

Package leaflet: Information for the user

Azelastine hydrochloride 0.5mg/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 hydrochloride 0.5mg/ml Eye drops, solution is called as Azelastine Eye drops.

What is in this leaflet:

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

1. What Azelastine Eye drops is and what it is used for

Azelastine Eye drops 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 Eye drops 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 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 aged 12 years and above.

Azelastine Eye drops is not suitable for treating eye infections.

2. What you need to know before you use Azelastine Eye drops

Do not use Azelastine 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 taking Azelastine 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 Azelastine Eye drops.
- 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 Eye drops

Although Azelastine Eye drops 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 Eye drops. If this happens, wait until your sight clears before you drive or use machinery.

Azelastine Eye drops contains benzalkonium chloride

This medicine contains 0.125 mg benzalkonium chloride in each 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 Eye drops

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

Remember:

- Azelastine Eye drops 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 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.

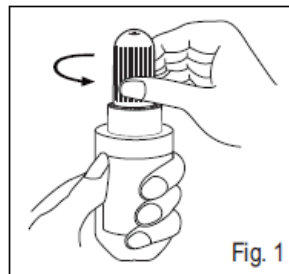
Relief of symptoms of allergic conjunctivitis should be noticed after 15-30 minutes.

INSTRUCTIONS FOR USE

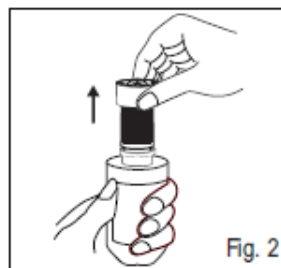
Using the Blow fill seal container for the first time:

Opening the bottle for the first time

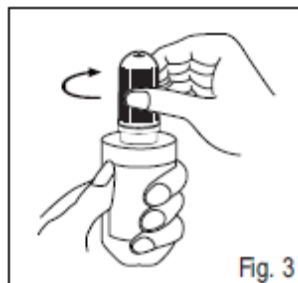
1. Turn the cap in counter clockwise direction. This will break the tamper-proof base ring (Fig.1).



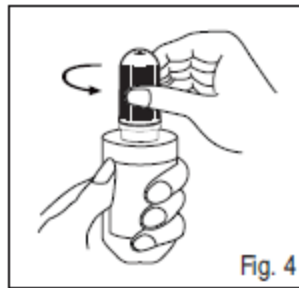
2. Remove the tamper-proof base ring by retaining the cap on the container (Fig.2).



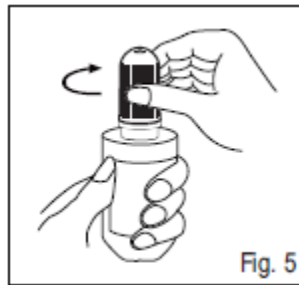
3. Tighten the cap on the nozzle completely by turning clockwise. The spike in the cap will pierce the tip of the bottle (Fig.3).



4. To open the bottle, remove the cap by turning it in the counter clockwise direction (Fig.4).



5. Tighten the cap on the container after every use (Fig.5).

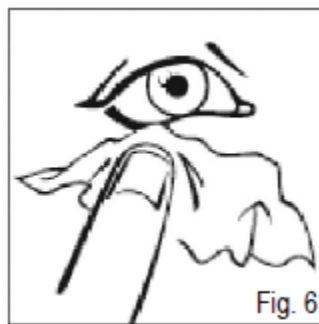


Once the bottle has been opened in this way apply the eye drops as instructed below.

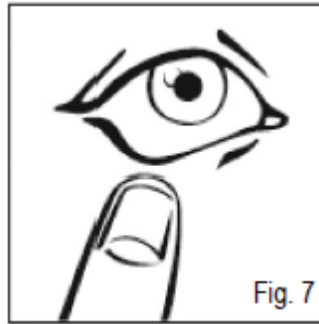
Using your Eye drops

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

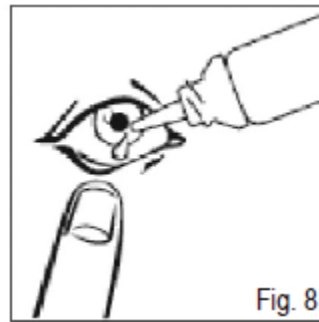
1. Wash your hands.
2. Gently wipe around your eyes with a tissues to remove any moisture (Fig. 6).



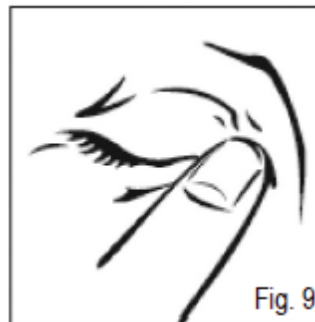
3. Unscrew the top of the bottle and check that the dropper is clean.
4. Gently pull your lower eye lid down (Fig. 7)



5. Carefully place the drop inside the middle of your lower eyelid (Fig. 8). 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 (Fig. 9). 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.

Duration of treatment

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

Do not take Azelastine Eye drops for more than 6 weeks.

If you use more Azelastine Eye drops than you should

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

If you forget to use Azelastine 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 forgotten dose.

If you stop using Azelastine Eye drops

If you interrupt the use of Azelastine Eye drops 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 every body gets them.

These affects include:

- Common (may affect up to 1 in 10 people): Slight irritation (burning, itching, watering) in the eyes after putting in Azelastine Eye drops. 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 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 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 28 days. This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater. 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 Eye drops 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), sodium hydroxide and water for injections.

What Azelastine Eye drops looks like and contents of the pack

Azelastine Eye drops is a clear, colourless solution, practically free from any visible particles.
AzelaStine Eye drops filled in 10 mL LDPE Blow fill seal (BFS) container with white colour polypropylene spiked cap having a tamper-proof base ring.

One bottle contains either 6, 8 or 10ml eye drops, solution.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised on 09/2018