

Package Leaflet: Information for the user
EXOCIN: ofloxacin 0.3% w/v eye drops, solution

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

2. What you need to know before you use EXOCIN

Do not use EXOCIN

- If you are allergic (hypersensitive) to ofloxacin, or any of the other ingredients of EXOCIN listed in section 6 (e.g. Benzalkonium chloride), or any other quinolones.
- in children and adolescents.

Warnings and Precautions

Talk to your doctor or pharmacist before using EXOCIN.

Take special care with EXOCIN if you have or suffer from:

- a defect or ulceration of the surface of the eye
- epilepsy or other brain disorders or nerve conditions
- liver or kidney problems
- severe dehydration

Use of contact lenses is not recommended in patients receiving treatment for an eye infection, however if you do need to wear contact lenses, please see section Important information about some of the ingredients of EXOCIN.

Severe skin conditions have been reported with other products containing ofloxacin.

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)

are female or elderly or you are taking other medicines that result in abnormal ECG changes (see section taking other medicines).

Children and Adolescents

EXOCIN should not be used by children or adolescents.

Other medicines and EXOCIN

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. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), tricyclic antidepressants, some antimicrobials (that belong to the group of macrolides), some antipsychotics.

Pregnancy and breast-feeding:

It is recommended that EXOCIN is not used during pregnancy or if you are breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

EXOCIN may cause short term blurring of vision when used. Do not drive or operate hazardous machinery unless your vision is clear.

EXOCIN contains Benzalkonium chloride

This medicine contains 0.05mg of benzalkonium chloride in 1ml of solution which is equivalent to 0.005% w/v.

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

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.

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.





Adults

The usual dose is 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. Talk to your doctor if symptoms persist for more than 10 days.

EXOCIN comes as eye drops. 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:

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

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

If you use more EXOCIN than you should

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.

If you forget to use EXOCIN

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.

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, although not everybody gets them.

Serious side effects:

If you get any side effects related to an allergic reaction, stop using EXOCIN immediately and talk to your doctor –the signs and symptoms of an allergic reaction are presented below:

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:

If any of the side effects gets serious or long lasting, or if you notice any side effects not listed below, please tell your doctor or pharmacist.

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 eye (including eyelid swelling)
- eye pain
- dryness (mild stinging or burning)

Affecting the body:

- dizziness
- headache
- numbness
- 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 ECGm electrical activity of the heart)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via:

HPRA Pharmacovigilance

Website: www.hpra.ie

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

5. How to store EXOCIN

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

Do not use EXOCIN after the expiry date which is stated on both the label on the bottle and on the bottom of the carton that the bottle is packed in.
Do not use the product if the tamper-proof seal on the bottle is broken.

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

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 protect the environment.

6. Contents of the pack and other information

What EXOCIN contains

- The active substance is ofloxacin
- The other ingredients are benzalkonium chloride, sodium chloride; hydrochloric acid and sodium hydroxide (for pH adjustment) and purified water

What EXOCIN looks like and contents of the pack

- EXOCIN is an eye-drop and comes in a 5ml bottle.

Marketing Authorization Holder

Marketing Authorisation Holder

AbbVie Limited
Citywest Business Campus
Dublin 24
Ireland

Manufacturer

Allergan Pharmaceuticals Ireland
Castlebar Road
Westport
County Mayo
Ireland

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