

Applicant: FDC SA (Pty) Ltd
Product Name: ZOXAN Eye Drops
(Ciprofloxacin Ophthalmic Solution USP)
Dosage form and strength: Ophthalmic solution, 0.3% w/v

MODULE 1
1.5.5
Date of Review: 2022.03.15
Date of Response: 2022.12.22

Patient Information Leaflet

PROPOSED CLEAN PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PATIENT INFORMATION LEAFLET

ZOXAN Eye Drops 0.3% w/v, Ophthalmic Solution

Ciprofloxacin Hydrochloride USP, 3mg/ml

Read all of this leaflet carefully before you start taking ZOXAN Eye Drops

- 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 personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What ZOXAN Eye Drops is and what it is used for.
2. What you need to know before you use ZOXAN Eye Drops
3. How to use ZOXAN Eye Drops
4. Possible side effects.
5. How to store ZOXAN Eye Drops
6. Contents of the pack and other information.

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1. What ZOXAN Eye Drops is and what it is used for

What ZOXAN is:

ZOXAN Eye Drops belongs to a group of medicines known as quinolone antibiotics.

What ZOXAN is used for:

It is used for the treatment of corneal ulcers and some other bacterial infections of the eye(s).

2. What you need to know before you use ZOXAN Eye Drops

Do not use ZOXAN Eye Drops:

- If you are hypersensitive (allergic) to ciprofloxacin or any other quinolone antibiotic or to any of the other ingredients of ZOXAN eye drops.

Warnings and precautions

Take special care with ZOXAN eye drops

- you must stop using ZOXAN Eye Drops if you develop a hypersensitivity reaction, such as skin rash, itchiness, tingling feeling, swelling of your face or tongue, or shortness of breath;
- use of ZOXAN Eye Drops for a long time may lead to other infections. If your symptoms get worse or suddenly return tell your doctor;
- ZOXAN Eye Drops is preserved with benzalkonium chloride. You should undergo regular eye examinations if you are using ZOXAN Eye Drops for a prolonged period of time. Benzalkonium chloride may cause side effects on your corneal permeability with prolonged or repeated use (see section ZOXAN Eye Drops contains benzalkonium chloride);
- if you feel pain, swelling or inflammation of the tendons while, or soon after taking this medicine, stop treatment and contact your doctor;
- if you are elderly or if you are taking medicines called 'corticosteroids' used to treat conditions

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such as pain and inflammation, asthma or skin problems then, you have a higher risk of getting tendon problems during treatment with ZOXAN Eye Drops. If you experience any inflammation or an inflammatory condition, stop treatment and immediately consult your doctor;

- only use ZOXAN Eye Drops in your eyes.
- do not wear contact lenses (hard or soft) during treatment with ZOXAN Eye Drops.
- in patients with corneal ulcer and frequent administration of ZOXAN Eye Drops, white medication residue has been observed which resolved after continued application of ZOXAN Eye Drops. The precipitate does not preclude the continued application of ZOXAN Eye Drops, nor does it adversely affect the course of the recovery process.

Other medicines and ZOXAN Eye Drops:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ZOXAN Eye Drops with these medicines may cause undesirable interactions.

Tell your doctor if you are taking any of the following medicines:

ZOXAN Eye Drops can react with some other commonly used medicines, such as:

- Warfarin (used to prevent blood clotting).
- Theophylline (used to treat asthma and included in some cough medicines).
- Caffeine.

Pregnancy, breast feeding and fertility

If you are pregnant or breastfeeding, or are planning to have a baby , please consult your doctor , pharmacist or other health care professional before using this medicine.

The safety of ZOXAN Eye Drops in pregnant women and breastfeeding mothers has not been established.

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Driving and using machines

It is not always possible to predict to what extent ZOXAN Eye Drops may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ZOXAN Eye Drops affects them.

If your sight is affected in any way following use of **ZOXAN Eye Drops** you should not drive or operate machinery.

ZOXAN Eye Drops contains Benzalkonium chloride.

There is a preservative in **ZOXAN Eye Drops** (benzalkonium chloride) that can discolour soft contact lenses and cause eye irritation. Therefore, do not use the drops while contact lenses are in your eyes.

Wait at least 15 minutes after using the eye drop before putting your lenses back in.

3. How to use ZOXAN Eye Drops

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

Always use ZOXAN Eye Drops exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

ZOXAN Eye Drops can be used by adults and children over the age of two years.

This will depend on whether you are being treated for corneal ulcers or for some other bacterial infection in your eye.

Corneal Ulcers:

Dosing is continued during the night time.

Day 1:

- Two(2) drops every 15 minutes for the first 6 hours and then 2 drops every 30 minutes

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Day 2:

- Two(2) drops every hour.

Day 3 to Day 14:

- Two(2) drops every 4 hours

Your doctor will tell you if treatment needs to be continued for longer than 14 days.

