

Package leaflet: Information for the user

Ofloxacin Devatis 3 mg/ml, oogdruppels, oplossing, Verpakking voor éénmalig gebruik Ofloxacin

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.

What is in this leaflet

1. What Ofloxacin Devatis is and what it is used for
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1. What Ofloxacin Devatis is and what it is used for

Ofloxacin Devatis is an eye drop to treat external eye infections such as bacterial conjunctivitis (inflammation of the conjunctiva) and keratitis (inflammation of the cornea) in adults and children caused by ofloxacin-sensitive organisms.

Ofloxacin is an antibacterial agent and belongs to a group of medicines called fluoroquinolones (sometimes shortened to quinolones).

2. What you need to know before you use Ofloxacin Devatis

Do not take:

- If you are allergic (hypersensitive) to ofloxacin, to any other quinolones (the group of this medicine) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Ofloxacin Devatis.

- if you are sensitive to other quinolone antibacterial agents
- if you suffer from defects or ulcers of the ocular surface.

Long term use may result in a new bacterial infection which does not respond to Ofloxacin Devatis.

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 Ofloxacin Devatis if you develop pain or swelling of the tendons (tendinitis)

Use of contact lenses is not recommended in patients receiving treatment for an eye infection.

Contact your doctor or pharmacist if you have any questions about using Ofloxacin Devatis.

Other medicines and Ofloxacin Devatis

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

If other eye drops/eye ointments are used apart from Ofloxacin Devatis, an interval of about 15 minutes should be kept between the applications of the medicines. Eye ointments should always be applied last.

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.

Your doctor can then decide whether you can use Ofloxacin Devatis.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Shortly after applying this product into the eye you may experience a few minutes of blurred vision. During this time you should not drive, use machines or work without stable footing.

3. How to use Ofloxacin Devatis

Always use Ofloxacin Devatis exactly as your doctor or pharmacist has told you to. Check with your doctor or pharmacist if you are not sure.

Dosage

Instil one drop of Ofloxacin Devatis in the affected eye(s) every two to four hours for the first two days, followed by four times daily.

To be effective Ofloxacin Devatis must be taken regularly.

The length of treatment should not exceed 14 days. If your symptoms persist after this time, please see your doctor.

Do not allow the tip of the single-dose container to touch your eye or areas around your eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the single-dose container, keep the tip of the container away from contact with any surface.

The solution from one individual single-dose container of Ofloxacin Devatis is to be used immediately after opening for administration to the affected eye(s). Since sterility cannot be maintained after the individual single-dose container is opened, a new container must be opened prior to each use and must be discarded immediately after administration.

How to use Ofloxacin Devatis:

1. Wash your hands before using the drops.
2. Remove the top from the single-dose container.
3. Make sure that the tip of the single-dose container does not touch anything.
4. Hold the single-dose container in one hand between the thumb and forefinger.
5. Tilt your head back, and use your other forefinger to pull down the lower eyelid.

6. Place the dropper tip close to your eye, but not touching the eye or lid, and gently squeeze the single-dose container to release one drop into your eye.
7. Close your eyelid and gently press the corner of your eye with your forefinger for one minute.
8. After instillation, discard the used single-dose container even if there is solution remaining.

Follow these instructions carefully. Consult your doctor or pharmacist if there is anything you do not understand.

Use in children

The product can be used in children.

If you use more Ofloxacin Devatis than you should

If you have applied too many drops to your eye(s), wash the eye(s) with clean water. Apply your next dose at the normal time.

If this medicine is swallowed by accident, contact your doctor straight away.

If you forget to use Ofloxacin Devatis

If you forget a dose apply it as soon as you remember, unless it is almost time for your next dose, in which case you should miss out the forgotten dose.

Apply your next dose as usual and continue with your normal routine.

Do not use a double dose to make up for a forgotten dose.

If you stop using Ofloxacin Devatis

Ofloxacin Devatis should be used as advised by your doctor.

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

4. Possible side effects

Like all medicines, Ofloxacin Devatis can cause side effects, although not everybody gets them.

If an allergic reaction (including swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles or lower legs) occurs stop using the eye drops and contact your doctor immediately.

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Ofloxacin Devatis, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.

Eye irritation and ocular discomfort are common side effects (may affect up to 1 in 10 users).

The following side effects are known to occur, but the number of people likely to be affected is unknown.

You should see your doctor if any of the following side effects cause you problems or if they do not resolve themselves:

Side effects affecting the eye:

- eye redness/eye allergy
- itching
- blurred vision
- increased tearing

- dry eyes
- eye pain
- sensitivity to light
- Swelling around the eyes (including eyelid swelling)

Side effects affecting the body:

- allergic reactions
- dizziness
- numbness
- nausea
- headache
- swelling of the face or the skin around the eye

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Nederlands Bijwerkingen Centrum Lareb, Website: www.lareb.nl. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ofloxacin Devatis

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 label after EXP. The expiry date refers to the last day of that month.

Store in the original package (sachet) in order to protect from light.

After opening of the sachet: use the single-dose containers within 28 days. Discard any unused single-dose containers after that time.

After opening of the single-dose container: use immediately and discard the single-dose container after use.

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 Ofloxacin Devatis contains

- The active substance is ofloxacin, 3 mg/ml.
- The other ingredients are sodium chloride, sodium hydroxide (E524) (for pH adjustment), hydrochloric acid (E507) (for pH adjustment) and water for injections

What Ofloxacin Devatis looks like and contents of the pack

Ofloxacin Devatis is a clear, pale light yellow solution, free from visible particles.

It is supplied in 0.5 ml single-dose containers in sachets. Each sachet contains 5 single-dose containers.

Ofloxacin Devatis is available in pack-sizes of 10 x 0.5 ml, 20 x 0.5 ml, 30 x 0.5 ml, 50 x 0.5 ml and 60 x 0.5 ml single-dose containers.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Devatis GmbH
Spitalstr. 22
79539 Lörrach
Germany

In het Register van Geneesmiddelen ingeschreven onder RVG 113360.

This medicinal product is authorised in the Member States of the EEA under the following names:

Netherlands	Ofloxacin Devatis 3 mg/ml, oogdruppels, oplossing, Verpakking voor éénmalig gebruik
Germany	Ofloxacin Devatis 3 mg/ml Augentropfen, Lösung im Einzeldosisbehältnis

Deze bijsluiter is voor het laatst goedgekeurd in november 2019.