

Package leaflet: Information for the user

Allergodil 0.05% eye drops, 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.
- 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.
- If after two days you do not feel better or feel worse, you should contact your doctor.

What is in this leaflet

1. What Allergodil eye drops are and what they are used for
2. What you need to know before you use Allergodil eye drops
3. How to use Allergodil eye drops
4. Possible side effects
5. How to store Allergodil eye drops
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1. What Allergodil eye drops are and what they are used for

Allergodil eye drops are an anti-allergy agent.

Allergodil eye drops are used for the prophylactic and symptomatic treatment of seasonal allergic eye inflammation (allergic conjunctivitis, hay fever) in adults and children over 4 years of age. (Seasonal allergies can, for example, be caused by the pollen of trees and grasses in certain seasons.)

Allergodil eye drops are also used for the prophylactic and symptomatic treatment of perennial allergic eye inflammation (allergic conjunctivitis) in adults and children over 12 years of age. (Perennial allergies can, for example, be caused by house dust, hair of pets or mould found all year round.)

2. What you need to know before you use Allergodil eye drops

Do not use Allergodil eye drops

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 Allergodil eye drops

- if you are not sure that your eye symptoms are caused by allergy. This is especially important if the symptoms only involve one eye, if your vision has worsened or if you have eye pain and no nasal symptoms;
- if the symptoms worsen and are not alleviated after 48 hours in spite of using Allergodil eye drops. Allergodil eye drops are not meant for use in case of eye infections.
- Benzalkonium chloride may be absorbed into soft contact lenses and change their colour. Remove contact lenses before administration and replace 15 minutes after administration.
- Benzalkonium chloride may cause eye irritation, especially if you have dry eyes or damage to the cornea (the transparent part of the front of the eye). If you experience any discomfort, tingling or pain in the eye after taking this medicine, consult your doctor.

Children

Seasonal allergic conjunctivitis:

Allergodil eye drops must not be used in children under 4 years of age.

Perennial allergic conjunctivitis:

Allergodil eye drops must not be used in children under 12 years of age.

Other medicines and Allergodil eye drops

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. No interaction with other medicines has been observed.

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 taking this medicine.

Breast-feeding: as a small amount of the active substance is excreted into breast milk, Allergodil eye drops should not be used while breast-feeding.

Driving and using machines

Using Allergodil eye drops may cause slight transient irritation, which is unlikely to affect/worsen your vision. If you experience transient impaired vision, do not drive a car, use machinery or mechanisms, or work without taking the relevant precautions until your vision has cleared.

Allergodil contains benzalkonium chloride

It contains 0.00375 mg of benzalkonium chloride per drop, equivalent to 0.00375 mg / 0.03 ml.

3. How to use Allergodil eye drops

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

Unless prescribed otherwise by your doctor, general usage is as follows:

Apply 1 drop of Allergodil eye drops into each eye twice per day (morning and evening). The dosage can be increased to up to 4 times per day in each eye if necessary.

Seasonal allergic conjunctivitis:

The above dosage can be used in adults and in children over 4 years of age. If contact with an allergen is expected, Allergodil eye drops should be applied before leaving the house to prevent an allergic reaction.

Perennial allergic conjunctivitis:

The above dosage can be used in adults and children over 12 years of age.

Method of administration:

- Take a clean napkin and dry the lower eyelid (see Figure 1). Remove the cap.
- Tilt your head slightly backward, gently pull the lower lid down (see Figure 2) and carefully administer 1 drop into the centre of the lower lid (see Figure 3).
- Make sure that the dropper tip does not touch the eye.
- Release the lower lid and gently press on the inside corner of the eye in the direction of the nose (see Figure 4). Slowly blink your eyes for a few times to ensure that the drop of medicine is evenly distributed on the entire eyeball.
- Remove the excess medicine that has run out of the eye.
- Repeat the procedure with the other eye.



Figure 1

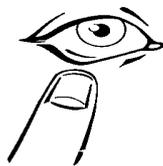


Figure 2

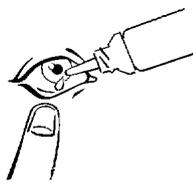


Figure 3



Figure 4

Even after the disappearance of the complaints, continue using Allergodil eye drops while in contact with the allergens (e.g. pollen, house dust).

Duration of treatment

As clinical trials have only proven the safety and tolerability of using the medicine for up to 6 weeks, the maximum duration of the use of Allergodil eye drops in case of perennial allergic conjunctivitis should be 6 weeks.

In case of seasonal allergic conjunctivitis, the eye drops should only be used for more than 6 weeks under a doctor's supervision.

Do not use Allergodil eye drops for more than 6 weeks without your doctor's recommendation.

If you use more Allergodil eye drops than you should

No specific overdose reactions are known in relation to administration into the eye and none are expected when the medicine is used in this manner.

If you forget to use Allergodil eye drops

Forgetting to use Allergodil eye drops does not require any extraordinary measures. Continue treatment by using the ordinary dose at the prescribed time. If necessary, Allergodil eye drops can be used between two prescribed dosing times.

If you stop using Allergodil eye drops

If possible, use Allergodil eye drops regularly until the complaints have disappeared. Typical symptoms can reappear soon if the treatment is prematurely terminated.

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.

Common (up to 1 person in 10): mild and transient eye irritation (e.g. stinging, itching, tears).

Uncommon (up to 1 person in 100): bitter taste in the mouth.

Very rare (up to 1 person in 10,000): hypersensitivity reactions.

Countermeasures

The above side-effects usually disappear quickly; thus, no special measures are necessary.

If you feel a bitter taste in the mouth after using Allergodil eye drops, this should disappear after 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 eye drops

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 label on the bottle and carton.

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

Expiry date after first opening the bottle

Do not use Allergodil eye drops for longer than 4 weeks after first opening the bottle.

This medicinal product does not require any special storage conditions.

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

6. Contents of the pack and other information

What Allegrodil eye drops contain

- The active substance is azelastine hydrochloride. 1 mL of solution contains 0.5 mg of azelastine hydrochloride. One drop of approximately 30 µl contains 0.015 mg of azelastine hydrochloride.
- The excipients are benzalkonium chloride, disodium edetate, hypromellose, sorbitol solution (crystallising), sodium hydroxide, and water for injection.

What Allergodil eye drops look like and contents of the pack

Allergodil eye drops are a clear, colourless solution.

Allergodil eye drops are available in a 6 mL package.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

SIA Meda Pharma
Mūkusalas 101
Rīga LV-1004
Latvia

Manufacturer

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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