

PACKAGE LEAFLET: INFORMATION FOR THE USER

UNIFLOX

0.3% w/v Eye drops, solution

OFLOXACIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 •

What is in this leaflet?

1. What UNIFLOX is and what it is used for
2. Before you take UNIFLOX
3. How to take UNIFLOX
4. Possible side effects
5. How to store UNIFLOX

1. WHAT UNIFLOX IS AND WHAT IS IT USED FOR

UNIFLOX is an eye-drop used to treat external eye infections such as some types of conjunctivitis.

UNIFLOX belongs to a group of medicines called 4-quinolone antibacterial agents.

UNIFLOX is not recommended for use in infants below the age of one year.

2. BEFORE YOU TAKE UNIFLOX

Do not take UNIFLOX

- If you are **allergic** (hypersensitive) to **ofloxacin**, **benzalkonium chloride**, any of the other ingredients, or any other quinolones.

Take special care with UNIFLOX

This product should be used with caution in patients sensitive to other quinolone antibacterial agents.

Long term use may result in a new bacterial infection which does not respond to UNIFLOX.

This product should be used with caution in patients with a defect or ulceration of the surface of the eye.

UNIFLOX potentially increases sensitivity to sunlight. You should avoid exposure to direct sunlight or sun during use of UNIFLOX.

Heart problems:

Caution should be taken when using this kind of medicine, if you were born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart), have salt imbalance in the blood (especially low level of potassium or magnesium in the blood), have a very slow heart rhythm (called 'bradycardia'), have a weak heart (heart failure), have a history of heart attack (myocardial infarction), you are female or elderly or you are taking other medicines that result in abnormal ECG changes (see section *Taking other medicines*).

Using other medicines

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

You must tell your doctor if you are taking other medicines that can alter your heart rhythm: medicines that belong to the group of anti-arrhythmics (e.g. quindine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), tricyclic antidepressants, some antimicrobials (that belong to the group of macrolides), some antipsychotics.

Pregnancy and breast-feeding

Tell your doctor **before** you start using UNIFLOX if you are pregnant or if you are breast-feeding. Your doctor can then decide whether you can use UNIFLOX.

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

Children

There is limited experience of the use of UNIFLOX in children. Talk to your doctor before you start using UNIFLOX in children.

Driving and using machines

Your sight may become blurred for a short time just after using UNIFLOX. You should not drive or use machines until your sight is clear again

Important information about some of the ingredients of UNIFLOX Contact lenses

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

3. HOW TO TAKE UNIFLOX

Always use UNIFLOX exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is **1 or 2 drops** into the affected eye(s) every **2 to 4 hours** for the first **2 days** and then **4 times a day** from then on.

To be effective UNIFLOX must be taken regularly.

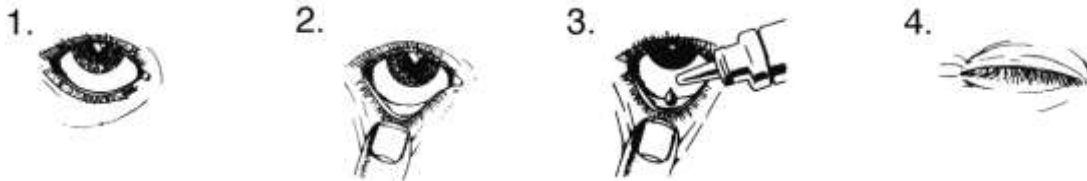
The length of **treatment should not exceed ten days**.

Instructions for use

You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first use it.

Apply your eye drops in the following way:

1. Wash your hands. Tilt your head back and look at the ceiling.
2. Gently pull the lower eyelid down until there is a small pocket
3. Turn the bottle upside down and squeeze it to release one or two drops into each eye that needs treatment.
4. Let go of the lower lid, and close your eye for 30 seconds



If a drop misses your eye, try again.

To avoid contamination, do not let the tip of the dropper touch 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.

If you use more UNIFLOX than you should

If you have placed too many drops in your eye(s), wash the eye(s) with clean water. Apply your next dose at the normal time.

If, by accident, anyone drinks this medicine, contact your doctor straight away. If you forget to use UNIFLOX

If you forget a dose apply it as soon as you remember, unless it is almost time for your next dose, in which case you should miss out the forgotten dose.

Then apply your next dose as usual and continue with your normal routine. Do not use a double dose to make up for a forgotten dose.

If you stop using UNIFLOX

UNIFLOX should be used as advised by your doctor. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, UNIFLOX can cause side effects, but not everyone gets them.

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

You should see your doctor if any of the following side effects prove troublesome or if they are long-lasting:

Side effects affecting the eye:

- Visual disturbance
- Tearing

- Mild stinging or burning
- Irritation
- Ocular discomfort
- Inflammation
- Redness
- Itching
- Allergic reactions in the eye (including itchiness of the eye and eyelid)
- Sensitivity to light
- A feeling that something is in your eye
- Eye swelling
- Dryness

Side effects affecting the body:

- Dizziness
- Nausea
- Allergic reactions (including swelling beneath the skin that can occur in areas such as the face, lips or other parts of the body; rash, itching or hives on the skin; swelling of the mouth, tongue or throat that can obstruct the airways which may cause wheezing, difficulty swallowing, breathing or shortness of breath; severe sudden life-threatening allergic reaction)
- Swelling of the face

Heart problems:

Frequency not known: abnormal fast heart rhythm, life-threatening irregular heart rhythm, alteration of the heart rhythm (called ‘prolongation of QT interval’, seen on ECG electrical activity of the heart).

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE UNIFLOX

Keep out of the reach and sight of children.

Once you have opened the bottle do not use it longer than 28 days, even if there is solution remaining.

Do not use UNIFLOX after the expiry date which is stated on the bottle label and the bottom of the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not use UNIFLOX if you notice the tamper-proof seal on the bottle is broken. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.