PATIENT INFORMATION LEAFLET
OCUCON

SCHEDULING STATUS:

S4

OCUCON 5mg/mL eye drop solution

Moxifloxacin

Read all of this leaflet carefully before you start using OCUCON

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- OCUCON 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 OCUCON is and what it is used for
2. What you need to know before you take OCUCON
3. How to take OCUCON
4. Possible side effects
5. How to store OCUCON
6. Contents of the pack and other information

1. What OCUCON is and what it is used for

OCUCON contains moxifloxacin, a fluoroquinolone-type antibiotic.

OCUCON is used for the treatment of infections of the eye (conjunctivitis) when caused by bacteria.

OCUCON may also be used to prevent bacterial infections before or after eye surgery.

2. What you need to know before you use OCUCON

Do not use OCUCON:

- if you are hypersensitive (allergic) to moxifloxacin, to other quinolones or any of the other ingredients of OCUCON (see section 6)

Warnings and precautions

Take special care with OCUCON:

- if you experience a severe allergic reaction to OCUCON stop using it and tell your doctor immediately. Allergic reactions include swelling of the hands, feet, ankles, face, lips, mouth or throat which may cause difficulty in breathing, rash or hives, large fluid-filled blisters, sores and ulceration (see Do not use OCUCON)
- if you use OCUCON longer than directed by your healthcare provider, the long-term use may lead to other infections. Discontinue if other infections occur and seek alternative therapy
- if you develop pain or swelling of the tendons (tendinitis), stop taking OCUCON. Tendon swelling and rupture have occurred in people taking oral or intravenous fluoroquinolones, such as moxifloxacin, particularly in older patients and in those treated concurrently with corticosteroids (used to treat inflammation)
- if you have been diagnosed with a condition called gonococcal conjunctivitis (severe infection of the eyes marked by intense swelling of the eyes and eyelids and by a profuse purulent discharge), including gonococcal ophthalmia neonatorum (eye infections occurring in the first 28 days of life), as OCUCON may not be the correct medicine to use
- if you wear contact lenses, stop wearing your lenses if you have any signs or symptoms of an eye infection. Wear your glasses instead. Do not start wearing your lenses again until the signs and symptoms of the infection have cleared and until you have stopped using OCUCON.

Children

- OCUCON is safe and effective and has no impact on the joints of the body that carry our body weight, i.e. the ankles, knees and hips
- OCUCON should not be given to newborn babies with eye infection caused by *Chlamydia trachomatis* or *Neisseria gonorrhoeae* instead they should be given appropriate systemic treatment
- OCUCON should not be used for the treatment of an eye infection caused by *Chlamydia trachomatis* (type of bacteria) in children younger than 2 years of age as it has not been tested in these patients
- OCUCON should not be used in children older than 2 years with eye infection caused by *Chlamydia trachomatis* instead they should be given appropriate alternative medicine.

Other medicines and OCUCON

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

No interaction tests have been done with other eye drops.

If you are using more than one type of eye drop medicine, the medicines must be used at least 5 minutes apart. Eye ointments should be used last.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using OCUCON.

OCUCON has not been proven to be safe in pregnant women.

No effects on pregnancy are anticipated since the systemic exposure to moxifloxacin from topical ocular application is negligible.

OCUCON is presumed to be excreted in breast milk. Your doctor will only prescribe OCUCON if it is safe for you to use, however, at the doses used, OCUCON is not expected to have any effect on the breastfed child.

Driving and using machines

OCUCON has no or negligible influence on the ability to drive and use machines, however OCUCON may cause blurred vision for a short time which may interfere with your ability to drive or use machines. If you experience temporary blurred vision or discomfort after using OCUCON you should wait until these symptoms disappear before driving or using machinery.

It is not always possible to predict to what extent OCUCON 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 OCUCON affects them.

3. How to use OCUCON

Do not share medicines prescribed for you with any other person.
Always use OCUCON exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

For treatment in bacterial infections such as conjunctivitis

The usual dose is one drop in the affected eye or eyes three times a day (in the morning, in the afternoon, and at night). Only use OCUCON in both eyes if your healthcare provider told you to do so.

For removing the bacteria before or after eye surgery (preoperative and postoperative sterilization)

The recommended dose is one drop of OCUCON in the affected eye (s) 5 times per day for 2 days before eye surgery/operation, and 3 times per day for 14 days after eye surgery/operation.

