

1.6 Product information

1.17.2 Patient information Leaflet (Auroflox (ofloxacin Ophthalmic solution 0.3%w/v))

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What Ofloxacin ophthalmic solution is and what it is used for
2. Before you use Ofloxacin ophthalmic solution
3. How to use Ofloxacin ophthalmic solution
4. Possible side effects
5. How to store Ofloxacin ophthalmic solution
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1. What Ofloxacin ophthalmic solution is and what it is used for

Ofloxacin ophthalmic solution is an eye-drop used to treat external eye infections such as some types of conjunctivitis.

Ofloxacin ophthalmic solution belongs to a group of medicines called 4-quinolone antibacterial agents.

Ofloxacin ophthalmic solution is not recommended for use in infants below the age of one year

2. Before you use Ofloxacin ophthalmic solution

Do not use Ofloxacin ophthalmic solution

- If you are allergic (hypersensitive) to ofloxacin, benzalkonium chloride, any of the other ingredients, or any other quinolones.

Take special care with Ofloxacin ophthalmic solution: This product should be used with caution in patients sensitive to other quinolone antibacterial agents.

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

This product should be used with caution in patients with a defect or ulceration of the surface of the eye.

Ofloxacin ophthalmic solution potentially increases sensitivity to sunlight. You should avoid exposure to direct sunlight or sun during use of Ofloxacin ophthalmic solution

Heart problems: Caution should be taken when using this kind of medicine, if you were born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart), have salt imbalance in the blood (especially low level of potassium or magnesium in the blood), have a very slow heart rhythm (called 'bradycardia'), have a weak heart (heart failure), have a history of heart attack (myocardial infarction), you are female or elderly or you are taking other medicines that result in abnormal ECG changes (see section Taking other medicines).

Using other medicines: Please tell your doctor or pharmacist if you are using or have recently used any other medicine, including medicines obtained without a prescription.

You must tell your doctor if you are taking other medicines that can alter your heart rhythm: medicines that belong to the group of anti-arrhythmics (e.g. quindine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), tricyclic antidepressants, some antimicrobials (that belong to the group of macrolides), some antipsychotics.

Pregnancy and breast-feeding: Tell your doctor before you start using Ofloxacin ophthalmic solution if you are pregnant or if you are breast-feeding. Your doctor can then decide whether you can use Ofloxacin ophthalmic solution.

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

Children: There is limited experience of the use of Ofloxacin ophthalmic solution in children. Talk to your doctor before you start using Ofloxacin ophthalmic solution in children.

Driving and using machines:

Your sight may become blurred for a short time just after using Ofloxacin ophthalmic solution. You should not drive or use machines until your sight is clear again

Important information about some of the ingredients of Ofloxacin ophthalmic solution

Contact lenses

- Normally you should not wear contact lenses whilst being treated with this product. However, there may be situations where use of contact lenses is unavoidable. In these situations remove the lenses before using Ofloxacin ophthalmic solution. Wait at least 15 minutes after using the eye drops before putting your lenses back in your eyes.
- A preservative in Ofloxacin ophthalmic solution (benzalkonium chloride) may cause eye irritation and is also known to discolour soft contact lenses.

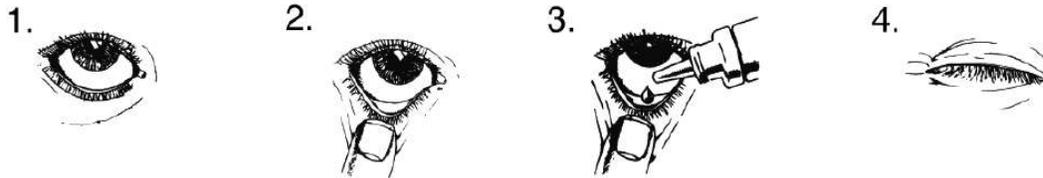
3. How to use Ofloxacin ophthalmic solution

Always use Ofloxacin ophthalmic solution exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is 1 or 2 drops into the affected eye(s) every 2 to 4 hours for the first 2 days and then 4 times a day from then on.

To be effective Ofloxacin ophthalmic solution must be taken regularly. The length of treatment should not exceed ten days.

Instructions for use You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first use it. Apply your eye drops in the following way:

1. Wash your hands. Tilt your head back and look at the ceiling.
2. Gently pull the lower eyelid down until there is a small pocket
3. Turn the bottle upside down and squeeze it to release one or two drops into each eye that needs treatment.
4. Let go of the lower lid, and close your eye for 30 seconds



If a drop misses your eye, try again.

To avoid contamination, do not let the tip of the dropper touch your eye or anything else. Replace and tighten the cap straight after use.

The proper application of your eye drops is very important.

If you have any questions ask your doctor or pharmacist.

If you use more Ofloxacin ophthalmic solution than you should

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

If, by accident, anyone drinks this medicine, contact your doctor straight away.

If you forget to use Ofloxacin ophthalmic solution

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.

Then 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 ophthalmic solution Ofloxacin ophthalmic solution should be used as advised by your doctor. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Ofloxacin ophthalmic solution can cause side effects, but not everyone gets them

Serious side effects:

If you have one or more of the following side effects, you may have had a serious allergic reaction. Stop taking Ofloxacin ophthalmic solution immediately and contact your physician.

Allergic reactions: Frequency not known (cannot be estimated from available data)

- Allergic reactions in the eye (including itchiness of the eye and/or eyelid)
- Inflammation of the skin due to allergy (including: rash, itching or hives)
- Severe sudden life-threatening allergic reaction (Anaphylactic) presenting as swelling beneath the skin that can occur in areas such as the face, lips or other parts of the body, swelling of the mouth, tongue or throat that can obstruct the airways which may cause wheezing, difficulty swallowing, breathing or shortness of breath

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

The following side effects are also known to occur: You should see your doctor if any of the following side effects prove troublesome or if they are long-lasting.

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

- Eye irritation
- Ocular discomfort

Frequency not known (cannot be estimated from available data)

Side effects affecting the eye:

- Visual disturbance
- Tearing
- Inflammation
- Redness
- Sensitivity to light
- A feeling that something is in your eye
- Eye swelling
- Swelling around the eyes (including eyelid swelling)
- Eye pain
- Dryness (mild stinging or burning)

Side effects affecting the body:

- Dizziness
- Nausea

Side effects affecting the heart:

- Abnormal fast heart rhythm
- Life-threatening irregular heart rhythm
- Alteration of the heart rhythm (called 'prolongation of QT interval', seen on ECG electrical activity of the heart)

4. How to store Ofloxacin ophthalmic solution

Keep out of the reach and sight of children.

Once you have opened the bottle do not use it longer than 28 days, even if there is solution remaining.

Do not use Ofloxacin ophthalmic solution after the expiry date which is stated on the bottle label and the bottom of the carton after EXPIRY. The expiry date refers to the last day of that month.

Do not store above 30°C. Do not use Ofloxacin ophthalmic solution if you notice the tamper-proof seal on the bottle is broken. Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

5. Further Information

What Ofloxacin ophthalmic solution contains

- The active substance is Ofloxacin 0.3% w/v.
- The other ingredients are benzalkonium chloride, sodium chloride and purified water

What Ofloxacin ophthalmic solution looks like and contents of the pack

Ofloxacin ophthalmic solution is an eye drop solution in a LDPE container. Each carton contains one container with Package insert.

Marketing Authorisation Holder:

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Manufacturer

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