

Package leaflet: Information for the patient

Levofloxacin 5mg/ml Eye Drops Solution

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- The full name of this medicine is Levofloxacin 5mg/ml Eye Drops Solution but within the leaflet it will be referred to as Levofloxacin Eye Drops.

What is in this leaflet

1. What Levofloxacin Eye Drops are and what they are used for
2. What you need to know before you use Levofloxacin Eye Drops
3. How to use Levofloxacin Eye Drops
4. Possible side effects
5. How to store Levofloxacin Eye Drops
6. Contents of the pack and other information

1. What Levofloxacin Eye Drops are and what they are used for

Levofloxacin is an antibiotic of the type called fluoroquinolones (sometimes shortened to quinolones). It works by killing some types of bacteria that can cause infections.

When levofloxacin is given in eye drops, it is used in children aged 1 year or over and in adults to treat bacterial infections that affect the front surfaces of the eye.

One type of infection in this area is called bacterial conjunctivitis, which is an infection of the covering of the front of the eye (conjunctiva).

Levofloxacin Eye Drops are not recommended to be used in children aged below 1 year.

You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

2. What you need to know before you use Levofloxacin Eye Drops

Do not use Levofloxacin Eye Drops:

- if you are allergic to levofloxacin or other quinolones or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, ask your doctor or pharmacist first.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Levofloxacin Eye Drops

- if an allergic reaction occurs even after a single dose, stop using the medicine
- if you observe worsening of your eye symptoms during treatment, please contact your doctor as soon as possible

- if you do not see any sign of recovery within a certain treatment period agreed with your doctor, please contact your doctor as soon as possible
- generally, no types of contact lenses should be worn when the eye is infected
- Levofloxacin Eye Drops contain the preservative benzalkonium chloride, which may cause eye irritation.

Tendon swelling and rupture have happened in people taking oral or intravenous fluoroquinolones, particularly in older patients and in those treated concurrently with corticosteroids. Stop taking Levofloxacin Eye Drops if you develop pain or swelling of the tendons (tendinitis).

Children and adolescents

The special warnings and precautions for using this medicine are the same for adults, adolescents and children aged ≥ 1 year.

Other medicines and Levofloxacin Eye Drops

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist if you are applying any other type of eye drop or eye ointment before you start to use Levofloxacin Eye Drops.

If you are using other eye drops, you should wait at least 15 minutes between applying Levofloxacin Eye Drops and any other type of eye drop.

Pregnancy, breast-feeding and fertility

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 using this medicine.

Levofloxacin Eye Drops should be used during pregnancy only if the potential benefit justifies the potential risk to the growing baby.

Although very small amounts of levofloxacin reach the blood and the breast milk, respectively, after instilling eye drops it is very unlikely that the eye drops would harm the growing baby. Your doctor is informed about the potential risk and will advise you whether to take Levofloxacin Eye Drops in this case.

Your fertility (ability to become pregnant or to father a child) is not impaired when you apply Levofloxacin Eye Drops following its instructions for use.

Driving and using machines

Levofloxacin Eye Drops have minor influence on the ability to drive and use machines.

If the eye drops cause blurring of your sight when you use them, you should wait until this clears before driving or operating machinery.

Levofloxacin Eye Drops contains benzalkonium chloride

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 Levofloxacin 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.

Levofloxacin Eye Drops are for ocular use and have to be applied to the outer surface of the eye. For patients above 1 year of age, the recommended dose is as follows:

Days 1 – 2

- Use one to two drops in the affected eye(s) every two hours.
- Use a maximum of 8 times per day.

Days 3 – 5

- Use one to two drops in the affected eye(s).
- Use a maximum of 4 times per day.

In elderly patients no adjustment of the usual dose is required.

The usual total treatment course is five days. Your doctor will advise you how long to apply the drops.

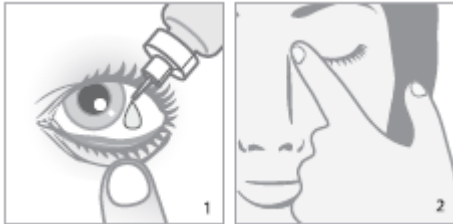
If you are putting any other medicine in your eye, you should wait at least 15 minutes between applying the different types of drops.

Use in children and adolescents

No dosage modification is required in children ≥ 1 year old and in adolescents. Levofloxacin Eye Drops are not recommended to be used in children aged below 1 year.

