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

This medicine is dispensed with a doctor's prescription only

OFLOX®
Ophthalmic Solution

Active ingredient and concentration:
Ofloxacin 0.3% w/v

Inactive ingredients and allergens in this medicine: See section 2 under '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 further questions, consult your doctor or pharmacist.
This medicine has been prescribed to treat your illness/for you. Do not pass it on to others. It may harm them, even if it seems to you that their illness/medical condition is similar to yours.
This medicine is not intended for children or adolescents.

1. What is this medicine intended for?
Oflox is for the treatment of external ocular infections caused by ofloxacin-sensitive organisms.
Therapeutic group: anti-infective from the fluoroquinolone group.

2. Before using this medicine
Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient ofloxacin or to any of the other ingredients in this medicine that appear in section 6 (e.g. benzalkonium chloride) or other quinolones.
- In children and adolescents.
- You are pregnant or may be pregnant or breast-feeding.

Special warnings about using this medicine
Before using Oflox, tell your doctor if you have or you suffer from:

- a defect or ulceration of the surface of the eye.
- epilepsy or other brain or nerve disorders.
- liver or kidney problems.
- severe dehydration.

Use of contact lenses is not recommended in patients receiving treatment for an eye infection. However if you do need to wear contact lenses, read the section 'Important information about some of this medicine's ingredients'.
serious skin problems have been reported when using other products that contain ofloxacin.
Oflox may increase sensitivity to sunlight. Avoid exposure to direct sunlight or sun while using Oflox.

Heart problems:

Use this type of medicine with caution, if:

- you were born with or have a family history of prolonged QT interval (seen on ECG, which records the electrical activity of the heart).
- you have salt imbalance in the blood (especially low level of potassium or magnesium in your blood).
- you have a very slow heart rhythm (called 'bradycardia').
- you have a weak heart (heart failure).
- you have a history of heart attack (myocardial infarction).
- you are a woman or elderly, or you are taking other medicines that result in abnormal ECG changes (see section 'Drug interactions').

Children and adolescents

Oflox should not be used by children or adolescents.

Drug interactions

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

You must tell your doctor if you are taking other medicines that can affect your heart rhythm: medicines that belong to the group of antiarrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), tricyclic antidepressants, some antimicrobial medicines (that belong to the group of macrolides), some antipsychotics.

Pregnancy and breast-feeding

Do not use Oflox during pregnancy or if you are breast-feeding. 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.

Driving and using machines

Oflox may cause short-term blurring of vision when used. Do not drive or operate hazardous machinery unless your vision is clear.

Important information about some of this medicine's ingredients

Oflox contains Benzalkonium chloride.

This medicine contains 0.05 mg of benzalkonium chloride in 1 ml of solution which is equivalent to 0.005% w/v.

Benzalkonium chloride is a preservative which may be absorbed by soft contact lenses and may change the colour of the contact lenses. It is recommended that you do not wear contact lenses whilst being treated with this medicine. However, there may be situations where use of contact lenses is unavoidable. In these situations, 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 this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dosage and treatment regimen of this medicine. Only your doctor will determine your dose and how you should take this medicine.

Adults

The usual recommended dose is:

One or two drops, three or four times daily in the affected eye(s). In most cases, treatment should not be continued for more than ten days. Talk to your doctor if your symptoms persist for more than ten days.

Do not exceed the recommended dose.

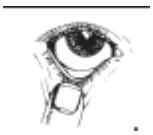
Do not swallow.

Directions for use:

Oflox comes as eye drops. Your prescription label tells you how many drops to use at each dose.

Contact lenses should not be worn during instillation of the drug. After instillation, you should wait at least 15 minutes before putting them back in.

Apply your eye drops in the following way:

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

Avoid touching the dropper tip against 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.

Long-term use may result in a new bacterial infection which cannot be successfully treated with Oflox.

If you have accidentally taken a higher dose

The application of too many drops is unlikely to lead to unwanted side effects. If you accidentally place too many drops in your eye(s), apply your next dose at the scheduled time.

If a child has accidentally swallowed some of this medicine, proceed immediately to a doctor or hospital emergency room, and bring the medicine package with you.

If you forget to take the medicine
If you forget to take the medicine, apply it as soon as you remember. If, however, it is almost time for your next dose, you should omit the missed dose altogether and then follow your normal routine.
Persist with the treatment as recommended by the doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop using this medicine
Oflox should be used as instructed by your doctor.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take your medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. <u>Side effects:</u>
As with any medicine, using **Oflox** may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Serious side effects:
If any side effects associated with an allergic reaction appear, stop using Oflox and contact immediately your doctor. The signs and symptoms of an allergic reaction are presented below:
<u>Allergic reactions:</u>
Unknown frequency (the frequency of these effects has not been established yet)
- Allergic reactions in the eye (including itching in the eye and/or eyelid).
- Inflammation of the skin due to allergy (including rash, itching or hives).
- Severe sudden life-threatening allergic reaction (anaphylactic reaction) presenting as swelling beneath the skin that can occur in areas such as the face, lips, or other parts of the body, swelling of your 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 Oflox, 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 happen:
Common side effects - effects that occur in 1-10 in 100 users
- Eye irritation
- Ocular discomfort

Unknown frequency (the frequency of these effects has not been established yet)
<u>Side effects affecting the eye:</u>
- visual disturbance
- tearing
- inflammation
- redness

- sensitivity to light
- a feeling that something is in your eye
- eye swelling
- swelling around the eye (including eyelid swelling)
- eye pain
- dryness (mild stinging or burning)

Side effects affecting the body:

- dizziness
- headache
- numbness
- nausea

Side effects affecting the heart:

- abnormal fast heart rhythm
- life-threatening irregular heart rhythm
- alternation of the heart rhythm (called 'prolongation of QT interval', seen on ECG electrical activity of the heart)

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 of 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?

Avoid poisoning! This medicine, and all other medicines, must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

- Store below 25°C.
- Keep out of the reach and sight of children.
- Do not use the medicine after the expiry date (exp. date) which is stated on both the label on the bottle and on the carton that the bottle is packed in. The expiry date refers to the last day of that month.

Do not use the product if the tamper-proof seal on the bottle is broken.
Throw the bottle away 28 days after opening even if there is solution remaining.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
sodium chloride, benzalkonium chloride, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment) and purified water.

What the medicine looks like and what are the contents of the package:
Oflox is an eye-drop and comes in a 5 ml bottle. The solution is clear to yellow-light green solution.

Manufacturer's name and address: Allergan Pharmaceuticals Ireland, Castlebar Road, Westport, County Mayo, Ireland.

Registration holder's name and address: AbbVie Biopharmaceuticals Ltd., 4 Haharash St., Hod Hasharon, Israel.

Revised in March 2023 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 117-23-27973