

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Floxal® Eye ointment

Active ingredient

1 g contains 3 mg ofloxacin

Inactive ingredients and allergens, see section 2 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

To treat infections of the anterior eye sections caused by ofloxacin-sensitive pathogens (bacteria):

- chronic conjunctivitis
- keratitis and corneal ulcers
- chlamydia infections

Therapeutic group: Gyrase inhibitor antibiotics, fluoroquinolones.

2. Before using this medicine

Do not use this medicine if:

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| <ul style="list-style-type: none">• You are sensitive (allergic) to the active ingredient (ofloxacin), to other quinolones or to any of the other ingredients in this medicine (see section 6 'Additional information').• You are breastfeeding. |
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Special warnings about using this medicine

Talk to your doctor before treatment with Floxal®.

During treatment with Floxal®, remember the following:

- Tendon swelling and rupture have occurred in patients taking oral or intravenous fluoroquinolones, particularly in older patients and in those treated concurrently with corticosteroids. Stop using Floxal® and consult your doctor if you develop pain or swelling of the tendons (tendinitis).
- It is not recommended to use contact lenses during eye infection.
- Extensive sunbathing or use of UV light (e.g. sunbathing lamps, solarium) should be avoided if possible.
- Floxal® should be used with caution in patients with corneal defects or corneal ulcers.

- As with other antibiotics, also in the case of long-term use of Floxal[®], there is a possibility of increase in non-sensitive organisms. If such infections develop during treatment, your doctor should take appropriate measures.
- Use Floxal[®] with caution if you have hypersensitivity to other quinolone antibiotics.

Children and adolescents

There is no information regarding the safety and efficacy of using the medicine in children below 1 year of age.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Interactions with other medicines are unknown.

Pregnancy and breastfeeding

If you are pregnant, breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Although there is no evidence of development of congenital defects (teratogenicity) in humans, if possible, use of this medicine should be avoided during pregnancy.

Since ofloxacin is excreted in breast milk, do not breastfeed while using this medicine.

Driving and using machines

After application in the eye, the medicine may cause blurred vision for several minutes.

Therefore, during this time, you must not operate machines or drive.

Important information about some of this medicine's ingredients

This medicine contains lanolin (wool fat), which may cause local skin irritation (e.g. contact dermatitis).

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The medicine is intended for use in the eye.

Only your doctor will determine your dose and how you should use this medicine.

If not instructed otherwise, the recommended dosage is usually:

Apply a 1 cm long piece of the ointment (equivalent to 0.12 mg ofloxacin) in the sick eye 3 times a day (5 times a day for chlamydia infections). Do not use the medicine for longer than 14 days.

Note: If you are additionally using other eye drops/eye ointments, keep an interval of 15 minutes between the medicines, and always apply Floxal[®] ointment last.

Do not exceed the recommended dose.

- Do not swallow.
- For external use only.

If you use a higher dose of Floxal[®] than you should

No cases of overdose have been reported so far.

If you apply too much ointment, wash the eye with water.

If you forget to use Floxal®

Do not apply a double quantity to make up for the forgotten dose, but apply the medicine as soon as you remember, and then apply the same quantity at the same time intervals/frequency as described above or as instructed by your doctor.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop treatment with this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take a medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Floxal® may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

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

Hypersensitivity manifested by conjunctival redness and/or slight stinging in the treated eye may occur. In most cases, these symptoms last for a short time only.

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

Eye irritation, ocular discomfort.

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

Corneal sediments, especially in pre-existing corneal diseases.

Very rare side effects (affect up to 1 in 10,000 users):

Systemic (general) hypersensitivity reactions (including dyspnoea, swelling, swollen tongue, anaphylactic shock).

Side effects of unknown frequency (the frequency of these effects has not been established yet):

Blurred vision, increased tearing, dry eye, eye pain, allergic reactions in the eye (including itching of the eye or eyelid), sensitivity to light, swelling around the eyes (including eyelid swelling), redness of the eyes, nausea, swelling of the face, dizziness, foreign body sensation in the eye, conjunctivitis, corneal inflammation.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store the medicine below 25°C.
- After first opening the tube, use the medicine within 6 weeks.

6. Additional information

In addition to the active ingredient, this medicine also contains:

White petrolatum, liquid paraffin, wool fat.

What the medicine looks like and contents of the pack:

A light yellow ointment of soft consistency.

Each pack contains a tube with 3 g of ointment.

Registration holder's name and address:

Fischer Pharma RX Ltd., 7 Hamasger St., Or Yehuda, 6022307

Manufacturer's name and address:

Dr. Gerhard Mann, chem.-pharm. Fabrik GmbH, Brunsbutteler Damm 165/173 Berlin, Germany

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
165-34-35520-00

Revised in July 2023 according to MOH guidelines.

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