

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

GENFLOC 5 mg/ml Ophthalmic Solution

Moxifloxacin. Sterile solution.

Read all of this leaflet carefully before you start using GENFLOC

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

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

1. What GENFLOC is and what it is used for

GENFLOC eye drops are used for the treatment of infections of the eye (conjunctivitis) when caused by bacteria. The active ingredient is moxifloxacin, an anti-infective belonging to a group of antibiotics called fluoroquinolones.

2. What you need to know before you use GENFLOC

Do not use GENFLOC

If you are allergic (hypersensitive) to moxifloxacin, to other quinolones, or any of the other ingredients of GENFLOC (listed in section 6).

Warnings and precautions

Special care should be taken with GENFLOC:

- If you experience any allergic (hypersensitivity) reaction.
- 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 the medicine.
- If you develop pain or swelling of the tendons (tendinitis) stop taking GENFLOC. Tendon swelling and rupture have happened in people taking oral or intravenous fluoroquinolones, particularly in older patients and in those treated concurrently with corticosteroids.

Use of GENFLOC for a long time may lead to other infections.

Children and adolescents

GENFLOC is not recommended for the treatment of eye infections caused by *Chlamydia trachomatis* (a bacterial infection) in patients less than 2 years of age. Patients older than 2 years of age should receive injectable treatment.

Other medicines and GENFLOC

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

GENFLOC is unlikely to interact with other medicines because it is administered into the eye and therefore very little is absorbed into the blood.

Pregnancy, breastfeeding 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 healthcare provider for advice before using this medicine.

You should not use GENFLOC if you are pregnant unless your doctor has told you to. You should not breastfeed when you are using GENFLOC.

Driving and using machines

Temporary blurred vision or other visual disturbances may occur with GENFLOC. You should wait until your vision clears before driving or using machinery if you experience blurred vision at instillation.

3. How to use GENFLOC

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

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

The usual dose is 1 drop in the affected eye or eyes, 3 times a day for 4 days.

Your doctor will tell you how long your treatment with GENFLOC will last. Do not stop treatment earlier than advised by your doctor or pharmacist.

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

If you are using GENFLOC in combination with another eye drop medicine, wait 5-15 minutes before applying the second eye drop.

Instructions for use:

(Please also refer to pictograms at the end of the leaflet)

- First wash your hands.
- Avoid touching the eye (or any other surface) with the tip of the bottle.
- If you wear contact lenses, they should be removed before using the eye drops. Wait until the signs and symptoms of the infection have cleared and until you have stopped using the medicine before you wear your contact lenses.
- These drops are supplied as a sealed bottle. Twist off the cap.
- Tilt your head back and look upward.
- Pull the lower eyelid gently downwards.
- Hold the bottle upside down above the eye and gently squeeze the bottle to release a drop into your eye.
- Keep the affected eye closed and press your fingertip against the inside corner of the closed eye, and hold for 1 minute.
- Repeat for the other eye if necessary.
- Replace and tighten the cap immediately after use.

If you use more GENFLOC than you should

Rinse it all out with warm water. Do not put in any more drops until it is time for your next regular dose.

If you forget to use GENFLOC

Continue with the next dose as planned. Do not use a double dose to make up for a forgotten dose.

If you stop using GENFLOC

To be effective GENFLOC must be used every day. Do not stop using this medicine until your doctor tells you so.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

GENFLOC can have side effects.

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

If any of the following happens, stop using GENFLOC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing, blueness of the skin.
- rash or hives.
- These are all very serious side effects. If you have them, you may have had a serious reaction to GENFLOC. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

eye pain, eye irritation.

Less frequent side effects:

Effects in the eye

dry eye, itchy eye, redness of the eye, eye surface inflammation or scarring, broken blood vessel in eye, abnormal eye sensation, eyelid abnormality, itching, redness or swelling, corneal disorder, blurred or reduced vision, inflammation or infection of the conjunctiva, eye strain, eye swelling, 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.

General side effects

Headache, bad taste, vomiting, nose discomfort, feeling of a lump in the throat, decreased iron in blood, abnormal liver blood tests, abnormal skin sensation, pain, throat irritation, shortness of breath,

irregular heart rhythm, dizziness, increased allergic symptoms, itching, rash, skin redness, nausea and urticaria.

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

Reporting of side effects

If you experience side effects, talk to your doctor or pharmacist.

You can report side effects to Gen-Eye (Pty) Ltd via email: pharmacovigilance@gen-eye.co.za or telephonically on 011 312 3812. 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 GENFLOC.

5. How to store GENFLOC

Store all medicines out of reach of children.

Store at or below 25 °C. Keep the container well-closed and in the outer carton. Protect from light.

Do not use more than 28 days after opening.

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

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 GENFLOC contains

The active substance is moxifloxacin 5 mg.

The other ingredients are boric acid, sodium chloride, water for injection.

Tiny amounts of sodium hydroxide and hydrochloric acid may be added to keep acidity levels (pH levels) normal.

What GENFLOC looks like and contents of the pack

The medicine is a yellow coloured, clear solution, free from visible particles of foreign matter.

Each bottle contains 5ml of GENFLOC Ophthalmic Solution.

Holder of Certificate of Registration

Gen-Eye (Pty) Ltd¹

Royal Palm Business Estate

Unit 7, 646 Washington Street

Halfway House, Midrand, 1685

This leaflet was last revised in

10 June 2022

Registration number

49/15.1/0909

Access to the corresponding Professional Information:

The corresponding Professional Information is available electronically on www.gen-eye.co.za.

Alternatively, to obtain this Professional Information please contact

Gen-Eye (Pty) Ltd on 011-312 3812 or email info@gen-eye.co.za.

¹ Company Registration number.: 2009/009360/07

Apply your eye drops in the following way:



- Wash your hands.
- Tilt your head back and look upward.
- Gently pull the lower eyelid down.



- Bring the eye drops near the eye, turn the bottle upside down and gently squeeze it to release the drop into the eye.
- Avoid touching the eye, eyelids or lashes with the dropper.



- Let go of the lower lid, and close your eye for 30 seconds.
- While your eyes are closed, gently press your fingers on the inner corner(s) of your eye(s). This will prevent the eye drops from draining out of the eye.

- If a drop misses your eye, try again.
- Wipe away any excess with a clean tissue.
- Replace and tighten the cap straight after use to avoid contamination.