Before applying the drops:

If possible, ask someone else to apply the drops for you. Ask them to read these instructions with you before applying the drops.



- 1) Wash your hands.
- 2) Open the bottle. **Take special care that the tip of the dropper bottle does not touch your eye, the skin around your eye or your fingers.**
- 3) Tilt your head backwards and hold the bottle upside down over the eye.
- 4) Pull the lower eyelid downwards and look up. Gently squeeze the bottle and let one drop fall into the space between the lower eyelid and the eye (picture 1).
- 5) Close the eye and press the inner corner of the eye with your finger for about one minute. This can prevent the eye drop from draining down the tear duct (picture 2).
- 6) Wipe off any excess solution from the skin around the eye.
- 7) Put the cap back on and close the bottle tightly.

If another drop is needed, and when both eyes are to be treated, repeat steps 3 to 7.

Levofloxacin Eye Drops should not be injected into the interior part of the eyeball.

If you use more Levofloxacin Eye Drops than you should

If you use more Levofloxacin Eye Drops than you should, flush the eye(s) with water and tell your doctor or pharmacist.

If you forget to use Levofloxacin Eye Drops

If you forget to use the eye drops, put in the next dose as soon as you remember. Do not use a double dose to make up for a forgotten dose.

If you swallow Levofloxacin Eye Drops by accident

The amount of levofloxacin in the provided bottle is too small to cause side effects. However, if you are concerned, tell your doctor or pharmacist who will advise you on any necessary measures.

If you stop using Levofloxacin Eye Drops earlier than instructed, it may delay the healing process.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

About one in ten people have a side effect when using Levofloxacin Eye Drops. Most of these affect only the eye and may not last very long. If you have any severe or persistent side effects you should stop using these eye drops and seek urgent advice from your doctor.

Very rarely this medicine can cause severe allergic reactions (may affect up to 1 in 10,000 people). The following symptoms can occur even after just one dose of Levofloxacin Eye Drops:

- swelling and tightness in the throat
- breathing difficulties.

In rare cases other allergic reactions can develop. Symptoms of such reactions are:

- worsening of redness and itching of the eyes
- increased or sudden swelling of eyelids.

Stop using Levofloxacin Eye Drops and contact a doctor immediately if any of these symptoms occur.

Tell your doctor if any of the following side effects get serious or lasts longer than a few days:

Common (may affect up to 1 in 10 people):

- burning feeling in the eye
- decreased vision or mucus in the eye.

Uncommon (may affect up to 1 in 100 people):

- stinging or irritation of the eyes
- painful eyes
- dry or sore eyes
- swelling or redness (bloodshot eyes) of the conjunctivae (front covering of the eye) or eyelid
- sensitivity to light
- itchy eyes
- sticky eyelids
- headache
- rash around the eye
- stuffed or runny nose.

Rare (may affect up to 1 in 1,000 people):

- allergic reactions such as skin rash
- tendon inflammation, tendon rupture.

Very rare (may affect up to 1 in 10,000 people):

- swelling and tightness in the throat
- breathing difficulty.

Additional side effects in children and adolescents

Frequency, type and severity of side effects in children and adolescents are expected to be the same as in adults.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Levofloxacin Eye Drops

Keep this medicine out of the sight and reach of children.

Unopened bottle: This medicinal product does not require any special storage conditions.

Opened bottle: Do not store above 25°C. Keep bottle in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the bottle label and carton after “EXP”. The expiry date refers to the last day of that month.

Do not use this medicine if the tamper-evident seal is broken.

To prevent infections, you must throw away the bottle 28 days after you first opened it, and use a new bottle.

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 Levofloxacin Eye Drops contain

- The active substance is levofloxacin.
1ml contains 5.12mg of levofloxacin hemihydrate equivalent to 5mg of levofloxacin.
- The other ingredients are benzalkonium chloride (0.05mg in 1ml eye drops, solution; preservative), sodium chloride, sodium hydroxide or hydrochloric acid (for pH adjustment) and water for injections.

What Levofloxacin Eye Drops look like and contents of the pack

- Levofloxacin Eye Drops are a clear, pale yellow to pale greenish-yellow solution, free from visible particles.
- White LDPE 5ml bottle with a white LDPE dropper and a white high density polyethylene (HDPE)/ LDPE tamper-evident seal cap.
- 1 bottle per carton.

Marketing Authorisation Holder

Accord, Barnstaple, EX32 8NS, UK

Manufacturer

Balkanpharma-Razgrad AD
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