

**Approved Patient Information Leaflet for Medicines for Human Use:**

**AVOXA EYE DROPS**

**SCHEDULING STATUS:** S4

**AVOXA 0,5 % EYE DROPS, solution**

**Moxifloxacin hydrochloride**

**Read all of this leaflet carefully before you start taking / using/ are given AVOXA EYE DROPS**

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

**1. What AVOXA EYE DROPS is and what it is used for**

AVOXA EYE DROPS are used for the treatment of infections of the eye (conjunctivitis) when caused by bacteria.

The active ingredient is moxifloxacin. It is an ophthalmological anti-infective.

## **2. What you need to know before you use AVOXA EYE DROPS**

### **Do not use AVOXA EYE DROPS**

- if you are hypersensitive (allergic) to moxifloxacin or other quinolones, or any of the other ingredients of AVOXA EYE DROPS (listed in section 6).

### **Warnings and precautions**

Tell your doctor or health care provider before using AVOXA EYE DROPS.

Take special care with AVOXA EYE DROPS if you have:

- eye problems and eye surgeries
- any allergies to any medications or allergic reactions including hives, swelling of the face, lips, tongue, and/or throat which may cause or had caused difficulty in breathing or swallowing (also see section on SIDE EFFECTS).
- Tendon swelling and rupture, This has happened in people taking oral or intravenous fluoroquinolones, particularly in older patients and in those treated concurrently with corticosteroids. Stop using **AVOXA EYE DROPS** if you start to feel pain or swelling of the tendons (tendonitis).
- Use of **AVOXA EYE DROPS** for a long time may lead to other infections.

If you wear contact lenses, you should consult your doctor before using this medicine. AVOXA EYE DROPS must not be instilled into the eye while wearing contact lenses. Remove the contact lenses before application of AVOXA EYE DROPS and wait 15 minutes after instillation of the dose before reinsertion.

### **Children and adolescents**

AVOXA EYE DROPS can be used for children and adolescents.

### **Other medicines and AVOXA EYE DROPS**

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

AVOXA EYE DROPS can affect or be affected by other medicines you are using, including other eye drops. Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This includes medicines obtained without a prescription.

### **Pregnancy and breastfeeding**

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**

It is not always possible to predict to what extent AVOXA 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 AVOXA EYE DROPS affects them.

### **3. How to use AVOXA EYE DROPS**

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

Always use AVOXA EYE DROPS exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are not sure.

**Dose for Adults and children:**

The usual dose is one (1) drop in the affected eye(s) three (3) times a day, in the morning, in the afternoon and in the evening.

**Method of administration**

Only use AVOXA EYE DROPS in both eyes if your doctor has told you to. Only use AVOXA EYE DROPS for dropping in your eyes.

The infection normally improves within 5 days. If no improvement is seen, contact your doctor.

**Duration of administration**

Your doctor will tell you how long your treatment with AVOXA EYE DROPS will last. Do not stop treatment early. If you have the impression that the effect of AVOXA EYE DROPS is too strong or too weak, tell your doctor or pharmacist.

**Multidose eye drops:** Do not allow the tip of the container to touch the eye or areas around the eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the container, wash your hands before using this medicine and keep the tip of the container away from contact with any surface. If you think your medicine may be contaminated, or if you develop an eye infection, contact your doctor immediately concerning continued use of this bottle.

**Instructions for use**



1. Before using the medicine for the first time, be sure the Safety Strip on the front of the bottle is unbroken. A gap between the bottle and the cap is normal for an unopened bottle.
2. First wash your hands, then tear off the Safety Strip to break the seal.
3. To open the bottle, unscrew the cap by turning it the left. Do not pull the cap directly up and away from the bottle. Pulling the cap directly up will prevent your dispenser from operating properly.
4. Tilt your head back and pull your lower eyelid down slightly to form a pouch between your eye and eyelid.



