PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

EXOCIN® Ofloxacin 3,0 mg/ml, ophthalmic solution

Read all of this leaflet carefully before you start using EXOCIN®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- EXOCIN® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT EXOCIN® CONTAINS

- The active substance is ofloxacin.
- The other ingredients are benzalkonium chloride 0,005 % m/v, sodium chloride and purified water.

2. WHAT EXOCIN® 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.

3. BEFORE YOU USE EXOCIN®

Do not use EXOCIN®:

- If you are hypersensitive (allergic) to ofloxacin, benzalkonium chloride, or sodium chloride;
- If you are pregnant or breastfeeding.

Safety and effectiveness in infants below the age of one year have not been established.

Take special care with EXOCIN®:

- If you have a defect or ulceration of the surface of the eye;
- If you are sensitive to other quinolone antibacterial agents.

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using EXOCIN®.

This medicine should not be used during pregnancy or breastfeeding.

Driving and using machinery

On instillation of the eye drops, your vision may be briefly blurred. Do not drive or operate hazardous machinery unless your vision is clear.

Important information about some of the ingredients of EXOCIN®

Contact lenses

Do not use the drops while your contact lenses are in your eyes. Wait at least 15 minutes after using the eye drops before putting your lenses back in your eyes. A preservative in EXOCIN® (benzalkonium chloride) may cause eye irritation and is also known to discolour soft contact lenses.

Using other medicines with EXOCIN®

Always tell your healthcare professional if you are taking other medicine. (This includes complementary or traditional medicines.)

4. HOW TO USE EXOCIN®

Do not share medicines prescribed for you with any other person.

Always use EXOCIN® exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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.

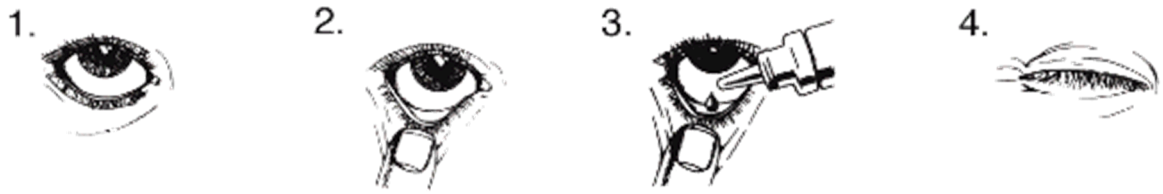
Your doctor will tell you how long your treatment with EXOCIN® will last. Do not stop treatment early. To be effective EXOCIN® must be used regularly. The length of treatment should not exceed ten days. If you have the impression that the effect of EXOCIN® is too strong or too weak, tell your doctor or pharmacist.

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, or in the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or Poison Control Center.

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.

Effects when treatment with EXOCIN® is stopped

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.

5. POSSIBLE SIDE EFFECTS

EXOCIN® can have side effects. Not all side effects reported for EXOCIN® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using EXOCIN®, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Dizziness
- Short lived eye irritation
- Sensitivity to light
- Eye stinging and/or burning
- Eye redness and/or swelling
- Numbness
- Nausea
- Headache
- Itching
- Skin rash
- Difficulty breathing

If any of the side effects become serious, or if you notice any side effects not mentioned in this leaflet, please tell your doctor, pharmacist or other healthcare professional.

Reporting of side effects

If you get side effects, talk to your doctor. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of EXOCIN®.

In case of a side effect, please contact MEAPV@abbvie.com

6. STORING AND DISPOSING OF EXOCIN®

- Store at or below 25 °C.
- Store all medicines out of reach of children.
- Once you have opened the bottle do not use it longer than 30 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 use EXOCIN® if you notice the tamper-proof seal on the bottle is broken.
- Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF EXOCIN®

EXOCIN® is supplied in sterile dropper bottles containing 5 ml solution.

8. IDENTIFICATION OF EXOCIN®

EXOCIN® is a clear, pale to light yellow-green solution practically free from particulate matter.

9. REGISTRATION NUMBER

Z/15.1/347

10. NAME AND ADDRESS OF REGISTRATION HOLDER

AbbVie (Pty) Ltd
Building 7
Waterfall Corporate Campus
74 Waterfall Drive
Midrand
1685
South Africa
Tel: +27 (0)11 031 1600

11. DATE OF PUBLICATION

Date of registration: 9 August 1994
Date of most recent patient information leaflet as approved by Council: 21 April 2023

Access to the corresponding Professional Information

For the professional information please email medicalinfo.za@abbvie.com