Package leaflet: Information for the user

Ofloxacin mibe, 3 mg/ml eye drops solution

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 effect not listed in this leaflet. See section 4.

What is in this leaflet

1. What <product name> is and what it is used for

<product name> is an eye drop to treat eye infections of the anterior segment caused by ofloxacin sensitive organisms.

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

2. What you need to know before you use <product name>

Do not use <product name>:

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

Warnings and precautions
Talk to your doctor or pharmacist before using <product name>
- if you excessively expose yourself to sunlight or ultraviolet light (e.g. sunlamp, solarium etc.) during the treatment with <product name>. Both are to be avoided due to a potential sensitivity to light
- if you are sensitive to other quinolone antibacterial agents
- if you wear soft contact lenses. Avoid to wear contact lenses when you have an eye infection (see section "<product name> contains benzalkonium chloride").

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

As with other antibiotics an increase of non-sensitive pathogens may also occur under long term treatment with <product name>. If such an infection should occur during treatment, your doctor will take appropriate measures.

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

<product name> if you develop pain or swelling of the tendons (tendinitis).

Children and adolescents

Safety and effectiveness in infants below the age of one year have not been established.
Talk to your doctor before you start using this medicine in children.

Other medicines and <product name>
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

Since the systemic exposure of oflaxacin is anticipated to be very low after use of <product name>, no relevant interactions are however expected.

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

Pregnancy and breast-feeding
You must tell your doctor if you are pregnant or breast-feeding. Your doctor will advise if you can use this medicine.

Driving and using machines
Application of <product name> may lead to blurred vision. These symptoms may last for a few minutes. Do not use machinery, work without firm hold or drive during this time.

<product name> contains 0.025 mg benzalkonium chloride per ml
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 <product name>

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist, if you are not sure.

For all ages the recommended dose is:
Instill **1 drop** of <product name>
- **every 2 to 4 hours** into the conjunctival sac of the affected eye(s) **for the first two days**
- and **4 times a day** from then on.

Contact your doctor in case your eye infection gets worse or does not improve within some days.

Do not use the product for more than 14 days.

Note: If you are also using other eye drops/eye ointments, an interval of approximately 15 minutes should be observed between the doses and any eye ointment should always be applied last.

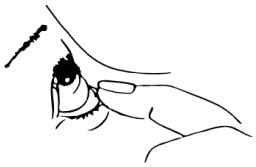
Directions for use
You must not use the content of the bottle if the tamper-proof closure on the bottle neck is broken before you first use it. To open the bottle unscrew the cap by turning it until the tamper-proof closure breaks. Instil the eye drops as follows:

Wash your hands.

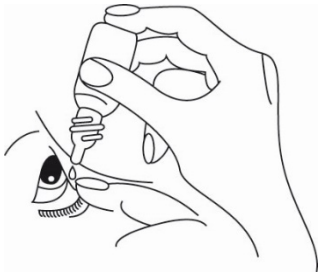
To prevent contamination, please ensure that the dispenser tip does not touch your eye nor the eyelid or the area around the eye or any other objects.

Take <product name> and prepare a mirror.

Open the bottle. Hold the bottle between thumb and fingers with the opening to the bottom. Lean back your head. Pull the lower eyelid down with the index finger, until some kind of sac forms between eyelid and eye.



Position the tip of the dripper very closely to your eye. Use the mirror if necessary. Look upwards and drop one drop into the conjunctival sac by slightly pressing the bottle.



Close your eye and press onto the corner of your eye beside the nose for a minute. This prevents <product name> from passing into the rest of the body via the tear duct.

If you use the eye drops in both eyes, repeat the procedure for the other eye.

Immediately after use, close the bottle by screwing the cap back on tightly in order to avoid contamination.

Wipe off excess fluid from your cheek with a clean cloth.

Correct administration of the eye drops is very important. If you have any questions, ask your doctor or pharmacist.

If you use more <product name> than you should
No case of overdose has been reported so far.

If systemic side effects occur following incorrect use or an accidental overdose these are to be treated systemically. Please contact your doctor in this case.

If you forget to use <product name>

Do not use a double dose to make up for a forgotten dose. Apply the forgotten dose as soon as you remember. Afterwards, proceed with the same amount and in the same interval/rhythm as stated above, or as instructed 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, this medicine can cause side effects, although not everybody gets them.

If an allergic reaction (including eye allergy) occurs stop using the eye drops and contact your doctor immediately. The frequency of this side effect is very rare (may affect up to 1 in 10,000 people).

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of < product name >, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. The frequency of this side effect is not known (cannot be estimated from available data).

Hypersensitivity reactions in the form of redness of the conjunctiva and/or mild burning in the treated eye are possible. However, these symptoms are usually short term. The frequency of this side effect is not known (cannot be estimated from available data).

The following other side effects are known to occur:

Common (may affect up to 1 in 10 people):
- Eye irritation.
- Ocular discomfort.

Rare (may affect up to 1 in 1,000 people):
- Corneal deposits (especially in patients with pre-existing corneal diseases)

Not known (frequency cannot be estimated from the available data):
- Dizziness
- Vision blurred
- Sensitivity to light
- Swelling of the eye, face or around the eyes (including eyelid swelling)
- A feeling that something is in the eye
- Tearing
- Dry eye
- Eye pain
- Itching of the eye or eyelids
- Redness of the eyes
- Nausea
- Inflammation of the conjunctiva
- Corneal inflammation

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly:

<to be completed nationally>.

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

5. How to store <product name>

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 outer carton and label after {abbreviation used for expiry date}. The expiry date refers to the last day of that month.
After opening, do not use the eye drops after 4 weeks.

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

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 <product name> contains

- The active substance is: ofloxacin.
  1 ml solution contains 3 mg ofloxacin.
  One single dose (1 drop) contains 0.1 mg ofloxacin.
- The other ingredients are:
  Sodium chloride, benzalkonium chloride, hydrochloric acid and sodium hydroxide solution (for pH adjustment), water for injections.

What <product name> looks like and contents of the der pack
<product name> is a clear yellowish eye drops solution.
Each bottle contains 5 ml eye drops solution.

<product name> is available in packs with

1 x 5 ml
2 x 5 ml
3 x 5 ml and
6 x 5 ml

eye drops, solution.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<to be completed nationally>

This medicinal product is authorised in the member states of the EEA under the following names:

Germany	<product name>
Poland	<product name>
Sweden	<product name>

This leaflet was last revised in 2019-11-14.