

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

This medicine is dispensed with a doctor's prescription only

# **Oflo-Avenir**

Eye Drops, Solution

**Active ingredient and concentration:**

Ofloxacin 0.3% w/v

Inactive ingredients and allergens: 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 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. **This medicine is not intended for children or adolescents.**

**1. What is this medicine intended for?**

**Oflo-Avenir** is for the topical treatment of external eye infections such as conjunctivitis.

**Therapeutic group:** Antibiotic 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 any of the other ingredients in the medicine that are listed in section 6 (e.g. benzalkonium chloride) or other quinolines.
- In children and adolescents.
- If you are pregnant or breast-feeding.

**Special warnings about using this medicine**

**Before using Oflo-Avenir 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'.

There are reports of serious skin problems when using other products that contain ofloxacin.

**Oflo-Avenir** may increase sensitivity to sunlight. Avoid exposure to direct sunlight or

sun while using **Oflo-Avenir**.

### **Heart problems:**

Use this type of medicine with caution, if:

- you have family history of or were born with 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 (bradycardia).
- you have a weak heart (you suffer from 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 on taking other medicines).

### **Children and adolescents**

**Do not give this medicine to 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.**

Especially if you are taking other medicines that can alter 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 (from a class called macrolides), some antipsychotics.

### **Pregnancy and breast-feeding**

Do not use **Oflo-Avenir** during pregnancy or while 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**

**Oflo-Avenir** 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**

**Oflo-Avenir contains benzalkonium chloride**

**This medicine contains 0.05 mg benzalkonium chloride in each 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 product. However, there may be situations where use of contact lenses is unavoidable. In these situations, you should remove your contact lenses before using this medicine and put them back in 15 minutes later.

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 the medicine according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dosage or about how to take this medicine. Only your

doctor will determine your dosage and how you should take the medicine. The recommended dosage is usually: One or two drops, three or four times daily in the affected eye(s).

### **Treatment duration**

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. This medicine is for external use only.

### **Directions for use**

**The medicine comes as eye drops. Your prescription states 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.

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.

The bottle of drops may not be full; this is done to enable better control of the rate of instillation.

Apply your eye drops in the following way:

<p>1.</p>  <p>Wash your hands. Tilt your head back and look at the ceiling.</p>	<p>2.</p>  <p>Using your index finger, gently pull down the lower eyelid to create a small pocket.</p>	<p>3.</p>  <p>Turn the bottle upside down and squeeze it to release one drop into the pocket created in each eye that needs treatment.</p>	<p>4.</p>  <p>Close your eyes gently. Do not blink. Keep your eyes shut for 1-2 minutes.</p>
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Immediately after putting the drops in your eye, use your middle finger to press the inner corner of the affected eye. Continue pressing for 1-2 minutes after putting the drops in your eye. This helps prevent the medicine from being absorbed into your body, and in this way helps prevent side effects.

- After using the medicine, wash your hands carefully to remove any medicine residue.
- To avoid spreading the infection, do not use the same container of medicine for more than one person.

The proper application of your eye drops is very important. If you have any questions, consult your doctor or pharmacist.

Long-term use may result in a new bacterial infection, which cannot be treated with **Oflo-Avenir**.

#### **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 it is almost time for your next dose, you should skip the missed dose and then follow your normal routine.

#### **If you stop using Oflo-Avenir**

The medicine should be used according to your doctor's instructions.

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

Persist with the treatment as recommended by the 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 the dose each time 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. Side effects**

Like all medicines, **Oflo-Avenir** 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 you experience any side effects associated with an allergic reaction, stop using Oflo-Avenir immediately and talk to your doctor. The signs and symptoms of an allergic reaction are listed below:**

Allergic reactions:

**Unknown frequency** (cannot be estimated from the existing data)

- 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, difficulty breathing or shortness of breath.
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of **Oflo-Avenir**, appearing initially as reddish target-like spots or circular patches often with blisters on the trunk.

**The following side effects are also known to occur:**

**If any side effect gets worse or lasts a long time, or if you notice any side effects that are not on the list, tell your doctor or pharmacist.**

**Common side effects** (affects 1-10 in 100 users):

- Eye irritation
- Ocular discomfort

**Unknown frequency** (cannot be estimated from existing data)

**Side effects that affect the eye:**

- visual disturbance
- tearing
- inflammation
- redness
- sensitivity to light
- a feeling that a foreign object is in your eye
- eye swelling
- swelling around the eye (including eyelid swelling)
- eye pain
- dryness (mild stinging or burning)

**Side effects that affect the body:**

- dizziness
- headache
- numbness
- nausea

**Side effects that affect the heart:**

- abnormal fast heart rhythm
- life-threatening heart rate disorders (life-threatening irregular heart rhythm)
- changes in heart rhythm (called 'QT interval prolongation', seen on ECG, which records the 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.**

### **Report 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](http://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 infants, to avoid poisoning. 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/bottle. The expiry date refers to the last day of that month.
- Store below 25°C.
- Store in the original package to protect against light.
- After the first opening, it may be used for 30 days. Afterwards, throw the bottle away even if there is solution remaining.

### **6. Additional information**

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

Sodium chloride, benzalkonium chloride 50% solution, hydrochloric acid 5N, sodium hydroxide 5N and water for injection.

#### **What the medicine looks like and what are the contents of the package:**

**Oflo-Avenir** is a clear eye drop solution free of visible particles, in a plastic bottle. Each bottle contains 10 ml of solution. Each package contains one bottle.

**Registration holder's name and address:** BioAvenir Ltd., 1 David Hamelech St., Herzelia Pituach 4666101.

**Manufacturer's name and address:** Farmigea, Pisa, Italy.

Revised in December 2021 according to guidelines of Ministry of Health.

Registration number of the medicine in the Ministry of Health's National Drug Registry:  
161-38-35277-00