

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**
THIS MEDICINE IS DISPENSED WITH A PHYSICIAN'S PRESCRIPTION ONLY

Rhinolast, Nasal Solution

Active ingredient:

Azelastine hydrochloride 0.1% w/v

Each squirt of the spray(0.14 ml) contains:

Azelastine hydrochloride 0.14 mg

Inactive and allergenic ingredients in the preparation: See Section 6, "Additional information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, consult your doctor or pharmacist.

This medicine has been prescribed to you. Do not pass it on to others. It may harm them, even if it seems that their medical condition is similar.

1. What is the medicine intended for?

Rhinolast is intended for the treatment of seasonal allergic rhinitis and perennial allergic rhinitis for adults and children 6 years and older.

Therapeutic group:

Potent selective second generation anti-histamine.

The medication acts by preventing the effect of histamine that the body produces as part of an allergic reaction.

Rhinolast is intended for the treatment of allergies that appear in specific seasons of the year, for example, the pollen allergy known as hay fever.

In addition, **Rhinolast** is intended for the treatment of allergies that occur all year round, for example allergy to house dust mites or allergies to cat or dog fur.

Usually, the allergy will cause you to have a runny nose, sneezing, itching, or a stuffy nose. **Rhinolast** can alleviate these symptoms.

2. Before using the medicine

Do not use this medicine if:

You are allergic to the active substance (azelastine hydrochloride) or to any of the additional ingredients the medicine contains (please see Section 6 'Additional information').

Special warnings regarding the use of this medicine

Consult your doctor or pharmacist before using **Rhinolast**.

Children and adolescents:

This medicine is not intended for children and infants under 6 years of age.

Drug interactions:

If you are taking, or have recently taken, any other medicines including non-prescription medicines or nutritional supplements, tell your doctor or pharmacist.

To date, no interactions with other medicines have been reported.

Pregnancy, breastfeeding, and fertility:

If you are pregnant, breastfeeding, think you may be pregnant, or plan to become pregnant, consult with your doctor or pharmacist prior to use.

Driving and using machinery:

Rhinolast has no effect on the ability to drive or use machinery.

3. How should you use the medicine?

Always use this medicine according to your doctor's instructions. If you are not sure about the dosage or treatment regimen, consult your doctor or pharmacist. The dosage and treatment regimen are determined by your doctor only. The dosage will appear on the label attached to the package by the pharmacist. If the dosage does not appear, or if you are unsure, ask your doctor or pharmacist.

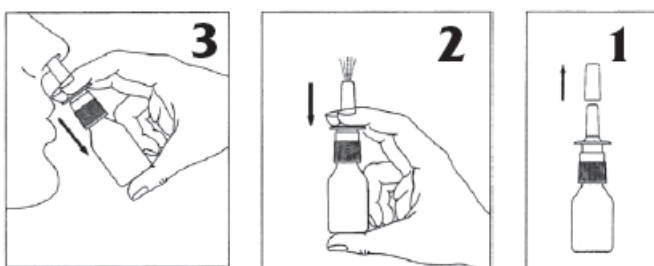
The usual dosage is generally:

One spray in each nostril, twice daily (morning and evening).

Do not exceed the recommended dose.

How to use Rhinolast spray

1. First, blow your nose.
2. Remove the protective cap (Diagram 1).
3. Before the first use, press the pump several times until you achieve an even spray (Diagram 2).
4. Spray once in each nostril while the head is upright. Do not tilt the head back (Diagram 3).
5. Wipe the pump's nozzle and return the protective cap.



If you have accidentally taken a higher dose, no symptoms are expected; consult your doctor if you are concerned.

If you have accidentally swallowed the medicine, or if a child has swallowed the medicine, immediately proceed to a doctor or to a hospital emergency room, and bring the package of the medicine with you.

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

If you forgot to take the medicine at the designated time, take the dose as soon as you remember, and afterwards, take the next dose at the usual time. Do not take a double dose in order to compensate for the forgotten one.

Continue the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, the use of **Rhinolast** may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Common side effects – effects that appear in 1-10 users out of 100:

- An unpleasant taste in your mouth, particularly felt if you tilt your head back during use. In rare cases, the unpleasant taste in your mouth can cause nausea.

Uncommon side effects – effects that appear in 1-10 users out of 1,000:

- Irritation of the nasal mucosa (stinging and itching), sneezing and nosebleed.

Very rare side effects – effects that appear in less than one user out of 10,000:

- Hypersensitivity reactions such as rash, pruritis, urticaria (hives).

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link “Report adverse effects associated with medicines” found on the homepage of the Ministry of Health website (www.health.gov.il), which directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>.

5. How should the medicine be stored?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants in order to prevent poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use this medicine after the expiry date (exp. date), which appears on the label of the bottle and the outer package. The expiry date refers to the last day of that month.

Storage conditions:

- Do not store at a temperature above 25°C. Do not refrigerate.
- May be used for 6 months after opening.
- 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. Additional information

- In addition to the active ingredient, the medicine also contains:
Purified water, sodium chloride, disodium phosphate dodecahydrate, hypromellose, disodium edetate, citric acid
- Each squirt (0.14 ml) contains 0.14 mg of the active ingredient Azelastine Hydrochloride.
- **What the medicine looks like and what the package contains:**

Rhinolast contains 5 ml, 10 ml, or 20 ml of a transparent solution packaged in a brown glass bottle. It may be that not all package sizes are marketed.

- **Registration holder’s name and address:** Megapharm Ltd., 15 HaTidhar St., Ra’anana, Israel
- **Manufacturer’s name and address:** Madaus, Troisdorf, Germany
- Revised in October 2024
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 118-44-29866-00

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