Other Bacterial conjunctivitis

- 1 or 2 drops every 2 hours for two days while you are awake, then 1 or 2 drops every four hours while you are awake until the bacterial infection is resolved.

It is important that you continue to use ZOXAN Eye Drops for the full treatment period as advised by your doctor.

You should not use ZOXAN Eye Drops for more than 21 days, unless your doctor says otherwise.

Always use ZOXAN Eye Drops exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

Instructions for use:

- Wash your hands before you start.
- Tighten the cap on the nozzle. The spike in the cap will pierce the tip of the vial.
- Hold the bottle pointing down, between your thumb and fingers.
- Tilt your head back.
- Pull down your lower eyelid with a finger, until there is a 'pocket' between the eyelid and your eye.

The drop will go in here.

- Bring the bottle tip close to the eye. Do this in front of a mirror if it helps.
- **Do not touch your eye or eyelid**, surrounding areas or other surfaces with the dropper. It could infect the drops.

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- **Gently press on the base of the bottle** to release one drop at a time
- **Do not squeeze the bottle**, only a gentle press on the bottom is needed.
- If you use drops in both eyes, repeat the steps for your other eye. Put the bottle cap firmly back on immediately after use.

If a drop misses your eye, try again.

If you use more ZOXAN Eye Drops than you should

If you use more ZOXAN Eye Drops than you should it can be washed out of your eye with warm water.

If you or someone else accidentally drinks the contents of ZOXAN Eye Drops, consult your doctor or pharmacist.

If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to use ZOXAN Eye Drops

If you forget to use **ZOXAN Eye Drops**, skip the missed dose and wait until your next dose is due.

Do not use a double dose to make up for forgotten individual doses.

If you stop using ZOXAN Eye Drops

Do not stop using this medicine early, even if your symptoms have disappeared. If you stop using this medicine before you are supposed to, your symptoms may re-occur.

4. Possible side effects

ZOXAN Eye Drops can have side effects.

Not all side effects reported for **ZOXAN Eye Drops** are included in this leaflet. Should your general

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health worsen or if you experience any untoward effects while using **ZOXAN Eye Drops**, please consult your healthcare professional for advice.

If any of the following happens, stop taking ZOXAN Eye Drops and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ZOXAN Eye Drops. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Burning;
- discomfort;
- redness of the eye or inside of the eyelid;
- white particles in your eyes. If you notice white particles in your eyes, continue to use ZOXAN Eye Drops but tell your doctor immediately;
- bad taste in your mouth.

The following side effects have been reported less frequently:

- Itching;
- feeling of something in the eye;
- crusting on the eyelid;

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- swollen eyelid(s);
- decreased vision;
- watery eyes;
- sensitivity to light;
- damage to or staining of the eye surface (cornea);
- eye pain;
- dry eye;
- eye discharge;
- eyelid scales;
- eyelid redness;
- headache;
- dizziness;
- ear pain;
- inflammation inside the nose;
- nasal sinus discharge;
- diarrhoea;
- abdominal pain;
- skin inflammation;
- nausea.

The following side effects have been reported but the frequency is unknown:

- Tendon disorder

If you notice any side effects not mentioned in this leaflet , please inform your doctor or pharmacist.

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Reporting of side effects

If you get 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 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 ZOXAN Eye Drops.

5. How to store ZOXAN Eye Drops

Store all medicines out of reach of children.

Store at or below 25°C.

Discard product 30 days after opening.

Do not refrigerate or freeze.

Do not use the drops after the expiry date on the bottle and the carton.

The expiry date refers to the last day of that month.

Store in original package.

Keep the container in the outer carton.

Return all unused medicine to your pharmacist

Do not dispose of unused medicine in drains or sewerage system

Do not pass this medicine on to others. It may harm them, even if their symptoms are same as yours.

6. Contents of the pack and other information

What ZOXAN EYE DROPS contains

- The active substance is:

Ciprofloxacin hydrochloride equivalent to Ciprofloxacin 0.3% w/v

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- The other ingredients are:

Disodium edentate, Mannitol (pearlitol SD 200), Sodium acetate (anhydrous), Glacial acetic acid, Sodium hydroxide, Hydrochloric acid, Water for Injections.

Zoxan Eye Drops contain Benzalkonium chloride 0.01 % w/v as a Preservative

What ZOXAN Eye Drops looks like and contents of the pack

ZOXAN Eye Drops is a clear colourless solution practically free from particles.

ZOXAN Eye Drops is supplied in 5mL, 10 mL labelled LDPE bottle closed with a white opaque HIPS spike cap packed in a carton with pack insert.

HOLDER OF CERTIFICATE OF REGISTRATION

FDC SA (Pty) Limited
Unit J3, The Willows Office Park,
Farm Road, The willows,
Pretoria, 0081,
South Africa

This leaflet was last revised in

14/03/2023

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A40/15.1/0091

Access to the corresponding Professional Information

Please find the submitted Professional information