

Allergodil® 0.5 mg/ml Eye Drops, Solution

Azelastine hydrochloride

777124V175/1D

Please read this leaflet carefully before you start to take your medicine. This leaflet provides a summary of the information known about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

Remember this medicine is for you. Only a doctor can prescribe this medicine and it may harm someone else, even if their symptoms are the same as yours.

About your medicine**• What is your medicine?**

The full name of your medicine is **Allergodil 0.5 mg/ml Eye Drops, Solution** (common name Azelastine hydrochloride) (referred to throughout this leaflet as "Allergodil").

Allergodil contains a solution of 0.05% azelastine hydrochloride. Each drop contains 0.015 mg azelastine hydrochloride.

Allergodil also contains benzalkonium chloride, disodium edetate, hypromellose, sorbitol, sodium hydroxide and water.

Allergodil is a clear, colourless, sterilised, water based solution which comes in a polyethylene bottle with dropper attachment. The bottle contains 6 ml of eye drops.

• What your medicine does

Allergodil 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.

• Who produces your medicine?

The marketing authorization for **Allergodil** is held by:

MEDA Pharma GmbH & Co. KG

Benzstrasse 1

61352 Bad Homburg

Germany

Allergodil is manufactured by:

Tubilux Pharma S.p.A.

Via Costarica 20/22

00040 Pomezia / Rome

Italy

• What your medicine is used for

Allergodil is used to treat and prevent both seasonal allergic conjunctivitis (hay fever, which is allergy to pollen) and perennial allergic conjunctivitis (which is 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** should help with the eye symptoms.

Before using your medicine**• You should not take Allergodil**

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

• Important points to note before starting to use your medicine.

- Are you pregnant?
- Are you breast feeding?

If the answer to any of these questions is yes, you must tell your doctor - he may decide to alter your treatment.

• What about other medicines that you may be taking?

Allergodil is not known to react with any other medicines.

• What about food and drink?

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

• What to do if you see a different doctor, or have to go to hospital.

If you see any other doctor or go to hospital for treatment, tell your doctor about all your medicines, including **Allergodil**.

Special warnings and precautions

Allergodil is not recommended for use whilst wearing contact lenses.

Allergodil is not intended for the treatment of eye infections.

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

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

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

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.

Using your medicine

• How to use your medicine

To help you to instill **Allergodil** 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. Wash your hands then;

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



(Diagram 1)



(Diagram 2)



(Diagram 3)



(Diagram 4)

Instill one drop to each eye in the morning and the evening. In more severe cases, your doctor may prescribe one drop in each eye, four times a day. Always use **Allergodil** as prescribed by your doctor.

Allergodil is suitable for use in adults and children aged 4 years and over for the treatment of hay fever, but should not be used in children under 12 years for the treatment of perennial allergic conjunctivitis.

• What to do if you forget to use your medicine

If you forget to use your eye drops, use them as soon as you remember then instill the next dose at the normal time.

• What to do if you take an overdose

If you put too much **Allergodil** into your eyes you are unlikely to have any problems. If you are worried, contact your doctor. There is little risk of overdose associated with swallowing **Allergodil** because of the small amount of medicine that it contains, however if anyone, especially a child accidentally drinks **Allergodil**, contact your doctor or local hospital casualty department immediately.

After using your medicine

Allergodil may, like many other medicines, have some side-effects. These are not usually serious. Some people experience a slight irritation in their eyes after instilling **Allergodil**, this does not last long. You may develop a bitter taste in your mouth, which should quickly disappear, especially if you have a soft drink. In very rare cases, allergic reactions may occur.

If you notice any other problems, tell your doctor.

How to store your medicine

- Keep **Allergodil** in a safe place where children cannot see or reach it. Used wrongly, your eye drops could harm them.
- Do not use **Allergodil** after the expiry date on the bottle.
- Once you have opened your bottle of **Allergodil**, 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.
- Store below 25°C. Do not refrigerate.

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instruction is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instruction of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, it benefits and risks.
- Do not by yourself interrupt the period treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.