

1.3 South African labelling and packaging

1.3.2 Patient Information Leaflet (PIL)

1.3.2.1 Patient Information Leaflet- Approved

SCHEDULING STATUS

S4

PATIENT INFORMATION LEAFLET

OFLOXACIN 0,3 % w/v Eye Drops FDC 5 mL **(Ofloxacin 0.3% w/v)**

Read all of this leaflet carefully before you start using OFLOXACIN 0,3 % w/v Eye Drops FDC

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- **OFLOXACIN 0,3 % w/v Eye Drops FDC** 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 **OFLOXACIN 0,3 % w/v Eye Drops FDC** is and what it is used for.
2. What you need to know before you use **OFLOXACIN 0,3 % w/v Eye Drops FDC**.
3. How to use **OFLOXACIN 0,3 % w/v Eye Drops FDC**.
4. Possible side effects.
5. How to store **OFLOXACIN 0,3 % w/v Eye Drops FDC**.
6. Contents of the pack and other information.

1. What OFLOXACIN 0,3 % w/v Eye Drops FDC is and what it is used for

The active substance is Ofloxacin.

OFLOXACIN 0,3 % w/v Eye Drops FDC is used to treat external eye infections such as some types of conjunctivitis. **OFLOXACIN 0,3 % w/v Eye Drops FDC** belongs to a group of medicines called 4-quinolone antibacterial medicines.

2. What you need to know before you use OFLOXACIN 0,3 % w/v Eye Drops FDC

Do not use OFLOXACIN 0,3 % w/v Eye Drops FDC :

- If you are hypersensitive (allergic) to ofloxacin, or any of the other ingredients of **OFLOXACIN 0,3 % w/v Eye Drops FDC** (listed in section 6);
- If you are pregnant or breastfeeding
- Safety and effectiveness in infants below the age of one year have not been established.

Warnings and precautions

Take special care with **OFLOXACIN 0,3 % w/v Eye Drops FDC**:

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

Stop using **OFLOXACIN 0,3 % w/v Eye Drops FDC** in case of hypersensitivity reactions and contact your medical practitioner.

The symptoms may include

1. Cardiovascular collapse
2. Loss of consciousness
3. Angioedema (swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs).
4. Difficulty breathing or swallowing
5. Hives and
6. Itching

Long term use may result in a new bacterial infection which does not respond to **OFLOXACIN 0,3 % w/v Eye Drops FDC**.

If an allergic reaction to **OFLOXACIN 0,3 % w/v Eye Drops FDC** occurs, discontinue the product and contact your medical practitioner.

For children and adolescents

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

The use of **OFLOXACIN 0,3 % w/v Eye Drops FDC** eye drops in neonates with ophthalmia neonatorum caused by *Neisseria gonorrhoeae* or *Chlamydia trachomatis* is not recommended.

Other medicines and OFLOXACIN 0,3 % w/v Eye Drops FDC :

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

The systemic administration of some quinolones inhibits the metabolic clearance of caffeine and theophylline.

Pregnancy, breast feeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this medicine.

Driving and using machines

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

It is not always possible to predict to what extent **OFLOXACIN 0,3 % w/v Eye Drops FDC** 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 **OFLOXACIN 0,3 % w/v Eye Drops FDC** affects them.

OFLOXACIN 0,3 % w/v Eye Drops FDC contains benzalkonium chloride

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 **OFLOXACIN 0,3 % w/v Eye Drops FDC** (benzalkonium chloride) may cause eye irritation and is also known to discolour soft contact lenses.

3. How to use OFLOXACIN 0,3 % w/v Eye Drops FDC

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

Always use **OFLOXACIN 0,3 % w/v Eye Drops FDC** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The recommended dosage for the treatment of bacterial conjunctivitis is:

One drop every two to four hours for the first two days, then four times daily in the affected eye(s).

Treatment should not exceed ten days.

The recommended dosage regimen for the treatment of bacterial corneal ulcer is:

Days 1 and 2: Instil one to two drops into the affected eye every 30 minutes, while awake.

Awaken at approximately four and six hours after retiring and instil one to two drops.

Days 3 through 7 to 9: Instil one or two drops hourly, while awake.

Days 7 to 9 through treatment completion: Instil one to two drops, four times daily.

Instructions for use

Please follow these instructions carefully when using **OFLOXACIN 0,3 % w/v Eye Drops FDC**.

Use **OFLOXACIN 0,3 % w/v Eye Drops FDC** as prescribed by your doctor.

1. If you use other topically applied ophthalmic medications, they should be administered at least 10 minutes before or after the use of **OFLOXACIN 0,3 % w/v Eye Drops FDC**.

2. Wash your hands before each use.

3. Before using the medication for the first time, be sure the dust cover seal is unbroken.

4. Snap off the dust cover by turning it clockwise to break the seal.

5. Pull off the dust cover

6. Unscrew the tan coloured cap

7. Tilt your head backward and pull your lower eyelid down slightly to form pocket between your eyelid and your eye. Dispense drops with gentle pressure.

8. Replace the tan coloured cap after every use, screw the cap down.

If you use more OFLOXACIN 0,3 % w/v Eye Drops FDC 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 OFLOXACIN 0,3 % w/v Eye Drops FDC

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 OFLOXACIN 0,3 % w/v Eye Drops FDC

OFLOXACIN 0,3 % w/v Eye Drops FDC 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

OFLOXACIN 0,3 % w/v Eye Drops FDC can have side effects.

Not all side effects reported for **OFLOXACIN 0,3 % w/v Eye Drops FDC** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **OFLOXACIN 0,3 % w/v Eye Drops FDC**, please consult your doctor, pharmacist or other healthcare professional for advice.

Serious side effects:

If you have one or more of the following side effects, you may have had a serious allergic reaction. Stop taking **OFLOXACIN 0,3 % w/v Eye Drops FDC** immediately and contact your physician.

Allergic reactions:

Frequency unknown

- 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 **OFLOXACIN 0,3 % w/v Eye Drops FDC**, 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 unknown

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)

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

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 to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store OFLOXACIN 0,3 % w/v Eye Drops FDC

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Keep this medicine out of the sight and reach of children.

Store at temperature below 25°C. Protect from light.

Discard the bottle 28 days after opening, even if there is solution remaining.

Do not use **OFLOXACIN 0,3 % w/v Eye Drops FDC** after the expiry date which is stated on the carton and label after 'Expiry'. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What OFLOXACIN 0,3 % w/v Eye Drops FDC contains

The active substance is Ofloxacin.

The other ingredients are

Sodium Chloride USP

Benzalkonium Chloride NF

Hydrochloric Acid NF

Sodium Hydroxide NF

Water for Injection USP

What OFLOXACIN 0,3 % w/v Eye Drops FDC looks like and contents of the pack

It is available in 5.0 ml LDPE labelled bottle with insert cap assembly comprising of white colored, HDPE screw cap over a LDPE nozzle with tamper evident LDPE dust

cover, sealing the bottle cap. One such bottle is packed in a carton with pack insert.

HOLDER OF CERTIFICATE OF REGISTRATION

FDC SA (Pty) Limited
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South Africa

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Access to the corresponding Professional Information

Scan the QR code to access the corresponding professional Information (PI) and HCR details

