

# DYMISTA® 125/50 Nasal Spray

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using DYMISTA 125/50 Nasal Spray?

DYMISTA 125/50 Nasal Spray contains the active ingredient azelastine (as hydrochloride) and fluticasone propionate. DYMISTA 125/50 Nasal Spray is used to relieve 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.

For more information, see Section [1. Why am I using DYMISTA 125/50 Nasal Spray?](#) in the full CMI.

## **2. What should I know before I use DYMISTA 125/50 Nasal Spray?**

Do not use if you or your child have ever had an allergic reaction to azelastine (as hydrochloride) or fluticasone propionate or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you or your child have any other medical conditions, take any other medicines, or you are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use DYMISTA 125/50 Nasal Spray?](#) in the full CMI.

## **3. What if I am taking other medicines?**

Some medicines may interfere with DYMISTA 125/50 Nasal Spray and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

## **4. How do I use DYMISTA 125/50 Nasal Spray?**

- Spray one spray into each nostril in the morning and evening. This medicine is not recommended for children under 6 years of age.

More instructions can be found in Section [4. How do I use DYMISTA 125/50 Nasal Spray?](#) in the full CMI.

## 5. What should I know while using DYMISTA 125/50 Nasal Spray?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you or your child are using DYMISTA 125/50 Nasal Spray.</li><li>• DYMISTA 125/50 Nasal Spray is suitable for long term use. Continue using your medicine for as long as your doctor tells you to.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• If you miss a dose, do not use a double dose to make up for the dose that you or your child missed.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• DYMISTA 125/50 Nasal Spray is unlikely to make you or your child feel drowsy. However, if you are drowsy, do not drive a car or operate machinery.</li></ul>

### Looking after your medicine

- 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 DYMISTA 125/50 Nasal Spray after 6 months of first opening the bottle.

For more information, see Section [5. What should I know while using DYMISTA 125/50 Nasal Spray?](#) in the full CMI.

## 6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The most common and serious side effects are irritated nose (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 and headache.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# DYMISTA® 125/50 Nasal Spray

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

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using DYMISTA. **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 125/50 Nasal Spray.**

**Where to find information in this leaflet:**

- [1. Why am I using DYMISTA 125/50 Nasal Spray?](#)
- [2. What should I know before I use DYMISTA 125/50 Nasal Spray?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use DYMISTA 125/50 Nasal Spray?](#)
- [5. What should I know while using DYMISTA 125/50 Nasal Spray?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using DYMISTA 125/50 Nasal Spray

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

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nose and eyes) in adults and children 6 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 or your child 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 or your child's doctor if you have any questions about why this medicine has been prescribed for you or your child. Your or your child's doctor may have prescribed it for another purpose.**

## **2. What should I know before I use DYMISTA 125/50 Nasal Spray?**

### **Warnings**

#### **Do not use DYMISTA 125/50 Nasal Spray if:**

- you or your child 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 if you or your child:**

- 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 or your child 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 if you are pregnant or intend to become pregnant.

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

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 breastfeeding.

## **DYMISTA 125/50 Nasal Spray contains benzalkonium chloride**

DYMISTA 125/50 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 or your child 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 or your child 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

**Some medicines may interfere with DYMISTA 125/50 Nasal Spray and affect how it works.**

These medicines may be affected by DYMISTA 125/50 Nasal Spray or may affect how well it works. You or your child may need different amounts of your medicine, or you or your child 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 or your child are taking and if these affect DYMISTA 125/50 Nasal Spray.**

## **4. How do I use DYMISTA 125/50 Nasal Spray?**

### **How much to use**

#### **Adults and children 6 years and older**

- One spray into each nostril in the morning and evening.

#### **Children under 6 years**

- This medicine is not recommended for children under 6 years.

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

DYMISTA 125/50 Nasal Spray is suitable for long term use in adults and adolescents 12 years and older.

