

Package leaflet: Information for the patient

Azelastine hydrochloride/Fluticasone propionate Vygoris 137 micrograms /50 micrograms per actuation, nasal spray, suspension

azelastine hydrochloride/fluticasone propionate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What azelastine/fluticasone nasal spray is and what it is used for
2. What you need to know before you use azelastine/fluticasone nasal spray
3. How to use azelastine/fluticasone nasal spray
4. Possible side effects
5. How to store azelastine/fluticasone nasal spray
6. Contents of the pack and other information

1. What azelastine/fluticasone nasal spray is and what it is used for

The name of your medicine is Azelastine hydrochloride/Fluticasone propionate Vygoris 137 micrograms /50 micrograms per actuation, nasal spray, suspension (called azelastine/fluticasone nasal spray throughout this leaflet). It 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.

Azelastine/fluticasone nasal spray is used to relieve the symptoms of moderate to severe seasonal and perennial allergic rhinitis if the use of either intranasal antihistamine or corticosteroid alone is not considered sufficient.

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

Azelastine/fluticasone nasal spray relieves the symptoms of allergies, for example: runny nose, post nasal drip, sneezing and itchy or blocked nose.

2. What you need to know before you use azelastine/fluticasone nasal spray

Do not use azelastine/fluticasone nasal spray if you:

- are allergic to azelastine hydrochloride, fluticasone propionate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using azelastine/fluticasone nasal spray if you:

- have had a recent operation on your nose.
- 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 azelastine/fluticasone nasal spray to treat your allergies.
- have tuberculosis or an untreated infection.
- have a change in vision or a history of increased ocular pressure, glaucoma and/or cataracts. If this applies to you, you will be closely monitored whilst using azelastine/fluticasone nasal spray.
- suffer from impaired adrenal function. Care must be taken when transferring from systemic steroid treatment to azelastine/fluticasone nasal spray.
- 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 azelastine/fluticasone 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 (such as azelastine/fluticasone 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 azelastine/fluticasone nasal spray.

Children

This medicine is not recommended for children under 12 years.

Other medicines and azelastine/fluticasone nasal spray

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Some medicines may increase the effects of azelastine/fluticasone nasal spray and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat and medicines for the treatment of fungal infections: ketoconazole).

Pregnancy and breast-feeding

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

Azelastine/fluticasone nasal spray has a minor influence on the ability to drive and use machines. Very rarely, you may experience fatigue or dizziness due to the disease itself or when using azelastine/fluticasone nasal spray. In these cases, do not drive or operate machinery. Please be aware that drinking alcohol may enhance these effects.

Azelastine/fluticasone nasal spray contains benzalkonium chloride

This medicine contains 0.014 mg benzalkonium chloride in each actuation. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time. Tell your doctor or pharmacist if you feel discomfort when using the spray.

3. How to use azelastine/fluticasone nasal spray

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

It is essential to use azelastine/fluticasone nasal spray regularly to gain the full therapeutic benefit.

Contact with the eyes should be avoided.

Adults and adolescents (12 years and above)

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

Children under 12 years

This medicine is not recommended for children under 12 years.

Renal and hepatic impairment

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

Method of administration

For nasal use.

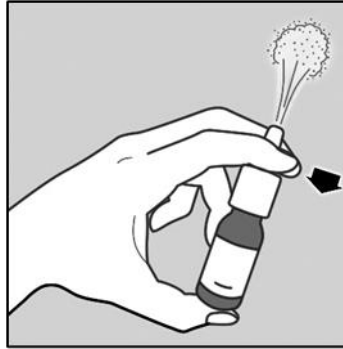
Read the following instructions carefully and use only as directed.

Instructions for use

Preparing the spray

1. Shake the bottle gently for 5 seconds by tilting it upwards and downwards and then remove the protective cap.
2. The first time the nasal spray is used, you must prime the pump by spraying it into the air.
3. Prime the pump by putting two fingers on either side of the spray pump and place your thumb on the bottom of the bottle.
4. Press down and release the pump 6 times until a fine mist appears (see figure a).

Figure a



5. Now your pump is primed and ready to use.
6. If the nasal spray has not been used for more than 7 days, you will need to re-prime the pump once by pressing down and releasing the pump.

Using the spray

1. Shake the bottle gently for 5 seconds by tilting it upwards and downwards and then remove the protective cap.
2. Blow your nose to clear your nostrils.
3. Keep your head tilted downwards towards your toes. Do not tilt head backwards.
4. Hold the bottle upright and carefully insert the spray tip into one nostril.
5. Close other nostril with your finger, rapidly press down once and sniff gently at the same time (see figure b).

Figure b



6. Breathe out through your mouth.
7. Repeat in your other nostril.
8. 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.
9. After each use, wipe the spray tip with a clean tissue or cloth and then replace the protective cap.
10. If you think the nozzle may be blocked, don't use a pin or anything sharp to clear it. Clean the spray tip with water.

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

Duration of treatment

Azelastine/fluticasone 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 azelastine/fluticasone 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 azelastine/fluticasone nasal spray, contact your doctor or nearest hospital as soon as possible.

If you forget to use azelastine/fluticasone nasal spray

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

If you stop using azelastine/fluticasone nasal spray

Do not stop using azelastine/fluticasone nasal spray without asking your doctor, because this puts the success of the treatment at risk.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

- Nosebleeds

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

- Headaches
- 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 this medicine.
- Unpleasant smell

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

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

Rare (may affect up to 1 in 1,000 people):

- Dry mouth

Very rare (may affect up to 1 in 10,000 people):

- Dizziness or drowsiness
- Cataracts, glaucoma or increased pressure in your eyes 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)

Seek immediate medical help if you have any of the following symptoms:

- **Swelling of face, lips, tongue or throat which may cause difficulty in swallowing/breathing and a sudden onset of skin rash. This could be signs of a severe allergic reaction. Please note: This is very rare.**

Unknown (frequency cannot be estimated from available data):

- Blurred vision
- Sores in the nose

Systemic side effects (side effects affecting the whole body) may occur when this medicine 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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store azelastine/fluticasone nasal spray

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle label and the outer carton after “EXP”. The expiry date refers to the last day of that month.

Do not refrigerate or freeze.

Shelf life after first opening: Dispose of any unused medicine 6 months after you first open the nasal spray.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What azelastine/fluticasone nasal spray contains

The active substances are azelastine hydrochloride and fluticasone propionate
Each gram of suspension contains 1000 micrograms of azelastine hydrochloride and 365 micrograms of fluticasone propionate.

Each actuation (0.14 g) delivers 137 micrograms of azelastine hydrochloride (equivalent to 125 micrograms of azelastine) and 50 micrograms of fluticasone propionate.

The other ingredients are: Disodium edetate, glycerol, microcrystalline cellulose, carmellose sodium, polysorbate 80, benzalkonium chloride, phenethyl alcohol and purified water.

What azelastine/fluticasone nasal spray looks like and contents of the pack

Azelastine/fluticasone nasal spray is a white, homogenous suspension.
It comes in an amber coloured glass bottle fitted with a spray pump, applicator and a protective cap.

The 25 mL bottle contains 23 g nasal spray, suspension (at least 120 actuations).

Pack size: 1 bottle

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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