5. Invert the bottle and press lightly with the thumb or index finger until a single drop is dispensed into the eye as directed by your doctor. **DO NOT LET YOUR EYE OR EYELID TOUCH THE DROPPER TIP.**



6. After using AVOXA EYE DROPS press a finger into the corner of your eye, by the nose, or close your eyelids for 2 minutes. This helps to stop the medicine from getting into the rest of the body.
7. Repeat steps 4 and 5 in the other eye if instructed to do so by your doctor.
8. Replace the cap by turning until it is firmly touching the bottle. Do not overtighten or you may damage the bottle and cap.
9. The dispenser tip is designed to provide a single drop; therefore, do NOT enlarge the hole of the dispenser tip.

10. After you have used all doses, there will be some AVOXA EYE DROPS left in the bottle. You should not be concerned since an extra amount of this medicine has been added and you will get the full amount of AVOXA EYE DROPS that your doctor prescribed. Do not attempt to remove the excess medicine from the bottle.

**If a drop misses your eye**

Try again.

**If you wear soft contact lenses**

Do not use the drops with your soft contact lenses in. After using the drops wait 15 minutes before putting your lenses back in.

**If you are using other eye drops**

If you are using AVOXA EYE DROPS with another eye drop, the drops should be instilled at least 10 minutes apart.

**If you use more AVOXA EYE DROPS than you should**

If you put too many drops in your eye, rinse it all out with warm water. Do not put in any more drops until it is time for your next regular dose.

**In the event of over-dosage, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre.** Take this leaflet and any remaining medicine with you, so that the doctor knows what you have taken.

**If you forget to use AVOXA EYE DROPS**

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



## **If you stop using AVOXA EYE DROPS**

If you want to stop using AVOXA EYE DROPS talk to your doctor first.

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

## **4. Possible side effects**

AVOXA EYE DROPS can have side effects.

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

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

- severe hypersensitivity/allergic type reactions with severe redness and itching of the skin or raised lumps on the skin (hives), swelling of the hands, feet, ankles, face, lips, tongue and/ or throat, which may cause difficulty in swallowing or breathing, collapse.

These are very serious side effects. If you have them, you may have had a serious reaction to AVOXA EYE DROPS. 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:

*Less frequent:*

- inflammation of the coloured part of the eye (iris), visual disturbances including refractive changes (in some cases due to withdrawal of medicine to treat excessive contraction of the pupil of the eye)

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:

- pain in the eye, eye irritation

Less frequent side effects:

- **Effects in the eye:** dry eyes, itchy eyes, redness of the eye, eye surface inflammation or scarring, broken vessel in the eye, abnormal eye sensation, eye abnormality, eye strain, eye swelling, corneal disorder, blurred or reduced vision, inflammation or infection of the conjunctiva
- **General:** headache, bad taste in the mouth, vomiting, nose discomfort, feeling of lump in the throat, decreased iron in blood, abnormal; liver blood tests, abnormal skin sensation, pain, throat irritation

Side effects with frequency unknown:

- **Effects in the eye:** infection in the eye, eye surface becomes cloudy, corneal swelling, deposits on the eye surface, increased pressure in the eye, scratch on the surface of the eye, eye allergy, increased tear production, sensitivity to light
- **General:** shortness of breath, irregular heart rhythm, dizziness, increased allergic symptoms, itching rash, skin redness, nausea, urticaria

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 or pharmacist or nurse. 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 AVOXA EYE DROPS.



## 5. How to store AVOXA EYE DROPS

- Store all medicines out of reach of children
- Store at or below 25 °C.
- Store unopened dropper container bottle in the original carton, until required for use.
- Do not use more than 28 days after opening.
- Do not use AVOXA EYE DROPS after the expiry date printed on the label affixed to dropper container bottle or printed on the carton.
- Return any expired or unused medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

### What AVOXA EYE DROPS contains

- The active substance is moxifloxacin hydrochloride.
- The other ingredients are boric acid, 1M hydrochloric acid solution, sodium chloride, sodium hydroxide and water for injections.

### What AVOXA EYE DROPS looks like and contents of the pack

AVOXA EYE DROPS 0,5 % is a clear yellow liquid solution.

AVOXA EYE DROPS, solution is packaged in 5 mL polyethylene bottles sealed with droppers and closed with polyethylene tamper-evident screw caps, in a cardboard carton.

Each dropper container contains 5 mL of AVOXA EYE DROPS.

Not all pack sizes may be marketed.

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