



OFLOXTM 0.3%

(Ofloxacin w/v eyedrops, solution)

Please read this leaflet carefully before you start to take your medicine.

If you have any questions, or are not sure about anything, ask your doctor or pharmacist.

- OFLOX's active ingredient is ofloxacin 3mg/ml.
- It also contains benzalkonium chloride, sodium chloride; hydrochloric acid and sodium hydroxide (for pH adjustment) and purified water.
- OFLOX is an eye-drop and comes in a 5ml bottle.
- The authorisation holder and manufacturer is Allergan Pharmaceuticals Ireland, Westport, Co. Mayo, Ireland.

Uses

OFLOX is for the topical treatment of external eye infections such as conjunctivitis.

Before you take this medicine

Take special care with OFLOX

Tell your doctor before using this medicine:

- (a) If you are pregnant or breast-feeding.
- (b) If you are allergic to the active ingredient, ofloxacin, or any other antibiotic.
- (c) If you are allergic to the preservative benzalkonium chloride or any of the other ingredients.
- (d) If you have a defect or ulceration of the surface of the eye.

Infants

There is very limited information on the use of OFLOX in infants.

If your doctor has prescribed OFLOX for the treatment of your infant and you want to discuss this further, please do not hesitate to contact your doctor again. If your infant becomes ill during treatment with OFLOX please contact your doctor immediately.

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

Important information about some of the ingredients of OFLOX

- Normally you should 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 remove the lenses before using OFLOX. Wait at least 15 minutes after using the eye drops before putting your lenses back in your eyes.
- A preservative in OFLOX (benzalkonium chloride) may cause eye irritation and is also known to discolour soft contact lenses.

Dosage

One or two drops three or four times daily in the affected eye(s). Dosage should not normally be continued for more than ten days. Follow the instructions on your prescription label carefully, and ask your doctor or pharmacist to explain anything that you do not understand.

To be effective it must be taken regularly.

How to use the product

OFLOX comes as eyedrops. 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.



Wash your hands.
Tilt your head back
and look at the
ceiling.

2.



Gently pull down
the lower eyelid
until there is a small
pocket.

3.



Turn the bottle
upside down and
squeeze it to release
a drop into each
eye that needs
treatment.

4.



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.

Missed doses

If you forget to take a dose 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.

Overdosage

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 normal time.

Side Effects

Like all medicines, OFLOX can have side effects, although not everybody gets them.

The following side effects are known to occur, but the number of people likely to be affected is unknown.

Side effects affecting the eye:

- visual disturbance
- tearing
- mild stinging or burning
- irritation
- ocular discomfort
- inflammation
- redness
- itching
- allergic reactions in the eye
- sensitivity to light
- a feeling that something is in your eye
- eye swelling
- dryness

Side effects affecting the body:

- dizziness
- headache
- numbness
- nausea
- allergic reactions
- swelling of the face

You should contact your doctor or pharmacist if these effects are troublesome or if they are long-lasting. You should also see your doctor if you experience any other unusual or unexpected effects.

Storage

Keep the bottle in a safe place out of the reach and sight of children. Store at a temperature that doesn't exceed 25°C.

Warnings

Do not use the product if the tamper-proof seal on the bottle is broken.

The product should not be used after the expiry date. (This is printed on both the label on the bottle and on the bottom of the carton that the bottle is packed in).

Throw the bottle away 28 days after opening, even if there is solution remaining.

This medicine is for your use only. It can only be prescribed by a doctor. Never give it to anyone else. It may harm them even if their symptoms are the same as yours.

Prepared: August 2009

(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 medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists



Allergan Pharmaceuticals Ireland
Westport, Co. Mayo, Ireland

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