

Package leaflet: Information for the user

Rhinolast 140 micrograms per Spray, Nasal Spray

Azelastine Hydrochloride

Read all of this leaflet carefully before you start taking 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.
- In this leaflet Rhinolast 140 micrograms per Spray, Nasal Spray will be called Rhinolast.

What is in this leaflet:

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

1. WHAT RHINOLAST IS AND WHAT IT IS USED FOR

Rhinolast belongs to a group of medicines called antihistamines. These work by preventing the effects of histamine that the body produces as part of an allergic reaction.

Rhinolast is used to treat allergic rhinitis. This is an allergy which may affect you only at certain times of the year (for example, allergy to pollen, called hayfever), or all round (for example, allergy to the house dust mite or dog and cat hairs).

Usually it affects you by causing a runny nose, sneezing, itching or blocked nose. Rhinolast should help control these symptoms.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE RHINOLAST

Do not take Rhinolast:

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

Warnings and precautions

Children

Rhinolast should not be used by children under 5 years of age.

Pregnancy and breastfeeding

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 taking this medicine.

Driving and using machines

Rhinolast has minor influence on the ability to drive and use machines.

Very rarely, you may experience fatigue, weakness or dizziness due to the disease itself or when using Rhinolast. In these cases, do not drive or operate machinery. Please be aware that drinking alcohol may enhance these effects.

3. HOW TO USE RHINOLAST

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

Adults and children over 12 years of age

The recommended dose for Rhinolast is one spray per nostril twice daily. In cases in which symptoms are more severe the dose may be increased to two sprays per nostril twice daily. Your doctor will advise you which dose to use.

Children aged from 5 to 12 years

The recommended dose for Rhinolast is one spray into each nostril twice daily.

How to use the spray

Rhinolast comes either as a bottle with an attached pump, or as a bottle with a separate pump which must be attached to the bottle prior to use. In case you received a separate bottle and pump, please follow the instructions on how to mount the pump on the bottle, as given in the next paragraph.

For separate bottle and pump

Open the bottle by unscrewing the cap. Place the spray pump nozzle on the bottle and screw the pump into the bottle. Follow the additional instructions below.

For attached pump and bottle

1. Remove the protective cap (Diagram 1).
2. Before using the spray for the first time, press the pump several times until an even spray emerges (Diagram 2).
3. Spray once into each nostril keeping your head upright. **DO NOT TILT YOUR HEAD BACKWARDS** (Diagram 3).
4. Wipe the pump and replace the protective cap.



Diagram 1

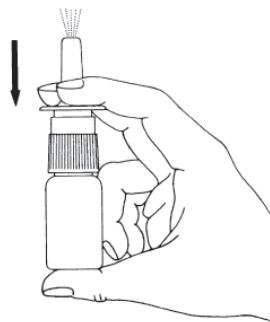


Diagram 2

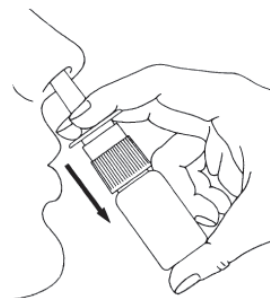


Diagram 3

If you use more Rhinolast than you should

If you spray too much Rhinolast into your nose you are unlikely to have any problems. If you are worried, contact your doctor. If anyone, especially a child, accidentally drinks Rhinolast, contact your doctor or local hospital casualty department immediately.

If Rhinolast is accidentally sprayed into the eyes, bathe them with plenty of water. They may sting for a while.

If you forget to use Rhinolast

If you forget to use your medicine, use it as soon as you remember then use the next dose at the normal time. Do not use a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

Common (may affect up to 1 in 10 people): A bitter taste in your mouth, especially if you tilted your head backwards when you used the nasal spray. This should disappear if you have a soft drink a few minutes after using Rhinolast. The bitter taste might cause you to feel sick.

Uncommon (may affect up to 1 in 100 people): Slight irritation of the inside of the nose. This can cause mild stinging, itching, sneezing and nosebleed.

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

Very rare (may affect up to 1 in 10,000 people): Hypersensitivity reactions such as rash, itching and urticaria (hives). Dizziness, fatigue, weakness.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE RHINOLAST

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 carton and bottle. The expiry date refers to the last day of that month.

Do not store below 8°C. Do not refrigerate, as this will affect your medicine.

Discard opened bottles 6 months after first opening, even if there is some medicine left in the bottle after this date.

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 Rhinolast contains**

The active substance is azelastine hydrochloride 0.1 % w/v. Each spray actuation delivers 0.14 ml containing 140 micrograms azelastine hydrochloride per spray.

The other ingredients are hypromellose, disodium edetate, citric acid, disodium phosphate dodecahydrate, sodium chloride and purified water.

What Rhinolast looks like and contents of the pack

Rhinolast is a clear spray solution. It comes in a polyethylene or glass bottle containing 5, 10, or 20 ml. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan IRE Healthcare Limited,
Unit 35/36, Grange Parade,
Baldoye Industrial Estate,
Dublin 13,
Ireland

Manufacturer

Madaus GmbH
51101 Cologne
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