Package leaflet: Information for the patient

Azelastine 0.5 mg/ml Eye Drops, Solution
Azelastine hydrochloride

Read all of this leaflet carefully before you start using 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. See section 4.
• In this leaflet Azelastine 0.5 mg/ml Eye Drops, Solution is called Azelastine.

What is in this leaflet
1. What Azelastine is and what it is used for
2. What you need to know before you use Azelastine
3. How to use Azelastine
4. Possible side effects
5. How to store Azelastine
6. Contents of the pack and other information.

1. What Azelastine is and what it is used for

Azelastine contains the active substance azelastine hydrochloride, which belongs to a group of medicines called antiallergics (antihistamines). Antihistamines work by preventing the effects of substances such as histamine that the body produces as part of an allergic reaction. Azelastine has been shown to reduce inflammation of the eye.

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

Azelastine 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 aged 12 years and above.

You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

Azelastine is not suitable for treating eye infections.

2. What you need to know before you use Azelastine

Do not use Azelastine:
• 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 Azelastine:
- 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 Azelastine
- if you wear contact lenses.

Children and adolescents
For the treatment of eye disorders caused by hayfever (seasonal allergic conjunctivitis):
Do not give this medicine to children below 4 years of age, because safety and efficacy have not been established.

For the treatment of eye disorders caused by an allergy (non-seasonal (perennial) allergic conjunctivitis):
Do not give this medicine to children below 12 years of age, because safety and efficacy have not been established.

Other medicines and Azelastine
Although Azelastine is not known to be affected by other medicines, tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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.

Driving and using machines
Your sight may become blurred for a short time after you use Azelastine. If this happens, wait until your sight clears before you drive or use machinery.

Azelastine contains benzalkonium chloride
This medicine contains 0.00375 mg benzalkonium chloride in each drop which is equivalent to 0.00375 mg / 0.03 ml.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use Azelastine

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Remember:
• Azelastine should only be applied to the eyes.

The recommended dose is:
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 Azelastine 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.

Relief of symptoms of allergic conjunctivitis should be noticed after 15-30 minutes.

Putting in your Azelastine 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

Duration of treatment
If possible, you should use Azelastine regularly until your symptoms have disappeared.

Do not take Azelastine for more than 6 weeks.

If you use more Azelastine than you should
If you put too much Azelastine into your eyes you are unlikely to have any problems. If you are worried, contact your doctor. If you accidentally swallow Azelastine, contact your doctor or nearest hospital casualty department as soon as possible.

If you forget to use Azelastine
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 stop using Azelastine
If you interrupt the use of Azelastine your symptoms are likely to return.

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.

These effects include:
• Common (may affect up to 1 in 10 people): Slight irritation (burning, itching, watering) in the eyes after putting in Azelastine. This should not last long.
• Uncommon (may affect up to 1 in 100 people): A bitter taste in your mouth. This should quickly disappear especially if you have a soft drink.
• Very rare (may affect up to 1 in 10,000 people): An allergic reaction (such as rash and itching).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Azelastine

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 bottle label and the outer carton. The expiry date refers to the last day of that month.
Once opened: Do not use this medicine if the bottle has been open for longer than 4 weeks.
This medicine does not require any special storage conditions.

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. Contents of the pack and other information

What Azelastine contains
The active substance is azelastine hydrochloride 0.05% (0.5 mg/ml). Each drop contains 0.015 mg azelastine hydrochloride.
The other ingredients are benzalkonium chloride, disodium edetate, hypromellose, liquid sorbitol (crystallising) (E420i), sodium hydroxide (E524) and water for injections.

What Azelastine looks like and contents of the pack
Azelastine is a clear, colourless solution.
Azelastine comes in a plastic bottle with a dropper attachment. One bottle contains either 6, 8 or 10 ml eye drops, solution. Not all pack sizes may be marketed.

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