VIGAMOX 0.5% EYE DROP Consumer Medication Information Leaflet (RiMUP)

Moxifloxacin (5mg/ml)

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What Vigamox is used for

VIGAMOX Solution is indicated for the treatment of patients 1 year of age and older with bacterial conjunctivitis.

How Vigamox works

Vigamox contains Moxifloxacin which is a fourth-generation fluoroquinolone antibacterial agent.

Before you use Vigamox

When you must not use it

Do not use Vigamox

- If you are allergic (hypersensitive) to Moxifloxacin or to other quinolones, any of the other ingredients of this medicine.
- Before you start to use it

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

How to use Vigamox

Always use this medicine exactly as your doctor or pharmacist or nurse has told you.

Check with your doctor or pharmacist or nurse if you are not sure.

- How much to use

Instill one drop in the affected eye 3 times a day for 7 days.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue using Vigamox for as long as your doctor recommends.

- If you forget to use it

If you forget to use Vigamox, continue with the next dose as planned. Do not use a double dose to make up for forgotten individual doses.

- If you use too much (overdose)

If you use more Vigamox 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.

While you are using it

- Things you must do
- Avoid contaminating the applicator tip with material from the eye, fingers or other source.
- Quinolones administered into the circulatory system have been associated with hypersensitivity reactions, even following a single dose. Discontinue use immediately and contact your physician at the first sign of a rash or allergic reaction.

- After cap is removed, if tamper evident snap collar is loose, remove before using product.
- Only use Vigamox for dropping in your eye(s).
- If a drop misses your eye, try again.
- If you are using other eye drop or eye ointment medicines, leave at least 5 minutes between each medicine. Eye ointments should be administered last.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Vigamox to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

- Only use Vigamox for dropping in your eye(s).
- Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.
- As with any antibiotic, use of Vigamox for a long time may lead to other infections.
- Tendon swelling and rupture have happened in people taking oral or intravenous fluoroquinolones, particularly in elderly patients and in those treated concurrently with corticosteroids. Stop taking Vigamox if you develop pain or swelling of the tendons (tendinitis).

Driving and using machines

You may find your vision is blurred for a time after you use Vigamox. Do not drive or use machines until this has worn off.

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

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience a severe allergic reaction and any of the following happen, stop taking Vigamox immediately and tell your doctor immediately: swelling of the hands, feet, ankles, face, lips, mouth or throat which may cause difficulty in swallowing or breathing, rash or hives, large fluid-filled blisters, sores and ulceration.

The following side effects have been seen with Vigamox:

- Common side effects (may occur in 1 to 10 users in 100):
 - o Effects in the eye: eye pain, eye irritation
- Uncommon side effects (may occur in 1 to 10 users in 1,000):
 - Effects in the eye: eye surface inflammation with surface damage, dry eye, broken blood vessel in the eye, itching or redness of the eye, eyelid swelling, eye discomfort
 - o General side effects: headache, lack of taste
- Rare side effects (may occur in 1 to 10 users in 10,000):
 - Effects in the eye: corneal disorder, inflammation of the conjunctiva, eyelid inflammation, eye swelling, blurred or reduced vision, tired eyes, eyelid redness
 - General side effects:
 anemia, abnormal skin
 sensation, nose discomfort,
 throat pain, feeling of a
 lump in the throat,
 vomiting, abnormal liver
 blood tests

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

 Effects in the eye: corneal ulcer, eye surface inflammation, increased tear production, sensitivity to light, eye discharge • General side effects: allergy, dizziness, irregular heart rhythm, shortness of breath, nausea, skin redness, itching, rash, hives.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Public→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Vigamox

- Storage

Do not store above 30°C. Discard 28 days after opening.

- <u>Disposal</u>

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Vigamox is supplied as a sterile ophthalmic solution in a natural low density polyethylene bottle, with dispensing plug and a white polypropylene closure.

Available in 5ml pack size.

- Ingredients
 - Active ingredient

Moxifloxacin 0.5% (5 mg/mL)

- Inactive ingredients

Sodium chloride, boric acid and purified water. May also contain hydrochloric acid/sodium hydroxide to adjust pH.

- <u>MAL number:</u> MAL20051461ARZ

Manufacturer

Alcon-Couvreur NV, Rijksweg 14, 2870, Puurs, Belgium.

Product Registration Holder

Novartis Corporation (M) Sdn. Bhd. Level 18, Imazium, No. 8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.

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