

## READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

### PATIENT MEDICATION INFORMATION

#### **PrVIGAMOX®**

Moxifloxacin Ophthalmic Solution  
0.5% w/v (as moxifloxacin hydrochloride)

Read this carefully before you start taking **PrVIGAMOX®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **VIGAMOX**.

#### **What is VIGAMOX used for?**

VIGAMOX is an antibiotic used to treat bacterial infection of the eye (pink eye).

#### **How does VIGAMOX work?**

VIGAMOX is an antibiotic that stops the growth of bacteria. This kills the bacteria and reduces eye infections.

#### **What are the ingredients in VIGAMOX?**

Medicinal ingredients: Moxifloxacin 0.5% w/v (as moxifloxacin hydrochloride)

Non-medicinal ingredients: Boric acid, purified water and sodium chloride. May also contain hydrochloric acid and/or sodium hydroxide to adjust pH.

#### **VIGAMOX comes in the following dosage forms:**

VIGAMOX is a clear greenish-yellow solution and comes in a 3 mL oval plastic bottle.

#### **Do not use VIGAMOX if you are:**

- Allergic to moxifloxacin or any of the ingredients in VIGAMOX (see **What are the ingredients in VIGAMOX?**)
- Allergic to other quinolones.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VIGAMOX. Talk about any health conditions or problems you may have, including if you:**

- Develop an allergic reaction (see **Serious side effects and what to do about them**). Stop taking VIGAMOX and get immediate medical help.
- Notice your infection gets worse. Stop taking VIGAMOX and get immediate medical help. As with any antibiotic, use of VIGAMOX for a long time may lead to other infections. Do NOT use VIGAMOX longer than your doctor tells you to.
- Develop pain or swelling in your tendons. Stop taking VIGAMOX and get immediate medical help. This is more likely to happen if you are elderly or taking corticosteroids at the same time as VIGAMOX.

**Other warnings you should know about:**

- VIGAMOX can be used in children as young as 1 year of age. VIGAMOX should not be used in children younger than 1 year of age.
- Do NOT wear contact lenses if you have an eye infection.
- Your vision may be temporarily blurry after using VIGAMOX. Wait until your vision clears before driving or using machinery.
- If you are pregnant or planning to become pregnant or are breast-feeding or planning to breastfeed, talk to your doctor or pharmacist before using VIGAMOX.
- Antibacterial drugs like VIGAMOX treat only bacterial infections. They do not treat viral infections, such as the common cold. Although you may feel better early in treatment, VIGAMOX should be taken exactly as directed. Misuse or overuse of VIGAMOX could lead to the growth of bacteria that will not be killed by VIGAMOX (resistance). This means that VIGAMOX may not work for you in the future. Do not share your medicine.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with VIGAMOX:**

- Tell your doctor or pharmacist if you are:
  - taking or have recently taken any prescription or non-prescription medicines,
  - using any other eye products,
  - taking corticosteroids as this may increase your chance of developing pain or swelling of your tendons.

**How to take VIGAMOX:**

1. Get the bottle of VIGAMOX and a mirror.
2. Wash your hands.
3. Twist off the cap. After cap is removed: if security snap collar is loose, remove before using VIGAMOX.
4. Hold the bottle, pointing down, between your thumb and fingers.
5. Tilt your head back.
6. Pull down your eyelid with a clean finger, until there is a “pocket” between your eyelid and eye. The drop will go in there.
7. Bring the bottle close to the eye. Use the mirror if it helps.
8. **Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper.** It could contaminate the drops.
9. Gently squeeze the bottle to release one drop of VIGAMOX solution.
10. If the drop misses you eye, wipe it up and try again.

11. If you need drops in both eyes, repeat the steps for your other eye.
12. Keep the bottle tightly closed when not in use.

**Usual dose:**

Apply one drop in the affected eye(s) three times a day (morning, afternoon and at night) unless your doctor tells you otherwise.

Use VIGAMOX for seven days or as long as your doctor tells you to.

**Overdose:**

If you use too much VIGAMOX, rinse it out of your eyes with warm water. Do not put any more drops of VIGAMOX in until it's time for your next dose.

If you accidentally swallow VIGAMOX, talk to your doctor or pharmacist.

If you think you have taken too much VIGAMOX, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you miss a dose, apply the missed dose as soon as possible and then go back to your regular dosing schedule. If the drop misses your eye, try again.

**What are possible side effects from using VIGAMOX?**

These are not all the possible side effects you may feel when taking VIGAMOX. If you experience any side effects not listed here, contact your healthcare professional.

Common eye side effects while using VIGAMOX include:

- mild temporary burning or stinging,
- itching or redness.

Other less common eye side effects include:

- dryness,
- sensation of pressure, discomfort, corneal inflammation, broken blood vessels in the white part of the eye, swelling of the eye or eyelid,
- blurry vision,
- temporary reduction of vision,
- pain, inflammation of the eye surface or eyelid, tired eyes, redness of the eyelid,
- watery eyes, sensitivity to light, eye discharge.

You may also experience reactions in other areas of your body, including:

- bad taste,
- headache,
- throat pain,

- abnormal liver blood tests,
- abnormal skin sensation,
- vomiting,
- nose discomfort,
- dizziness,
- irregular heart rhythm,
- shortness of breath,
- nausea,
- allergic reaction,
- skin redness or itching,
- rash or hives.

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNKNOWN</b> Severe allergic reaction: <ul style="list-style-type: none"> <li>• swelling of hands</li> <li>• feet</li> <li>• ankles</li> <li>• face</li> <li>• lips</li> <li>• mouth or throat</li> <li>• difficulty breathing</li> <li>• fever</li> <li>• rash or hives</li> <li>• large fluid-filled blisters</li> <li>• sores</li> </ul>			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

Store between 4°C and 25°C. Keep out of the reach and sight of children.

Do not use VIGAMOX after the expiry date (shown as EXP on the package). Discard 28 days after opening.

### **If you want more information about VIGAMOX:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website [www.novartis.ca](http://www.novartis.ca), or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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