Safety in children 6-11 years of age has not been studied beyond 3 months of use.

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

**Use only in the nose.**

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

#### **Preparing the spray**

1. Gently blow the nose before using the medicine.
2. Shake the bottle for 5 seconds and then remove the protective cap.

3. The first time DYMISTA 125/50 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 the nose to clear the nostrils.
2. Keep head tilted downwards towards the 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 the mouth.
6. Repeat in the other nostril.
7. Breathe in gently, and do not tilt head back after dosing. This will stop the medicine going into the 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.

## **If you forget to use DYMISTA 125/50 Nasal Spray**

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

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

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

## **If you use too much DYMISTA 125/50 Nasal Spray**

If you think that you or your child have used too much DYMISTA 125/50 Nasal Spray on one occasion, there is nothing to worry about.

However, if you or your child use too much of it over a long time (months or years), you may start to get unwanted side effects inside the 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 125/50 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 125/50 Nasal Spray.

### **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 6 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 125/50 Nasal Spray affects you.**

DYMISTA 125/50 Nasal Spray is unlikely to make you or your child feel drowsy. However, if you are tired, drowsy, dizzy or light-headed, do not drive a car or operate machinery

## Looking after your medicine

- 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.

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.

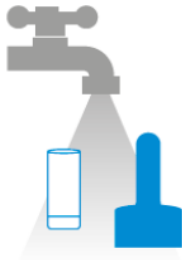
**Keep it where young children cannot reach it.**

## Cleaning instructions

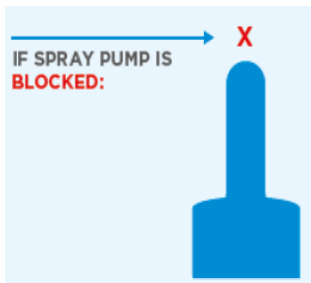
1. Remove the clear dust cap. Gently grip the sides of the white plastic spray tip and pull upwards to lift the plastic spray away from the glass bottle.



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 125/50 Nasal Spray with a sharp object. This can damage the nasal spray and stop you from getting the right dose of DYMISTA.



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 125/50 Nasal Spray bottle and press down firmly.
6. Re-prime the pump before using DYMISTA 125/50 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 or your child 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 or your child do experience any side effects with DYMISTA 125/50 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
<ul style="list-style-type: none"><li>● irritated nose. This can cause mild stinging, itching or sneezing</li><li>● a bitter or unpleasant taste in your mouth</li><li>● unpleasant smell</li><li>● cough, dry throat or throat irritation</li><li>● sore throat</li></ul>	<p><b>Speak to your doctor if you or your child have any of these less serious side effects and they worry you.</b></p>



<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● nose bleeds</li> <li>● nausea</li> <li>● headache</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● sleepiness or drowsiness</li> <li>● feeling weary, exhausted or weak</li> <li>● damage of the skin and mucous membrane in the nose</li> <li>● blurred vision or increased pressure in your eye.</li> <li>● 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.</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you or your child notice any of these serious side effects.</b></p>

**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](http://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 only available with a doctor's prescription.

### What DYMISTA 125/50 Nasal Spray contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"><li>● azelastine hydrochloride</li><li>● fluticasone propionate</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>● glycerol</li><li>● microcrystalline cellulose</li><li>● carmellose sodium</li><li>● phenethyl alcohol</li></ul>

	<ul style="list-style-type: none"> <li>• disodium edetate</li> <li>• benzalkonium chloride</li> <li>• polysorbate 80</li> <li>• purified water.</li> </ul>
<b>Potential allergens</b>	Antimicrobial preservatives: Benzalkonium and phenethyl alcohol

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

## **What DYMISTA 125/50 Nasal Spray looks like**

DYMISTA 125/50 Nasal Spray (AUST R 203131) 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.

## **Who distributes DYMISTA 125/50 Nasal Spray**

Viatrix Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

This leaflet was prepared in August 2024.

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