EXOCIN® 0.3% w/v
Eye drops, solution
Ofloxacin

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 symptoms 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)

What is in this leaflet:
1. **What EXOCIN is and what it is used for**
2. **What you need to know before you use EXOCIN**
3. **How to use EXOCIN**
4. **Possible side effects**
5. **How to store EXOCIN**
6. **Contents of the pack and other information**

1. What EXOCIN is and what it is used for

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

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

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

2. What you need to know before you use EXOCIN

Do not use EXOCIN
- If you are **allergic** (hypersensitive) to **ofloxacin**, **benzalkonium chloride,** any of the other ingredients, or any other quinolones.

Warnings and precautions
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 EXOCIN.

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

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

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)*.

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

Other medicines and EXOCIN
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, hydroquindine, 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 EXOCIN if you are pregnant or if you are breast-feeding. Your doctor can then decide whether you can use EXOCIN.

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

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

EXOCIN contains Benzalkonium Chloride

This medicine contains 0.05mg of benzalkonium chloride in 1 ml of solution.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

Benzalkonium chloride is a preservative which may be absorbed by soft contact lenses and may change the colour of the 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. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.

3. How to use EXOCIN

Always use EXOCIN 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.

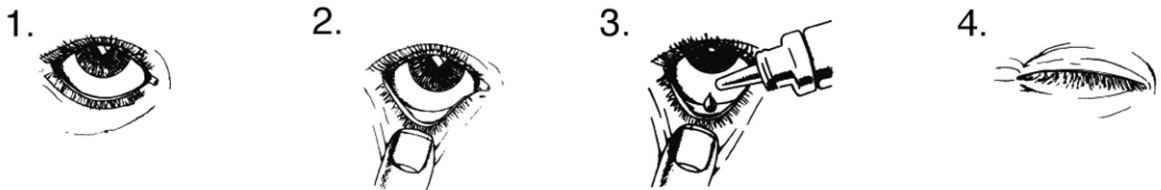To be effective EXOCIN must be taken regularly.

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 EXOCIN 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 EXOCIN
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 EXOCIN

EXOCIN 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, EXOCIN can cause side effects, but not everyone gets them.

Serious side effects:

If you have one or more of the following side effects, **you may have had a serious allergic reaction.** Stop taking EXOCIN immediately and contact your physician.

Allergic reactions:

Frequency not known (cannot be estimated from available data)

- Allergic reactions in the eye (including itchiness of the eye and/or eyelid)
- Inflammation of the skin due to allergy (including: rash, itching or hives)
- Severe sudden life-threatening allergic reaction (Anaphylactic) presenting as swelling beneath the skin that can occur in areas such as the face, lips or other parts of the body, swelling of the mouth, tongue or throat that can obstruct the airways which may cause wheezing, difficulty swallowing, breathing or shortness of breath
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of EXOCIN, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.

The following side effects are also known to occur:

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

Common side effects (may affect up to 1 in 10 people)

- Eye irritation
- Ocular discomfort

Side effects where the frequency is not known (cannot be estimated from available data)

Affecting the eye:

- Visual disturbance
- Tearing
- Inflammation
- Redness
- Sensitivity to light
- A feeling that something is in your eye
- Eye swelling
- Swelling around the eyes (including eyelid swelling)
- Eye pain
- Dryness (mild stinging or burning)

Affecting the body:

- Dizziness
- Nausea

Affecting the heart:

- 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. You can also report side effects directly via:

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

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

5. How to store EXOCIN

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 EXOCIN 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 EXOCIN 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.

6.   Contents of the pack and other information

What EXOCIN contains
- The active substance is Ofloxacin 0.3% w/v.
- The other ingredients are benzalkonium chloride, sodium chloride, sodium hydroxide (to adjust pH), hydrochloric acid (to adjust pH) and purified water

What EXOCIN looks like and contents of the pack
EXOCIN is an eye drop solution in a plastic bottle. Each carton contains 1 plastic bottle with a screw cap.

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Please be ready to give the following information: Ofloxacin 0.3% reference number PL 41042/0064. This is a service provided by the Royal National Institute of Blind People.