

PACKAGE LEAFLET

Package leaflet: Information for the patient

FLOXSOL0.3 % eye drops solution

Norfloxacin

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 (see section 4).

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. Content of the pack and other 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.

Warnings and precautions

- 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.

Remove contact lenses before application and wait at least 15 minutes before reinsertion (see "FLOXSOL 0.3%, eye drops solution contains benzalkonium chloride"). In case of concomitant treatment with other eye drops, instillations should be at least 15 minutes apart.

Children

Not applicable

Other medicines and FLOXSOL

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

Food, Beverages and FLOXOL

Not applicable

- **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.

If you are pregnant or breastfeeding, or planning to become pregnant, ask your doctor or pharmacist for advice before using this medication.

Driving vehicles and operating machinery

Not applicable

FLOXSOL 0.3%, eye drops in solution contains benzalkonium chloride

This medicine contains 1.2 microgram of benzalkonium chloride per drop.

Benzalkonium chloride can be absorbed by soft contact lenses and change their colour.

Remove contact lenses before application and wait at least 15 minutes before reinsertion.

Benzalkonium chloride can also cause eye irritation, especially if you have dry eye syndrome or corneal clouding (a clear layer on the front of the eye). If you experience any abnormal sensation, tingling or pain in your eyes after using this medicine, contact your doctor.

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.

Administration mode

Local route

IN OCULAR INSTILLATION

Wash hands thoroughly before instillation.

Avoid contact of the tip of the vial with the eye or eyelids.

Instill one drop into each eye, looking upwards and pulling the lower eyelid slightly downwards.

Re-cap the bottle after use.

If you use more FLOXSOL than you should:

Consult your doctor or pharmacist immediately.

If you forget to use FLOXSOL:

Do not use a double dose to make up for a forgotten dose.

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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system

5. HOW TO STORE FLOXSOL

Keep out of the sight and reach of children.

Do not use FLOXSOL after the expiry date indicated on the box and on the bottle. The expiration date refers to the last day of that month.

After opening, the medication should be kept for a maximum of 15 days.

Do not store above 30° C. This medicine is sensitive to light. Keep the bottle in the outer package.

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.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What FLOXSOL contains

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.

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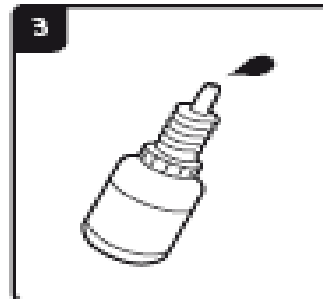
SP-918, Phase-III, RIICO Industrial Area, Bhiwadi, Dist Alwar (Rajasthan)-301019, India



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.