

PACKAGE LEAFLET: INFORMATION FOR THE USER

ALLERGODIL 0.5MG/ML

EYE DROPS, SOLUTION

AZELASTINE HYDROCHLORIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Allergodil Eye drops is and what it is used for
2. Before you use Allergodil Eye drops
3. How to use Allergodil Eye drops
4. Possible side effects
5. How to store Allergodil Eye drops

1. WHAT ALLERGODIL EYE DROPS IS AND WHAT IT IS USED FOR

Allergodil Eye drops contains an antihistamine called azelastine hydrochloride.

This compound prevents the effects of histamine (and other substances that the body produces), which are produced as part of an allergic reaction. Azelastine has been shown to reduce inflammation of the eye.

Allergodil Eye drops is used to treat and prevent both seasonal allergic conjunctivitis (hay fever, which is allergy to pollen) and perennial allergic conjunctivitis (which is an allergy to other substances, such as house dust mites and animal dander, and which can occur at any time of the year). The symptoms of these conditions are red, itchy and/or watery eyes, sometimes together with sneezing or a runny, itchy or blocked nose. Allergodil Eye drops should help with the eye symptoms.

Allergodil Eye drops can be used to treat and prevent eye disorders which you get with hayfever (seasonal allergic conjunctivitis) in adults and children age 4 years and above.

Allergodil Eye drops can be used for eye disorders caused by an allergy to substances such as house dust mites or animal hair (perennial allergic conjunctivitis) in adults and children age 12 years and above.

Allergodil Eye drops is not suitable for treating eye infections.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ALLERGODIL EYE DROPS

Do not use Allergodil Eye drops:

- If you have ever had an allergic reaction to azelastine hydrochloride, benzalkonium chloride (a preservative) or any of the other ingredients of Allergodil Eye drops.

Warnings and precautions

Talk to your doctor or pharmacist before using Allergodil Eye drops:

- if you are not sure whether your eye disorders are caused by an allergy, in particular if only one eye is affected; if your vision is impaired; or the eye hurts and you do not have any symptoms in your nose, you may have an infection rather than an allergy.
- if the complaints worsen or last longer than 48 hours without remarkable improvement despite the use of Allergodil Eye drops.
- If you see any other doctor or go to hospital for treatment, tell your doctor about all your medicines, including Allergodil Eye drops.

Allergodil Eye drops is not recommended for use whilst wearing contact lenses. Allergodil Eye drops contains the preservative benzalkonium chloride which is known to discolour soft contact lenses. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion.

Allergodil Eye drops is not intended for the treatment of eye infections.

Allergodil Eye drops contains a preservative called benzalkonium chloride to which you may be allergic.

Allergodil Eye drops should only be applied to the eyes, do not drink it.

Allergodil Eye drops should not be used for more than 6 weeks when used to treat perennial allergic conjunctivitis.

Other medicines and Allergodil Eye drops

Allergodil Eye drops is not known to be affected by other medicines.

Allergodil Eye drops with food and drink

Allergodil Eye drops is not known to react with any types of food and drink.

Pregnancy and breast-feeding

If you are pregnant, trying to become pregnant or breast-feeding ask your doctor or pharmacist for advice before using Allergodil Eye drops.

Driving and using machines

Like other eye drops, you may have a transient blurring of vision after instilling the eye drops. You should wait until this clears before driving or operating machinery.

3. HOW TO USE ALLERGODIL EYE DROPS

Always use Allergodil Eye drops exactly as your doctor has told you.

Important:

- If you are not sure of the correct dose or how to use this medicine, ask your doctor or pharmacist.

Eye disorders caused by hayfever (seasonal allergic conjunctivitis)

- Use in adults and children aged 4 years and above
- The usual dose is one drop in each eye in the morning and evening.

If you anticipate contact with pollen, the usual dose of Allergodil Eye drops may be taken as a preventive measure before going outside.

Eye disorders caused by an allergy (non-seasonal (perennial) allergic conjunctivitis)

- Use in adults and children aged 12 years and above
- The usual dose is one drop in each eye in the morning and evening.

If your symptoms are severe, your doctor may increase your dose to one drop in each eye, up to four times a day.

If possible, you should use Allergodil Eye drops regularly until your symptoms have disappeared.

If you interrupt the use of Allergodil Eye drops your symptoms are likely to return.

Remember:

- Do not take Allergodil Eye drops for more than 6 weeks
- Allergodil Eye drops should only be applied to the eyes.

Putting in your Allergodil Eye drops

To help you put in your eye drops correctly, you may find it useful to sit in front of a mirror so you can see what you are doing for the first few times.

1. Wash your hands.
2. Gently wipe around your eyes with a tissues to remove any moisture (Diagram 1).
3. Unscrew the top of the bottle and check that the dropper is clean.
4. Gently pull your lower eye lid down (Diagram 2).
5. Carefully place the drop inside the middle of your lower eyelid (Diagram 3). Take care not to let the dropper touch your eye.
6. Release your lower eye lid and gently press on the inner corner of your eye against the bridge of your nose (Diagram 4). Keeping your finger pressed against your nose, slowly blink your eyes a few times to spread the drop across the surface of your eye.
7. Blot away any excess medicine with a tissue.
8. Repeat this for your other eye.



Diagram 1



Diagram 2



Diagram 3



Diagram 4

If you use more Allergodil Eye drops than you should

If you put too much Allergodil Eye drops into your eyes you are unlikely to have any problems. If you are worried, contact your doctor. If you accidentally swallow Allergodil Eye drops, contact your doctor or nearest hospital casualty department as soon as possible.

If you forget to use Allergodil Eye drops

Use your eye drops 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 about the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines Allergodil Eye drops can cause side effects. Not everybody gets them and they are not usually serious. These effects include:

- **Common** (1 to 10 of 100 patients treated): Slight irritation (burning, itching, watering) in the eyes after putting in Allergodil Eye drops. This should not last long.
- **Uncommon** (1 to 10 of 1,000 patients treated): A bitter taste in your mouth. This should quickly disappear especially if you have a soft drink.
- **Very rare** (less than 1 of 10,000 patients treated): An allergic reaction (such as rash and itching).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ALLERGODIL EYE DROPS

Keep **Allergodil Eye drops** in a safe place where children cannot see or reach it. Used wrongly, your eye drops could harm them.

This medicinal product does not require any special storage conditions.

Do not use **Allergodil Eye drops** after the expiry date given on the bottle label and the outer carton. The expiry date refers to the last day of that month.

Once you have opened your bottle of **Allergodil Eye drops**, do not use it for longer than 4 weeks, even if there is some medicine left in the bottle after this time. Take your bottle back to a pharmacist for disposal of the unused eye drops and ask your doctor for a new prescription.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

This leaflet was last revised in 12/2012.