g) benzalkonium chloride in each spray. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your 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 ALLERGY Nasal Spray may cause sleepiness or drowsiness.
- Ritonavir, an antiviral medicine
- Ketoconazole, an antifungal medicine
- Cimetidine, a medicine that inhibits stomach acid production

Some medicines may interfere with DYMISTA ALLERGY Nasal Spray and affect how it works.

These medicines may be affected by DYMISTA ALLERGY 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DYMISTA ALLERGY Nasal Spray.

4. How do I use DYMISTA ALLERGY Nasal Spray?

How much to use

Adults and children 12 years and older

- One spray into each nostril in the morning and evening.
- Only use in adolescents 12 - 17 years on medical advice.

Children under 12 years

- This medicine is not recommended for children under 12 years.

DYMISTA ALLERGY Nasal Spray is suitable for use up to 6 months. Do not use DYMISTA ALLERGY Nasal Spray continuously for more than 6 months without the advice of your doctor or pharmacist.

How to use DYMISTA ALLERGY Nasal Spray

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

1. Gently blow your nose before using the medicine.
2. Shake the bottle for 5 seconds and then remove the protective cap.
3. The first time DYMISTA ALLERGY Nasal Spray is used, prime the pump by squirting it into the air.
4. Prime the pump by putting two fingers on either side of the spray pump and place your thumb on the bottom of the bottle.
5. Press down and release the pump 6 times until a fine mist appears.
6. The pump is now primed and ready to use.
7. 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

1. Blow your nose to clear your nostrils.
2. Keep your head tilted downwards towards your toes. Do not tilt head backwards.
3. Hold the bottle upright and carefully insert the spray tip into one nostril.
4. Close other nostril with your finger, rapidly press down once and sniff gently at the same time.
5. Breathe out through your mouth.
6. Repeat in your other nostril.
7. 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.
8. After each use, wipe the spray tip with a clean tissue or cloth and then replace the protective cap.

Use DYMISTA ALLERGY Nasal Spray regularly

It is important that you use DYMISTA ALLERGY Nasal Spray regularly. While the effect of the antihistamine (azelastine hydrochloride) is rapid, it may take several days for the full anti-inflammatory action (from fluticasone propionate) to take effect. Taking it regularly will help prevent your symptoms returning quickly.

If you forget to use DYMISTA ALLERGY Nasal Spray

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

Always use DYMISTA ALLERGY Nasal Spray exactly as your doctor or pharmacist has told you.

If you use too much DYMISTA ALLERGY Nasal Spray

If you think that you have used too much DYMISTA ALLERGY 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.

You should immediately:

- **phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or**
- **contact your doctor, or**
- **go to the Emergency Department at your nearest hospital.**

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using DYMISTA ALLERGY Nasal Spray?

Things you must do

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.

Remind any doctor, dentist or pharmacist you visit that you are using DYMISTA ALLERGY Nasal Spray.

See your doctor or pharmacist if:

- symptoms are not relieved within 7 days
- your nose bleeds
- you develop signs or symptoms of a nasal or sinus infection such as fever, pain or swelling, or discoloured nasal discharge
- you have eye pain or visual disturbances

Things you should 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.
- Do not give this medicine to a child under the age of 12 years.
- Do not exceed the recommended dose.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DYMISTA ALLERGY Nasal Spray affects you.

DYMISTA ALLERGY Nasal Spray is unlikely to make you feel drowsy. However, if you are tired, drowsy, dizzy or light-headed, do not drive a car or operate machinery. Alcohol intake may make drowsiness worse.

Looking after your medicine

- Keep DYMISTA ALLERGY Nasal Spray in a cool dry place where the temperature stays below 25°C.
- Do not refrigerate or freeze this medicine.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

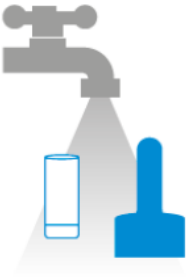
Keep it where young children cannot reach it.

Cleaning instructions

1. 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.

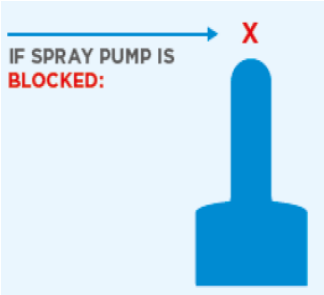


2. Wash the dust cap and plastic spray tip in warm tap water.

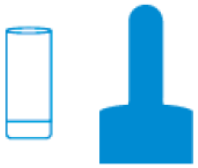


3. If plastic spray tip is blocked do not try to unblock DYMISTA ALLERGY Nasal Spray with a sharp object.

   This can damage the nasal spray and stop you from getting the right dose of DYMISTA ALLERGY.



4. Allow to dry completely.



5. When dry, place the clear protective cap onto the plastic spray tip. Then carefully place the spray tip back onto the DYMISTA ALLERGY Nasal Spray bottle and press down firmly.
6. Re-prime the pump before using DYMISTA ALLERGY Nasal Spray again.

When to discard your medicine

Discard after 6 months of first opening the bottle.

Do not use this medicine after the expiry date.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects with DYMISTA ALLERGY Nasal Spray, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about these side effects.

Less serious side effects

Less serious side effects	What to do
• 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	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• 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. • 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.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What DYMISTA ALLERGY Nasal Spray contains

Active ingredient (main ingredient)	• azelastine hydrochloride • fluticasone propionate
Other ingredients (inactive ingredients)	• glycerol • microcrystalline cellulose • carmellose sodium • phenethyl alcohol • disodium edetate • benzalkonium chloride • polysorbate 80 • purified water.
Potential allergens	Antimicrobial preservatives: Benzalkonium chloride and phenethyl alcohol

Do not take this medicine if you are allergic to any of these ingredients.

What DYMISTA ALLERGY Nasal Spray looks like

DYMISTA ALLERGY Nasal Spray (AUST R 407306) 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 17 mL bottle contains 120 sprays. Available in packs of 1 x 17 mL bottle and 2 x 17 mL bottles.

Some strengths, pack sizes and/or pack types may not be marketed.

Who distributes DYMISTA ALLERGY Nasal Spray

Viatris Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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DYMISTA® is a Viatris company trade mark

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