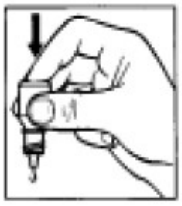
Instructions for the use of OCUCON

- Take the OCUCON eye drops and stand in front of a mirror
- wash your hands
- twist off the cap. After the cap is removed, if the tamper proof seal is loose, remove it before using OCUCON
- open the bottle, being careful not to touch the dropper tip
- hold the bottle, pointing down, between your thumb and fingers. Tilt your head back. Pull down your eyelid with a clean finger, until there is a “pocket” between your eyelid and your eye. This is where you will place the eye drop (Picture 1)
- bring the bottle tip close to the eye. Use the mirror if it helps
- don’t touch your eye or eyelid, surrounding areas or other surfaces with the container or bottle tip. It could infect the drop
- gently press the bottom of the bottle to release one drop of OCUCON at a time (Picture 2)
- after using OCUCON, press a finger into the corner of your eye, by the nose for 2 - 3 minutes. (Picture 3)
- repeat the above steps for your other eye if you are to take drops in both eyes. Ensure that you wash your hands before you proceed with your other eye. This will help prevent the spread of infection from one eye to the other.

How to use



1



2



3

OCUCON is for use as an eye drop only. If a drop misses your eye, try again.

If you are using other eye drops, leave at least 5 minutes between putting in OCUCON and the other drops.

If eye ointments form part of your treatment, they should be used last.

Your doctor will tell you how long your treatment with OCUCON will last. Do not stop treatment early because your infection may return.

If you have the impression that the effect of OCUCON is too strong or too weak, tell your doctor or pharmacist.

If you use more OCUCON than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Although it is unlikely that you are able to use too much OCUCON, in the event that you do, rinse the eyes with warm water. After rinsing, do not put anymore drops OCUCON into your eye until it's time for your next dose.

If you forget to use OCUCON

If you forget to use OCUCON, use a dose as soon as you remember, then continue to use OCUCON at the usual times. Do not use a double dose to make up for a forgotten dose.

If you stop using OCUCON

Even if you feel better, do not alter or discontinue the daily dose of OCUCON without first consulting your doctor as your infection may return.

4. Possible side effects

OCUCON can have side effects.

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

If any of the following happens, stop using OCUCON 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 OCUCON. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- increased heartbeat (palpitations)
- feeling of a lump in the throat

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- eye pain, eye irritation

Less frequent side effects:

- general fatigue, weakness, pale skin (symptoms of a drop in red blood cells - anaemia)
- a bitter or bad taste following instillation of the eye drops
- headache, pins-and-needles sensation
- dry eye, burning or stinging, itching in the eye, redness of the eye, eye surface inflammation or scarring, broken blood vessel in eye, abnormal eye sensation, eyelid abnormality, eyelid itching, redness, swelling or flakes or crusts forming around the root of the eyelashes
- blurred vision, decreased ability to make out the shapes and details of the things you see, tired eyes or difficulty keeping your eyes open
- nose discomfort, throat irritation, sore throat
- vomiting, altered or no taste
- abnormal liver blood tests.

The following side effects have been reported but the frequency for them to occur is not known:

- dizziness
- infection in the eye, eye surface becomes cloudy, corneal swelling, deposits on the eye surface, increased pressure in eye, scratch on surface of eye, eye allergy, eye discharge, increased tear production, sensitivity to light or a feeling that there is something in your eye despite nothing being there
- nausea
- difficulty breathing
- skin rash, abnormal skin sensation, swollen red bumps on the skin, severe itchy skin
- inflammation or rupture of the tendons in the hand, ankle or shoulder.

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. 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 OCUCON. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store OCUCON

Store all medicines out of reach of children.

Store at or below 30 °C.

Use within 28 days of opening.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What OCUCON contains

The active substance is moxifloxacin hydrochloride.

Each 1 mL contains moxifloxacin hydrochloride, equivalent to moxifloxacin 5 mg.

The other ingredients are

Boric acid, sodium chloride, sodium hydroxide (to adjust the pH), water for injection.

What OCUCON looks like and contents of the pack

OCUCON is presented as a clear, greenish-yellow solution free from foreign particles.

OCUCON is packed in a natural LDPE ophthalmic dispenser of 10 mL with a plastic LDPE transparent dropper insert and a white HDPE cap with a tamper proof seal containing 5 mL of eye drops solution.

Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, 7945

Cape Town

South Africa

Tel: + 27 21 707 7000

or 0860-PHARMA (742 762)

This leaflet was last revised in

07 February 2025

Registration number(s)

A51/15.1/0137