

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by it

Patient package insert in accordance with the Pharmacists' Regulations (Preparations) - 1986

The medicine is dispensed according to a doctor's prescription only

VIGAMOX

Eye Drops, Solution.

Composition: Moxifloxacin (as Hydrochloride) 0.5%
Inactive ingredients appear in section 6 - "Further information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

For treatment of conjunctivitis caused by bacteria susceptible to the medicine.

Therapeutic group: Fourth-generation fluoroquinolone antibiotic.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you have a known sensitivity to moxifloxacin or to any of the ingredients of the medicine or to other quinolone antibiotics.

Special warnings regarding use of the medicine

- **If you experience an allergic reaction to Vigamox.** Allergic reactions are uncommon and serious allergic reactions are rare. If you experience any allergic reaction or any side effect, please see section 4.
- **If you wear contact lenses** – stop wearing contact lenses if signs or symptoms of an eye infection occur. Wear glasses instead. Do not start wearing lenses again until the signs of the infection have cleared and until you have stopped using Vigamox.
- Tendon swelling and rupture occur in people taking oral or intravenous fluoroquinolones, particularly in older patients and in those treated concurrently with corticosteroids. Stop using Vigamox if you develop pain or swelling of the tendons (tendinitis).
- Vigamox can be used in children, elderly patients and patients with kidney or liver dysfunction. As with any antibiotic, use of Vigamox for a protracted period may lead to other infections.

If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist.

3. Pregnancy and breastfeeding

If you are pregnant, planning a pregnancy or are breastfeeding, consult the doctor or pharmacist before using the medicine.

4. Driving and using machines

You may experience blurry vision for a short time after using the medicine. Do not drive or operate machines until this effect has passed.

5. Treatment in children and infants:

Vigamox preparation is safe and effective for use in children and infants. There is not enough information regarding use of Vigamox in newborns, therefore its use is not recommended for them.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only.

The recommended dosage unless otherwise prescribed by a doctor: 1 drop in the treated eye, 3 times a day for 4 days.

Do not exceed the recommended dosage.

This medicine should be used at specified times as prescribed by the attending doctor.

Do not swallow! This medicine is intended for external use only.

- To avoid contamination, do not allow the tip of the bottle to touch any surface (including the eye itself). Keep the bottle tightly closed.
- The bottle of drops may not be full; this is intended to allow better control of the drip rate.
- Do not squeeze the bottle; gentle pressure on the base of the bottle is sufficient to remove the drop.
- How to use the drops: Using a mirror can make it easier to use the medicine. First, wash your hands. Tilt your head back. Using the index finger, pull down the lower eyelid to form a "pocket" (Fig. 1). Instill the medicine into the "pocket" that is formed (Fig. 2). Close your eyes gently. Do not blink. Keep your eyes closed for 1 to 2 minutes.
- In addition to the instructions given above - immediately after instilling the drop into the eye, press with the middle finger on the inner corner of the eye (Fig. 3). Continue applying pressure for 1 to 2 minutes after instilling into the eye. This action helps to avoid absorption of the medicine into the body and thus helps prevent side effects.
- After using the medicine, wash your hands thoroughly to clean them of any residue of the medicine.
- To avoid spreading infection, do not use the same bottle of medicine for more than one person.



- If you have not been able to instill into the eye - try again.
- If you need to instill a drop into the other eye, **wash**

your hands to avoid spreading infections from one eye to the other and then repeat the above instructions also for the other eye.

- Close the bottle tightly immediately after use.
- If you use more than one type of eye drops, wait at least 5-10 minutes between instilling Vigamox and other eye drops. Eye ointments should only be used after you have finished using the eye drops.

If you accidentally take a higher dosage, wash your eye with lukewarm water.

If you took an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

If you forget to take this medicine at the required time, do not take a double dose. Take a dose as soon as you remember. However, if it is almost time to take the next dose, skip the forgotten dose and return to the normal dosing regimen with the next dose.

Adhere to the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with this medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

If you have additional questions about use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Vigamox may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop using the medicine and refer immediately to a doctor if you suffer from a serious allergic reaction or from one of the following symptoms: swelling of the hands, feet, ankles, face, lips, mouth or throat that may cause difficulty in swallowing or breathing, rash or urticaria (a stinging skin rash), blisters, sores and ulcers.

Other side effects:

Common side effects - effects that occur in 1-10 users out of 100:

Eye effects: eye pain, eye irritation.

Uncommon side effects - effects that occur in 1-10 users out of 1,000:

Eye effects: dry eye, itchy eye, redness of the eye, eye surface inflammation or scarring, broken blood vessel in the eye, abnormal eye sensation, eyelid abnormality, itching, redness or swelling.

General effects: headache and bad taste in the mouth.

Rare side effects - effects that occur in 1-10 users out of 10,000:

Eye effects: corneal disorder, blurred or reduced vision, inflammation or infection of the conjunctiva, eye strain, eye swelling.

General effects: vomiting, nose discomfort, feeling of a lump in the throat, decreased blood iron, abnormal results of blood tests for liver enzymes, abnormal skin sensation, pain, throat irritation.

Effects of known frequency - effects whose frequency has not yet been determined:

Eye effects: infection in the eye, cloudy eye surface, corneal swelling, deposits on the eye surface, increased ocular pressure, scratch on the surface of eye, eye allergy, eye discharge, increased tear production, sensitivity to light.

General effects: shortness of breath, irregular heart rhythm, dizziness, increased allergic symptoms, itching, rash, skin redness, nausea and stinging skin rash (urticaria).

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine, and any other medicine, must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor!
- Close tightly to prevent penetration of air and humidity. Even under recommended packaging/storage conditions, medicines are kept for a limited period only.
- Do not use the medicine after the expiry date (exp. date) that appears on the carton/label. The expiry date refers to the last day of that month.
- Do not dispose of medicines into the wastewater or household waste. Consult with the pharmacist on how to dispose of medicines after using in order to protect the environment.
- Store below 25°C. Do not use the medicine 28 days after first opening.
- Do not store different medicines in the same package.

6. FURTHER INFORMATION

In addition to the active ingredient the medicine also contains:

Sodium Chloride, Boric Acid, Hydrochloric Acid OR Sodium Hydroxide, Purified Water

What the medicine looks like and contents of the package: The medicine is a solution supplied in a pack containing a 5ml plastic bottle with a screw-on cap.

Registration Holder and address: Novartis Israel Ltd., 36 Shacham St., Petach-Tikva.

Manufacturer and address: Alcon Laboratories, Fort Worth, USA for Alcon Pharmaceuticals Ltd., Fribourg, Switzerland

This leaflet was checked and approved by the Ministry of Health in August 2017

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