

EXPHAR SA	March 2019	FLOXSOL Eye drops, solution 0.3 %
	Administrative Information and Product Information	Module 1 - Page 32 of 51

### 1.5.3 Patient Information Leaflet (PIL)

Current version

## FLOXSOL Norfloxacin eye drops solution 0.3%

**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 effects not listed in this leaflet.

**In this leaflet:**

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

### **1. WHAT FLOXSOL IS AND WHAT IT IS USED FOR**

This drug is an ocular eye drops solution containing an antibiotic: norfloxacin, from the fluoroquinolone class. This drug is indicated in the topical treatments for some severe ocular infection diseases due to bacteria which can be fight by this antibiotic: severe conjunctivitis, keratitis (bacterial corneal inflammation) and corneal ulcers.

### **2. BEFORE YOU USE FLOXSOL**

**Do not use Floxsol in case of:**

- allergy to any of the components of the eye drops,
- allergy to quinolones.

This drug must not generally be used during breast feeding, unless otherwise advised by your doctor.

**Take special care with Floxsol:**

- Do not inject, do not swallow.
- Treatment must be discontinued immediately at the slightest signs of cutaneous eruption or any signs of an allergic reaction.
- Do not touch the eye with the dropper.
- Wearing contact lenses should be avoided during treatment due to presence of benzalkonium chloride.
- In case of concomitant treatment with other eye drops, instillations should be at least 15 minutes apart.

**Taking other medicines**

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

EXPHAR SA	March 2019	FLOXSOL Eye drops, solution 0.3 %
	Administrative Information and Product Information	Module 1 - Page 33 of 51

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

Use of these eye drops may be considered during pregnancy, if necessary. If you discover that you are pregnant during treatment, consult your doctor: he is the only person who can adapt the treatment to your condition.

Administration of these eye drops is not recommended during breast feeding due to passage of this drug into the mother's milk.

Ask your doctor or pharmacist for advice before taking any medicine.

### **3. HOW TO USE FLOXSOL**

As a guide, the usual dosage is 1 or 2 drops 4 times a day in the affected eye (or eyes).

If you have the impression that the effect of Floxsol is too weak or too strong, consult your doctor or your pharmacist.

In order to be effective, this antibiotic must be used regularly at the prescribed doses and for as long as recommended by your doctor.

This medicine is only for ophthalmic use.

1. wash your hands prior to instillation.
2. avoid touching your eye or eyelid with the tip of the bottle.
3. squeeze one drop inside the lower lid while looking upwards.
4. put the cap back on the bottle after use.

#### **If you use more FLOXSOL than you should:**

In such cases please contact your doctor or pharmacist.

#### **If you forget to use FLOXSOL:**

Do not use a double dose to make up for a forgotten dose but use your drops as planned.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, FLOXSOL can cause side effects, although not everybody gets them.

Most frequently: sensations of burning or local stinging.

More rarely: redness and inflammation of the eye, excessive sensitivity to light and a bitter taste following administration.

Very rarely: deposits in the eye.

Due to the presence of benzalkonium chloride, risk of eczema and irritation.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **5. HOW TO STORE FLOXSOL**

Keep out of the sight and reach of children.

Do not use FLOXSOL after the expiry date which is stated on the carton. Do not store above 30° C. Keep the bottle in the outer pack in order to protect from light. Do not use the eye drops for more than 4 weeks after first opening.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

EXPHAR SA	March 2019	FLOXSOL Eye drops, solution 0.3 %
	Administrative Information and Product Information	Module 1 - Page 34 of 51

## 6. FURTHER INFORMATION

### What does FLOXSOL contain?

The active substance is norfloxacin at a concentration of 3 mg/ml.

The other ingredients are: sodium chloride, disodium edetate, benzalkonium chloride, acetic acid and water for injections.

### What FLOXSOL looks like and contents of the pack

FLOXSOL eye drops is available in bottle containing 5 ml of clear solution.

**This leaflet was last updated in 07/2018**

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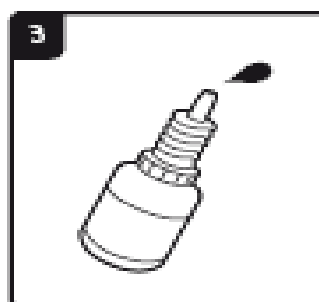
SP-918, Phase-III, RIICO Industrial Area, Bhiwadi, Dist Alwar (Rajasthan)-301019, India



1 With the spike:  
tighten the cap on the  
nozzle



2 The spike in the cap  
will pierce the tip of the  
bottle



3 Dispense drops with  
gentle pressure. Replace  
the cap after every use.