

Package leaflet: Information for the user

Allergodil 0.1% nasal spray, solution azelastine hydrochloride

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

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

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must talk to a doctor if you do not feel better or if you feel worse.
- 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 Allergodil nasal spray is and what it is used for
2. What you need to know before you use Allergodil nasal spray
3. How to use Allergodil nasal spray
4. Possible side effects
5. How to store Allergodil nasal spray
6. Contents of the pack and other information

1. What Allergodil nasal spray is and what it is used for

Properties

Allergy means an organism's abnormal reaction to a harmless substance.

An allergy may be caused, for instance, by pollen, house dust, cat or dog hair.

Allergodil nasal spray is meant for the quick alleviation of signs of allergy, and it contains the active substance azelastine hydrochloride. This active substance hinders the effects of histamine and other substances generated in the organism as a result of an allergic reaction.

Allergodil nasal spray reduces nasal secretion, sneezing, and the swelling of nasal mucous membranes. Due to its topical effect on the nasal mucous membranes, Allergodil nasal spray allows alleviating the signs of allergy quickly and efficiently in spite of its low active substance content.

Indications

Symptomatic treatment of seasonal (incl. hay fever) and perennial allergic rhinitis.

2. What you need to know before you use Allergodil nasal spray

Do not use Allergodil nasal spray:

- if you are hypersensitive (allergic) to azelastine hydrochloride or any of the other ingredients of Allergodil nasal spray.

Warnings and precautions:

- If the patient is a child, Allergodil nasal spray should not be used in children under 6 years of age;
- no special restrictions apply to elderly patients.

Allergodil nasal spray with food and drink

No interactions with food or drink have been reported. The consumption of alcohol should generally be avoided while using this medicine.

Pregnancy and breast-feeding

Talk to your doctor before using the medicine:

Even though animal trials have not demonstrated any adverse effect of the medicine on a foetus, the general properties of medicines should still be observed; thus, the use of Allergodil nasal spray should be avoided in the first three months of pregnancy.

Due to the lack of data about the effect of the medicine while breast-feeding, Allergodil nasal spray should not be used while breast-feeding.

Driving and using machines

In very rare cases, side effects of Allergodil nasal spray can include fatigue, weariness, exhaustion, dizziness or weakness (which may be caused by an illness). In these cases, the ability to drive a car or use a machine may be reduced. The above effects are magnified by the consumption of alcohol.

Other medicines and Allergodil nasal spray:

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

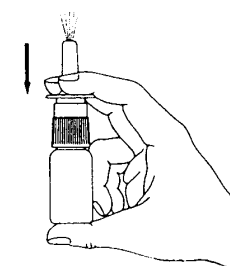
3. How to use Allergodil nasal spray

Always use Allergodil nasal spray exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

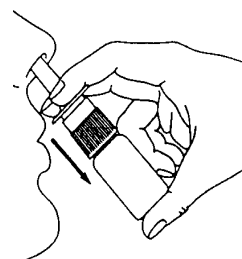
Unless your doctor has instructed otherwise, the following administration procedure should be applied. The prescriptions below should be carefully followed to ensure the proper functioning of Allergodil nasal spray. Keep your head in an upright position while using Allergodil nasal spray (see the images below).



1. Remove the protective cap.



2. Before using the spray for the first time, prime the pump 2–3 times until a dose of medicine is discharged.



3. Spray a dose of medicine into each nostril with your head held upright.

a
dose of medicine is discharged

4. Replace the protective cap after use.

How often should Allergodil nasal spray be used?

Unless otherwise prescribed by the doctor, one dose of Allergodil nasal spray (0.14 mg of azelastine hydrochloride) is administered into each nostril 2 times per day (morning and evening) (corresponds to a daily dose of 0.56 mg of azelastine hydrochloride).

How long should Allergodil nasal spray be used?

Allergodil nasal spray is suitable for long-term use. There are no restrictions on the duration of use.

If you use more Allergodil nasal spray than you should

Allergodil nasal spray is used for producing a local effect in the nose. Due to the low content of the active substance, there is no risk of poisoning in case of local overdose.

Talk to your doctor if a larger amount of Allergodil nasal spray has been ingested by accident (e.g. by children).

No cases of overdose have been observed in relation to administration into the nose. Results of animal trials show that accidental oral overdose may cause central nervous system symptoms (e.g. restlessness, agitation or severe fatigue or drowsiness). Treatment of side effects is symptomatic.

If you forget to use Allergodil nasal spray

If you have forgotten to use Allergodil nasal spray, administer the next dose at the prescribed time. If necessary, Allergodil nasal spray can be used between two prescribed dosing times.

If you stop using Allergodil nasal spray

Regular treatment with Allergodil nasal spray should be continued until the symptoms have disappeared. If the treatment is terminated prematurely, the possibility that the same symptoms will appear should be taken into consideration.

4. Possible side effects

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

Side effects that may occur while using Allergodil nasal spray

Occasionally, irritation of the inflamed nasal mucous membranes can occur after spraying. This includes stinging, itching, and sneezing. Symptoms of irritation of nasal mucous membranes include stinging, itching, and sneezing. Occasionally, nasal bleeding has been observed.

Irregularities in taste sensitivity can often occur.

Improper use (i.e. tilting the head too far backwards) can cause a bitter taste in the mouth which can, in rare cases, lead to nausea.

Very rarely, dizziness, fatigue, weariness, exhaustion and weakness can occur, which may impair reaction speed.

Very rare side effects also include hypersensitivity (rash, itching, hives), and in severe cases, anaphylactic reactions necessitating immediate medical assistance.

Measures to take in case of any side effects

In general, the side effects are temporary, meaning that no specific countermeasures are necessary.

If you feel a bitter taste in the mouth after using Allergodil nasal spray, this can be alleviated by drinking a non-alcoholic beverage (e.g. juice, milk).

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

5. How to store Allergodil nasal spray

Store at temperature 25 °C. Do not store in a refrigerator.

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

How long can the medicine be used for after first opening the bottle

An open bottle can be used for up to 6 months after opening.

What should be done if Allergodil nasal spray is frozen

If Allergodil nasal spray is kept at a temperature below 8 °C (e.g. due to storing the medicine in a refrigerator), Allergodil nasal spray will begin to partially crystallise. The crystallisation is visible when the bottle is held up towards a light. In this case, the solution must not be used.

After keeping the solution at room temperature for a while (several hours), the crystals will dissolve again, forming a clear transparent solution that can be used again.

6. Contents of the pack and other information

What Allergodil nasal spray contains

- The active substance is azelastine hydrochloride. The nasal spray contains 0.1% of the active substance azelastine hydrochloride. 1 dose (0.14 mL) contains 0.14 mg of azelastine hydrochloride.
- Other ingredients include hypromellose, disodium edetate, citric acid, dibasic sodium phosphate dodecahydrate, sodium chloride, distilled water.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

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DUBLIN
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Manufacturers

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