NOVARTIS

VIGAMOX

(moxifloxacin)

0.5 % w/v eye drops, solution

Patient Information Leaflet

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VIGAMOX 0.5% w/v eye drops (solution)

Moxifloxacin hydrochloride, 5 mg

Read all of this leaflet carefully before you start using VIGAMOX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- VIGAMOX 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

What VIGAMOX is and what it is used for

What VIGAMOX is:

The active ingredient is moxifloxacin an ophthalmological anti-infective.

What it is used for:

VIGAMOX eye drops are used for the treatment of infections of the eye (conjunctivitis) when caused by bacteria. VIGAMOX may also be used to prevent bacterial infections before or after eye surgery.

What you need to know before you use VIGAMOX

Do not use VIGAMOX:

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

Warnings and precautions:

Take special care with VIGAMOX:

- if you experience an allergic reaction to VIGAMOX. Allergic reactions occur uncommonly and serious reactions occur rarely. If you experience any allergic (hypersensitivity) reaction or any side effect please refer to section 4;
- 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;
- tendon swelling and rupture have happened in people taking oral or intravenous fluoroquinolones, particularly in older patients and in those treated concurrently with corticosteroids. Stop taking VIGAMOX if you develop pain or swelling of the tendons (tendinitis);
- as with any antibiotic, use of VIGAMOX for a long time may lead to other infections.

Children

VIGAMOX may be used for bacterial infections of eye in children at the same dose as in adults. Use of VIGAMOX to prevent bacterial infections before or after eye surgery in children has not been studied.

Other medicines and VIGAMOX:

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

Pregnancy and breastfeeding and fertility:

If you are pregnant or breastfeeding or planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking VIGAMOX.

Driving and using machinery:

It is not always possible to predict to what extent VIGAMOX may interfere with the daily activities of a patient. VIGAMOX may cause temporary blurred vision or other visual disturbances that may affect daily activities. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which VIGAMOX affects them.

How to use VIGAMOX:

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

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

- For treatment in bacterial infections such as conjunctivitis, blepharitis, dacryocystitis, hordeolum, tarsadenitis, keratitis (including corneal ulcer): the usual dose is one drop in the affected eye(s) 3 times a day for 7 days.
- For removing the bacteria before or after eye surgery (preoperative and postoperative sterilization): The recommended dose is one drop of VIGAMOX 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.
- Do not wear contact lenses if you have signs and symptoms of an eye infection.
- Wait at least 5 minutes between administrations if using VIGAMOX concurrently with other ophthalmic solutions.
- To prevent contamination of the dropper tip and solution, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip of the bottle.
- VIGAMOX is for topical ophthalmic use only and should not be injected sub-conjunctivally or introduced directly into the anterior chamber of the eye.

Your doctor will tell you how long your treatment with VIGAMOX will last.

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

If you use more VIGAMOX than you should:

Rinse it all out with warm water. If you recently had eye surgery, speak with your doctor for detailed instructions. Do not put in any more drops until it is time for your next regular dose.

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

If you missed a dose of VIGAMOX:

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

Possible side effects

VIGAMOX can have side effects.

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

If any of the following happens, stop taking VIGAMOX 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, shortness of breath;
- rash or itching, hives;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to VIGAMOX. 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:

- Irregular heart rhythm;
- 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:

The following side effects have been reported frequently:

- Eye pain;
- eye irritation.

The following side effects have been reported less frequently:

- Eye surface inflammation with surface damage;
- dry eye;
- broken blood vessel in the eye;
- itching or redness of the eye;
- eyelid swelling;
- eye discomfort;
- headache;
- bad taste;
- corneal disorder;
- inflammation of the conjunctiva;
- eyelid inflammation;
- eye swelling;
- blurred or reduced vision;
- tired eyes;
- eyelid redness;
- anemia (decreased iron in blood),
- abnormal skin sensation,

- nose discomfort,
- throat pain,
- vomiting;
- abnormal liver blood tests.

Additional side effects from post-marketing experience that have been reported for which the frequency is unknown:

- Corneal ulcer, eye surface inflammation, increased tear production, sensitivity to light, eye discharge;
- dizziness;
- skin redness.

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. This includes any possible side effects not listed in this leaflet. 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 VIGAMOX.

How to store VIGAMOX

- Store at or below 25 °C.
- Store all medicines out of reach of children.
- Store in the original package / container.

- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton / bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Stop using the bottle 4 weeks after first opening. This is to prevent infections.

Contents of the pack and other information

What VIGAMOX contains

The active substance is: 1 mL of solution contains 5.45 mg moxifloxacin hydrochloride equivalent to 5 mg moxifloxacin base

The other ingredients are*:*

- Sodium chloride
- Boric acid
- Hydrochloric acid (E507) and/or sodium hydroxide (E524) (to adjust pH)
- Purified water

What VIGAMOX looks like and contents of the pack

What VIGAMOX looks like:

VIGAMOX is a clear, greenish-yellow solution

Contents of the pack:

Bottle with 5 mL fill and dispensing plug, both natural low density polyethylene, with a white polypropylene closure.

Holder of Certificate of Registration

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Waterfall City, Jukskei View

Johannesburg

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website

BOTSWANA: S2 **Reg. No.**: BOT1001630
Namibia: NS2 **Reg. No.:** 17/15.1/0099

Manufacturer

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