

Package leaflet: Information for the user

Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing

Levofloxacin

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.

What is in this leaflet

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2. What you need to know before you use Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing
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1. What Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing is and what it is 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 Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing is 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 Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing

Do not use Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing

- 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 Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing

- 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.

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 Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing 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 in adults, adolescents and children aged >1 year.

Other medicines and Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing

Tell your doctor or pharmacist if you are using or have recently used or might use 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 Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing.

If you are using other eye drops, you should wait at least 15 minutes between applying Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing 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 taking this medicine.

Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing eye drops should be used during pregnancy only if the potential benefit justifies the potential risk to the unborn 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 Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing eye drops in this case.

Your fertility (ability to become pregnant or to father a child) is not impaired when you apply Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing following its instructions for use.

Driving and using machines

Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing has 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.

3. How to use Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing

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 Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing 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 recommended 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

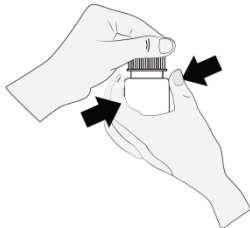
No dosage modification is required in children >1 year old and in adolescents. Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing is not recommended to be used in children aged below 1 year.

Before applying the drops:

- Wash your hands before opening the bottle.
- Do not use this medicine if you notice that the tamper-proof seal on the bottle neck is broken before you first use it.
- When using for the first time, before delivering a drop to the eye, you should practise using the dropper bottle by squeezing it slowly to deliver one drop away from the eye.
- When you are confident that you can deliver one drop at a time, choose the position that you find most comfortable for the instillation of the drops (you can sit down, lie on your back, or stand in front of a mirror).

Instillation

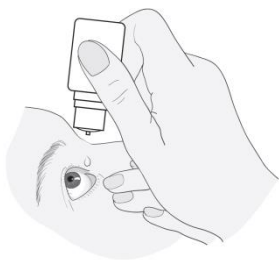
1. Hold the bottle directly below the cap and turn the cap to open the bottle. To avoid contamination of the solution, take special care that the tip of the bottle does not touch anything (i.e., the skin around your eye or your fingers).



2. Tilt your head backwards and hold the bottle above your eye.

3. Pull the lower eyelid down and look up. Gently squeeze the bottle in the middle and let one drop fall into your eye. Please note that there might be a few seconds delay between squeezing and the drop coming out. Do not squeeze the bottle too hard.

Ask your doctor, pharmacist or nurse for advise if you are not sure how to apply these eye drops.



4. Blink a few times so that the drop spreads over your eye.



5. Press your finger into the corner of the eye, by the nose, for a few minutes. This helps to stop the eye drops getting into the rest of your body.



6. Repeat steps 2. – 5. to deliver a drop into the other eye, if your doctor has told you to do this. Your doctor will tell you if one eye only needs to be treated, and if so, which eye is affected.

7. After each use and prior to recapping, shake the bottle holding it in a downwards direction, without touching the dropper tip, in order to remove any residual liquid on the tip. This is necessary in order to ensure delivery of subsequent drops.



8. After you complete your treatment as directed by your doctor, there will be some Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing left in the bottle. Do not attempt to use the excess medicine remaining in the bottle after you have completed the course of treatment. Do not use the eye drops for longer than 28 days after first opening of the bottle.

If you use more Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing than you should

If you use more Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing than you should, flush the eye(s) with water and tell your doctor or pharmacist.

If you forget to use Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing

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

If you swallow Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing by accident

The amount of levofloxacin in the provided amount of single-dose containers 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 Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing 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 Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing. Most of these affect only the eye and may not last very long. If you have any severe or persistent side effect you should stop using these eye drops and seek urgent advice from your doctor.

It is possible, even though rare, to develop an allergic reaction to Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing even after just one dose. You notice this because your eyes may become red or itchy, or the lids may be swollen. If this should happen, stop using Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing and contact your doctor immediately.

Common side effects (may affect up to 1 in 10 users)

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

Uncommon side effects (may affect up to 1 in 100 users)

- 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)
- sensitivity to light
- itchy eyes
- sticky eyelids
- headache
- rash around the eye
- stuffed or runny nose.

Rare side effects (may affect up to 1 in 1,000 users)

- allergic reactions such as skin rash.

Very rare side effects (may affect less than 1 in 10,000 users)

- 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 national reporting system listed in Appendix V](#).*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing

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 and carton after "EXP". The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

Keep the Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing bottle in the outer carton in order to protect from light.

After first opening: You can use Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing within 28 days after first opening of the bottle.

Discard any unused eye drops after that time. Store below 30°C. Keep the bottle in the outer carton in order to protect from light.

Do not use this medicine if you notice insoluble parts in the solution.

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 Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing contains

- The active substance is levofloxacin. 1 ml contains 5.12 mg of levofloxacin hemihydrate equivalent to 5 mg of levofloxacin.
- The other ingredients are sodium chloride, sodium hydroxide (E524), hydrochloric acid (E507) and water for injections.

What Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing looks like and contents of the pack

- Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing is a clear, light yellow coloured solution, free of visible particles in a white opaque bottle with a white nozzle sealed with a white cap.
- Pack size: 1 bottle containing 5 ml

Marketing Authorisation Holder and Manufacturer

Houder van de vergunning

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Dit middel is in het register ingeschreven onder RVG 123923

Deze bijsluiter is voor het laatst goedgekeurd in februari 2020