

APO- AZELASTINE/FLUTICASONE 125/50

Contains the actives Azelastine (as Azelastine hydrochloride) and Fluticasone propionate

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about Azelastine/Fluticasone 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 last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-AZELASTINE/FLUTICASONE 125/50 Nasal Spray. It contains the active ingredients azelastine hydrochloride and fluticasone propionate.

It is used to treat:

- Allergic rhinitis (hayfever and other allergies).
- 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

How it works

Azelastine/Fluticasone 125/50 Nasal Spray relieves the symptoms of allergies, for example:

- symptoms relating to the nose - runny nose, post nasal drip, sneezing, itchy or blocked nose

- 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.

How it works

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.

Due to the fast relief and the anti-inflammatory effect, Azelastine/Fluticasone 125/50 Nasal Spray is more effective on symptoms relating to the nose and eyes than

either antihistamine or corticosteroid therapy alone.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children under the age of 12 years.

Before you use this medicine

When you must not use it

Do not use this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, azelastine hydrochloride or fluticasone propionate or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing, difficulty breathing or tightness in chest; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **Do not give this medicine to a child under the age of 12 years.**
- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to use it

Before you start using this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:
 - Recent injury or surgery to your nose.
 - 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.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
5. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Taking other medicines

Some medicines may interact with azelastine or fluticasone. These include:

- A medicine or medicines that depress the central nervous system. Concurrent use with Azelastine/Fluticasone 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.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with azelastine or fluticasone.

How to use this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to use

Your doctor will tell you how much of this medicine you should use. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to use it

Use only in your nose.

To prevent symptoms, start using the medicine:

- before the hayfever season, or
- before coming into contact with something you know will cause your hayfever.

If you start using this medicine early, it will help reduce the severity of your symptoms.

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 Azelastine/Fluticasone 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 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.

How much to use:

The recommended dose of Azelastine/Fluticasone 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

Azelastine/Fluticasone 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.

When to take it

Use this medicine at the same time each day. Use the medicine once in the morning and once in the evening. Using it at the same time each day

will have the best effect and will also help you remember when to use it.

How long to take it for

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

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

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to use your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, use it as soon as you remember and then go back to administering your medicine as you would normally.

Do not administer a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

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

If you use too much (overdose)

If you think that you or anyone else may have used too much of this 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.

If someone has used too much immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice..

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using this medicine

Things you must do

Tell your doctor that you are using this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital
- you become pregnant.

Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you use this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Use your medicine to treat any other condition unless your doctor tells you to.
- Change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

This medicine is unlikely to make you feel drowsy. However, if you are drowsy, do not drive a car or operate machinery.

If you start using this medicine early, it will help reduce the severity of your symptoms.

Things that may be helpful

If possible, avoid situations that you know will trigger your symptoms.

To prevent symptoms, start using this medicine

- before the hayfever season, or
- before coming into contact with something you know will cause your hayfever.

If you start using this medicine early, it will help reduce the severity of your symptoms.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are using azelastine/fluticasone or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- 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 as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention:

- 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 you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- 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

Other side effects not listed above may occur in some patients.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Discard after 6 months of first opening the bottle.

Keep your medicine in a cool dry place where the temperature will stay below 25°C. Do not refrigerate or freeze this medicine.

Do not store your 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 this medicine where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-AZELASTINE/FLUTICASONE 125/50 Nasal Spray looks like

125 microgram/50 microgram nasal spray: is a white suspension.

Ingredients

Each nasal spray contains 125 micrograms of azelastine (as hydrochloride) and 50 micrograms of fluticasone propionate as the active ingredients.

It also contains the following inactive ingredients:

- disodium edetate
- glycerol
- polysorbate 80
- benzalkonium chloride
- phenethyl alcohol
- purified water
- the proprietary ingredient Avicel CL-611 (Proprietary Ingredient No. 111027)

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

APO-Azelastine/Fluticasone 125/50 is available in bottles of 120 metered sprays.

Australian Registration Numbers

APO-Azelastine/Fluticasone 125/50 125micrograms/50micrograms nasal spray (Bottle): AUST R 277525.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

APO and APOTEX are registered trade marks of Apotex Inc.

This leaflet was last updated in: September 2017.