Package leaflet: Information for the user

Rhinolast Nasal Spray

Azelastine hydrochloride

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 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
- Contents of the pack and other information

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 hay fever), or all year round (for example, allergy to the house dust mites 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.

This product may be used by adults and children aged 6 years and older.

2. What you need to know before you use Rhinolast

Do not use Rhinolast:

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

Warnings and precautions

Talk to your doctor or pharmacist before using Rhinolast.

Children

Rhinolast is not recommended for use in children below 6 years of age.

Other medicines and Rhinolast

Even if Rhinolast is not known to be affected by other medicines, tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

Rhinolast has no influence on the ability to drive and use machines.

3. How to use Rhinolast

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

Important:

If you are not sure of the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Adults and children 6 years and older:

 The usual dose is one squirt into each nostril in the morning and then again in the evening.

How to use the spray

- 1. Blow your nose first.
- 2. Remove the protective cap (Diagram 1).
- Before the first use, press the pump several times until an even spray emerges (Diagram 2). Spray once into each nostril keeping head upright. Do not tilt head backwards (Diagram 3).
- 4. Wipe the pump nozzle 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. Contact your doctor if you are worried.

If anyone, especially a child, accidentally drinks Rhinolast, contact your doctor or local hospital casualty department immediately.

If you accidentally get Rhinolast in your eyes, bathe them with plenty of water. They may sting for a while.

If you forget to use Rhinolast

Use the 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 missed dose.

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.

These effects include:

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

An unpleasant taste in your mouth especially if you tilt your head backwards when you are using the nasal spray. In rare cases the unpleasant taste might cause you to feel sick.

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

Slight irritation of the inside of the nose (stinging, itching), sneezing and epitaxis.

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

Hypersensitivity reactions (such as rash, pruritus, urticaria).

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 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 Rhinolast

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

Do not use this medicine after the expiry date which is printed on the bottle label and the carton. The expiry date refers to the last day of the month.

Once you have opened the bottle do not use it for longer than six months.

Do not store the spray in the fridge or below 8°C

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 squirt provides 140 micrograms azelastine hydrochloride.

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 polythene or glass bottle containing 5, 10, 20 or 22ml. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan Products Ltd., Station Close, Potters Bar, Hertfordshire, EN6 1TL, UK

Manufacturer

MADAUS GmbH, 51101 Cologne, Germany

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If this leaflet is difficult to see or read or you would like it in a different format, please contact Mylan Products Ltd. Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

