

# Floxedol® gel

Ofloxacin 0.3%

3 mg/ml eye gel

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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 Floxedol is and what it is used for
2. Before you use Floxedol
3. How to use Floxedol
4. Possible side effects
5. How to store Floxedol
6. Further information

### 1. WHAT FLOXEDOL IS AND WHAT IT IS USED FOR

Floxedol is an ophthalmic gel for eye application. The active ingredient is ofloxacin, a fluoroquinolone group antibiotic. Ofloxacin acts killing some types of causing disease bacteria.

Floxedol is intended for adults and one year old children or older.

Floxedol is used for the treatment of external ocular infections, caused by microorganisms that are sensitive to ofloxacin, such as:

- Conjunctivitis (conjunctival inflammation);
- Blepharitis (eyelids inflammation);
- Blepharconjunctivitis (conjunctival and eyelids inflammation);
- Dacryocystitis (lacrimal excretory system inflammation);
- Keratitis (corneal ulcers).

Floxedol is indicated for the prophylaxis of pre and postoperative infections and eyeball wounds, in general.

### 2. BEFORE YOU USE FLOXEDOL

#### Do not use Floxedol

If you are allergic (hypersensitive) to ofloxacin, to other quinolones (ciprofloxacin, levofloxacin and norfloxacin) or to any of the other components of Floxedol.

#### Take special care with Floxedol

- It is not advisable the use of Floxedol in children under 1 year old, unless the potential benefit outweighs the potential risk. The ofloxacin effectiveness and safety in children under 1 age years old and in newborns conjunctivitis prophylaxis are not well supported;
- If the infection do not improve after one week treatment or in case the eyes symptoms worsen consult your doctor in order to re-evaluate the clinical situation.

#### Using Floxedol with other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

#### Pregnancy and breast-feeding

Consult your doctor or pharmacist before taking any medicine.

#### Pregnancy

It is not advisable to use this medicine during pregnancy. There is no available data on the use of Floxedol by pregnant women. This medicine should only be used during pregnancy when the therapeutical benefits outweighs the potential risks for the fetus.

#### Breast-feeding

It is not advisable to use this medicine during lactation. Ofloxacin may be excreted via breast milk, as such, it should not be used during lactation. The breast-feeding interruption should be medically evaluated in case of treatment.

#### Driving and using machines

The use of Floxedol does not influence the ability to drive or to use machines. If after applying it you experience a blurred vision do not drive or use machines until you have re-established your normal condition.

#### Important information about some of the components of Floxedol

Floxedol contains benzalkonium chloride. Benzalkonium chloride may cause eye irritation. Avoid contact with soft contact lenses since that benzalkonium chloride may discolor them. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion.

### 3. HOW TO USE FLOXEDOL

Always use Floxedol exactly as your doctor tells you to.

You should check with your doctor or pharmacist in case of doubts.

The posology and treatment duration with Floxedol should be medically established according to the patients needs.

Usual recommended dose in children with one year old or above and adults:

1 <sup>st</sup> and 2 <sup>nd</sup> day	Apply 1 to 2 drops every 2 hours or every 4 hours, respectively.
From the 3 <sup>rd</sup> day	4 times a day (every 6 hours)
In more severe conditions (ex.: Keratitis)	The administration may be increased to 1 or 2 drops, applied every hour or every two hours.

Apply the eye gel into the conjunctival sac (between the eye and the eyelid).

Avoid touching the dropper tip with your eyes, fingers or other areas to prevent the contamination of the solution.

Seal the bottle immediately after use.

The treatment must continue for 48 hours after the symptoms disappearance.

In elderly, renal and hepatic insufficiency patients it is not necessary a dose adjustment.

### If you use more Floxedol than you should

No cases of overdose have been reported by the use of this medicine.

If you ingest the content of the bottle, you should see your doctor or pharmacist.

### If you forget to use Floxedol

If you forget to apply the dose, do it as soon as you remember. Do not take a double dose to make up for a missing dose.

### If you stop using Floxedol

Do not interrupt the medicine administration until the end of the medical recommended treatment even if you feel better.

If you have any further questions, ask your doctor or pharmacist.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Floxedol can cause side effects, but these are not experienced by all the users.

In general, ofloxacin ophthalmic gel is well tolerated after topical application.

The side effects are:

Frequency	Secondary effects
Rare	Transient eye irritation characterised by: <ul style="list-style-type: none"><li>- Burn sensation or eye discomfort;</li><li>- Stinging sensation;</li><li>- Redness;</li><li>- Itching (skin irritation);</li><li>- Photophobia (light sensitivity).</li></ul>
Very rare	<ul style="list-style-type: none"><li>- Dizziness;</li><li>- Nausea (sickness).</li></ul>

If any of the referred side effects worsen or in case you experience new ones, not mentioned in this leaflet, inform your doctor or pharmacist.

### 5. HOW TO STORE FLOXEDOL

- Do not store above 25°C;
- Use Floxedol within 28 days, after first opening the bottle;
- Keep out of the reach and sight of children;
- Do not use Floxedol after the expiry date which is stated on the outer label after "EXP". The expiry date refers to the last day of that month;
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer necessary. These measures will help to protect the environment.

### 6. FURTHER INFORMATION

#### What Floxedol contains:

- The active ingredient is ofloxacin;
- The other components are: hydroxypropyl methylcellulose, monosodium phosphate, disodium phosphate, sodium chloride (for osmolality adjustment), benzalkonium chloride (50% solution) and highly purified water. It might contain hydrochloric acid or sodium hydroxide (pH adjustment).

#### Floxedol appearance and contents of the pack.

Floxedol is a clear and lightly yellow gel. Floxedol is supplied in a white polyethylene bottle with dropper insert, containing 10 ml of eye gel. The bottle is sealed with a white screw cap with tamperproof closure (safety closure).

#### Marketing Authorisation Holder and

#### Manufacturer

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### THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines their benefits and risks.
- Do not by your-self interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of the children.

Council of Arab Health Minister,  
Union of Arab Pharmacists