Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about EYEZEP. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you using EYEZEP against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine.

You may need to read it again.

What EYEZEP is used for

EYEZEP is used for the treatment and prevention of seasonal and non-seasonal (perennial) allergic conjunctivitis, caused by allergies, such as to pollen (hay fever) or house dust mites. The effects are red, itchy and/or watery eyes, sometimes together with sneezing or a runny, itchy or blocked nose.

EYEZEP belongs to a group of medicines called antihistamines. It works by blocking the action of histamine and other substances produced by the body, which are causing your allergies.

EYEZEP is not addictive.

Before you use EYEZEP

When you must not use it

Do not use EYEZEP if you have an allergy to EYEZEP or any of the ingredients listed at the end of this leaflet.

Do not give EYEZEP to a child under 4 years, unless directed by the child's doctor.

The safety and effectiveness of EYEZEP in children under 4 years have not been established.

Do not use EYEZEP after the expiry date printed on the pack.

Do not use EYEZEP after 4 weeks of first opening the bottle.

Do not use EYEZEP if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using EYEZEP, contact your doctor or pharmacist.

Before you start to use it

Tell your doctor if you have allergies to:

- · Any other medicines
- Any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant. Your doctor will discuss the possible risks and benefits of using EYEZEP during pregnancy.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.
Your doctor will discuss the benefits and risks of using EYEZEP during breastfeeding.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

· Kidney disease

Tell your doctor or pharmacist if you are wearing contact lenses.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using EYEZEP.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and EYEZEP may interfere with each other if significant amounts of the eye drop is absorbed systematically. These include:

 Cimetidine, a medicine used to treat stomach ulcers and some other stomach conditions.

You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while using EYEZEP.

How to use EYEZEP

How much to use

Use one drop of EYEZEP in each eye every 12 hours as required.

This may be increased to one drop in each eye four times daily if required.

How to use it

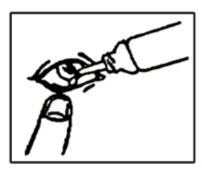
Wash your hands before using EYEZEP. Gently wipe around your eyes with a tissue to remove any moisture.



- 1. Remove the protective cap.
- 2. Unscrew the top of the bottle and check that the dropper is clean.
- 3. Gently pull your lower eyelid down.



 Carefully place one drop inside the middle of your lower eyelid. 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. Then keeping your finger pressed against your nose, slowly blink your eye a few times to spread the drop across the surface. Blot away any excess medication.



6. Repeat this procedure for your other eye. *How long to use it*

A new bottle of EYEZEP is required if used beyond 4 weeks.

The maximum duration of treatment is 6 weeks at a time.

Consult your doctor if your symptoms have not cleared up after 6 weeks.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use it as soon as you remember, and then go back to using your medicine as you would normally.

Do not use a double dose to make up for the dose that you missed.

 $\label{eq:expectation} \textbf{EYEZEP} \textbf{ should be used only when } \textbf{necessary.}$

If you use too much (overdose)

You are unlikely to have any problems. If you are worried, contact your doctor or pharmacist. There is little risk of overdose associated with swallowing EYEZEP because of the small amount of medicine it contains however if anyone, especially a child accidentally drinks EYEZEP, contact your doctor, pharmacist or the Poisons Information Centre (Phone 131126). Do this even if there are no signs of discomfort or poisoning

While you are using EYEZEP

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are using EYEZEP.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are using EYEZEP.

If you become pregnant while using EYEZEP, tell your doctor.

Things you must not do

Do not give EYEZEP to anyone else, even if they have the same condition as you.

Do not use EYEZEP to treat any other complaints unless your doctor or pharmacist tells you to. EYEZEP is not intended for the treatment of eye infections.

Things to be careful of

Make sure you know how you react to EYEZEP before you drive, operate machinery, or do anything else that could be dangerous if you are tired, drowsy, dizzy or light-headed.

EYEZEP is unlikely to make you feel drowsy. However, if you are drowsy, do not drive a car or operate machinery.

Be careful drinking alcohol while using EYEZEP.

If you drink alcohol, any drowsiness may be worse.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using EYEZEP.

Like other medicines, EYEZEP may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- · Irritation in the eyes
- · Stinging or burning in eyes
- Bitter taste in mouth

These side effects are usually mild and short-lived

Drinking a flavoured drink a few minutes after using EYEZEP may help any bitter taste to go away.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using EYEZEP

Storage

Keep your EYEZEP in a cool dry place where the temperature stays below 30°C.

Do not put EYEZEP in the fridge.

Do not leave it in the car on hot days or on windowsills.

Heat can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not use EYEZEP for longer than 4 weeks after the bottle is first opened.

Disposal

If your doctor or pharmacist tells you to stop using EYEZEP, or the bottle has passed the expiry date, or the bottle has been open for longer than 4 weeks, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

EYEZEP is a clear, colourless, water based solution, which comes in a polyethylene bottle with dropper attachment. The bottle contains 6 mL of solution which is equivalent to approximately 180 eye drops.

Ingredients

Active ingredient:

Azelastine (as hydrochloride) 0.0457%

Each drop contains 14 μg azelastine (as hydrochloride).

Other ingredients:

- Hypromellose
- Disodium edetate
- · Benzalkonium chloride
- Sorbitol solution 70% (crystallising)
- G 1: 1 1 :1
- Sodium hydroxide
- · Water for injections

EYEZEP does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Australia

Mylan Health Pty Ltd Level 1, 30 The Bond 30-34 Hickson Road Millers Point, NSW 2000

www.mylan.com.au Phone: 1800 314 527

Australian registered number:

AUST R 97489.

Date of preparation:

This leaflet was prepared in July 2018.

EYEZEP_cmi\Jul18/00