

## PACKAGE LEAFLET – INFORMATION FOR THE USER

### **MOXIVIG\* 0.5% w/v eye drops, solution** Moxifloxacin hydrochloride

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any of the side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What MOXIVIG is and what it is used for
2. What you need to know before you use MOXIVIG
3. How to use MOXIVIG
4. Possible side effects
5. How to store MOXIVIG
6. Contents of the pack and other information

#### **1. What MOXIVIG is and what it is used for**

MOXIVIG contains the active substance moxifloxacin. Moxifloxacin belongs to a class of antibiotics called fluoroquinolones used to treat bacterial infections of the eye.

MOXIVIG eye drops are used for the treatment of infections of the eye (conjunctivitis) when caused by bacteria.

#### **2. What you need to know before you use MOXIVIG**

##### **Do not use MOXIVIG**

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

##### **Warnings and precautions**

- Talk to your doctor or pharmacist:
- **If you experience an allergic reaction to MOXIVIG.** 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 MOXIVIG if you develop pain or swelling of the tendons (tendinitis).

As with any antibiotic, use of MOXIVIG for a long time may lead to other infections.

### Other medicines and MOXIVIG

**Tell your doctor or pharmacist** if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription.

### Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist before using VIGAMOX eye drops.

### Driving and using machines

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

## 3. How to use MOXIVIG

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

### The recommended dose is...

#### Adults, including the older, and children:

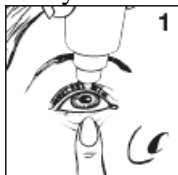
**1 drop** in the affected eye or eyes, **3 times a day** (in the morning, in the afternoon and at night).

MOXIVIG can be used in children, in patients over 65 years of age and patients with kidney or liver problems. There is only very limited information on the use of this medicine in the newborn and its use is not recommended in the newborn.

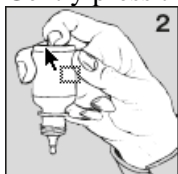
Only use the medicine in both eyes if your doctor told you to. **Only** use MOXIVIG for dropping in your eyes.

The infection normally improves within 5 days. If no improvement is seen, contact your doctor. You should continue to use the drops for a further 2 - 3 days or as long as your doctor told you to.

- Get the MOXIVIG bottle and stand in front of a mirror
- **Wash your hands**
- Twist off the cap
- After cap is removed, if tamper evident snap collar is loose, remove before using the product
- Hold the bottle, pointing down, between your thumb and fingers
- Tilt your head back. Pull down your eyelid with a clean finger, until there is a 'pocket' between the eyelid and your eye. The drop will go in here (**picture 1**)



- Bring the bottle tip close to the eye. Use the mirror if it helps
- **Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper.** It could infect the drops
- Gently press the bottom of the bottle to release one drop of medicine at a time (**picture 2**)



- After using MOXIVIG, press a finger into the corner of your eye, by the nose for 2 - 3 minutes (**picture 3**). This helps to stop the medicine getting into the rest of the body and is important in young children



- If you are using the drops in both eyes, **wash your hands before you repeat the steps for your other eye**. This will help prevent spreading the infection from one eye to the other
- Close the bottle cap firmly immediately after use

Now turn over >

### 3. How to use MOXIVIG (*continued*)

< *How to use:* see also side 1

**If a drop misses your eye**, try again.

**If you use more medicine 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.

**If you accidentally swallow MOXIVIG** contact your doctor or pharmacist for advice.

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

**If you are using other eye drops**, leave at least 5 minutes between putting in MOXIVIG and the other drops.

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

### 4. Possible side effects

Like all medicines MOXIVIG can cause side effects although not everybody gets them.

**You can usually carry on taking the drops**, unless the effects are serious or if you suffer a severe allergic reaction.

**If you experience a severe allergic reaction and any of the following happen, stop taking MOXIVIG 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.

#### Common side effects

(May affect up to 1 in 10 people)

**Effects in the eye:** eye pain, eye irritation

#### Uncommon side effects

(May affect up to 1 in 100 people)

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

**General side effects:** headache and bad taste

**Rare side effects**

*(May affect up to 1 in 1 000 people)*

**Effects in the eye:** corneal disorder, blurred or reduced vision, inflammation or infection of the conjunctiva, eye strain, eye swelling

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

**Not known**

*(Frequency cannot be estimated from the available data)*

**Effects in the eye:** infection in the eye, eye surface becomes cloudy, corneal swelling, deposits on the eye surface, increased pressure in eye, scratch on surface of eye, eye allergy, eye discharge, increased tear production, sensitivity to light

**General side effects:** shortness of breath, irregular heart rhythm, dizziness, increased allergic symptoms, itching, rash, skin redness, nausea and urticaria

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

**United Kingdom**

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

## **5. How to store MOXIVIG**

**Keep this medicine out** of the sight and reach of children.

Do not use this medication after the expiry date which is stated on the bottle and the carton after 'Exp'. The expiry date refers to the last day of that month.

This medicine does not need any special storage conditions.

**Stop using the bottle 4 weeks after first opening.** This is to prevent infections.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

**What MOXIVIG contains**

The active substance is moxifloxacin. One ml of eye drops contains 5 mg of moxifloxacin (as moxifloxacin hydrochloride, 5.45 mg).

One eye drop contains 190 micrograms of moxifloxacin.

The other ingredients are: sodium chloride, boric acid, purified water.

Tiny amounts of sodium hydroxide and hydrochloric acid may be added to keep acidity levels (pH levels) normal.

### **What MOXIVIG looks like and the contents of the pack**

The medicine is a liquid (a clear, greenish–yellow solution) supplied in a pack containing one 5 ml plastic bottle with a screw cap.

### **Marketing Authorisation Holder**

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