# APOHEALTH Allergy and Hayfever Relief Nasal Spray

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

#### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using this medicine. 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 this medicine.

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

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

#### 1. Why am I using this medicine?

APOHEALTH Allergy and Hayfever Relief Nasal Spray is sprayed into the nose to treat moderate to severe allergic rhinitis (hayfever and other allergies affecting the nose) for up to 6 months in adults and children 12 years and older. It relieves sneezing and runny, itchy or blocked nose.

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 the symptoms of allergic rhinitis.

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

This medicine provides rapid nasal symptom relief from 5 minutes.

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.

# 2. What should I know before I use this medicine?

#### Warnings

#### Do not use this medicine 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 this medicine 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.

#### APOHEALTH Allergy and Hayfever Relief Nasal Spray contains benzalkonium chloride

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 of this medicine 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 this medicine and affect how it works.

These medicines may be affected by this medicine or may affect how well it works. You may need different amounts of your 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 this medicine.

#### 4. How do I use this medicine?

#### 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.

This medicine is suitable for use up to 6 months. Do not use this medicine continuously for more than 6 months without the advice of your doctor or pharmacist.

#### How to use with this medicine

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:

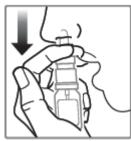
- 1. Gently blow your nose before using the medicine.
- 2. Shake the bottle for 5 seconds and then remove the protective cap.

- 3. The first time 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:



 Blow your nose to clear your nostrils. Close one nostril with your finger. Tilt your head forward slightly. Hold the bottle upright and carefully insert the spray into one nostril.



 For each spray, press firmly downward on the spray and breathe gently inward through the nostril.
 Breathe out through your mouth. Repeat in your other nostril.



3. After each use, wipe the spray tip with a clean tissue or cloth and then replace the protective cap.

#### Use this Medicine Regularly

It is important that you use this medicine 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 this medicine

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 this medicine exactly as your doctor or pharmacist has told you.

#### If you use too much medicine

If you think that you have used too much medicine 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 (by calling 13 11 26), 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 this medicine?

#### 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 this medicine.

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.

#### 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 this medicine affects you.

This medicine 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 this medicine 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:**

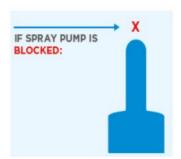
 Remove the protective (dust) cap. Gently pull upward on the spray pump to lift away from the bottle.



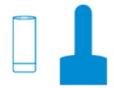
Wash the protective cap and plastic spray pump tip in warm tap water.



 If plastic spray tip is blocked do not try to unblock with a sharp object. This can damage the nasal spray and stop you from getting the right dose.



4. Allow to dry completely.



- When dry, place the clear protective cap onto the plastic spray tip. Then carefully place the spray tip back onto bottle and press down firmly.
- 6. Re-prime the pump before using 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 this medicine, 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 the side effects.

#### Less serious side effects

Less serious side effects	What to do
<ul> <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> <li>nose bleeds</li> <li>nausea</li> <li>headache</li> </ul>	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

#### Serious side effects

Serious side effects	What to do
<ul> <li>sleepiness or drowsiness</li> <li>feeling weary, exhausted or weak</li> <li>damage of the skin and mucous membrane in the nose</li> </ul>	Call your doctor straight away or go straight to the Emergency

- 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

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 <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. 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 this medicine contains

Active ingredient (main ingredient)	azelastine hydrochloride     fluticasone propionate
Other ingredients (inactive ingredients)	<ul> <li>disodium edetate</li> <li>glycerol</li> <li>polysorbate 80</li> <li>benzalkonium chloride</li> <li>phenethyl alcohol</li> <li>purified water</li> <li>the proprietary ingredient Avicel CL-611 (Proprietary ingredient I.D. 111027)</li> </ul>
Potential allergens	N <b>A</b>

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

This medicine is gluten free, lactose free, sucrose free, tartrazine free and free of other azo dyes.

#### What this medicine looks like

APOHEALTH Allergy and Hayfever Relief Nasal Spray azelastine (as hydrochloride) 125 micrograms and fluticasone propionate 50 microgram nasal spray bottle is a white suspension.

AUST R 469985.

## Who distributes this medicine

Arrotex Pharmaceuticals Pty Ltd 15-17 Chapel Street, Cremorne, VIC 3121

This leaflet was prepared in April 2025.