

## **Package leaflet: Information for the user**

### **Moxifloxacin 5mg/ml eye drops, solution** Moxifloxacin

**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 signs of illness are the same as yours.
- If you get any 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 Moxifloxacin is and what it is used for
2. What you need to know before you use Moxifloxacin
3. How to use Moxifloxacin
4. Possible side effects
5. How to store Moxifloxacin
6. Contents of the pack and other information

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

Moxifloxacin 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 Moxifloxacin**

##### **Do not use Moxifloxacin**

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

If you have further questions, ask your doctor for advice.

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

Talk to your doctor or your pharmacist before using Moxifloxacin:

- If you experience an allergic reaction to Moxifloxacin. 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.

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

##### **Other medicines and Moxifloxacin**

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

### **Pregnancy and breast-feeding**

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

### **Driving or using machines**

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

## **3. How to use Moxifloxacin**

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

Only use Moxifloxacin for dropping in your eyes.

### **The recommended dose**

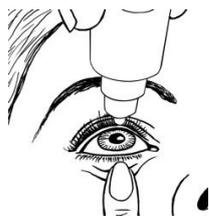
In adults, including the elderly, and children is: **1 drop** in the affected eye or eyes, **3 times a day** (in the morning, in the afternoon and at night).

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

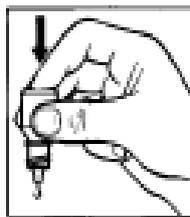
Only use the medicine in both eyes if your doctor told you to.

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.

### **How to use**



**1**



**2**



**3**

- Get the Moxifloxacin bottle and a mirror
- Wash your hands
- Twist off the cap
- Hold the bottle, pointing down, between your thumb and middle finger
- 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 Moxifloxacin at a time (picture 2).
- **Do not squeeze the bottle:** it is designed so that a gentle press on the bottom is all that it needs (picture 2)
- After using Moxifloxacin, press a finger to the corner of your eye, by the nose for 2-3 minutes (picture 3). This helps to stop Moxifloxacin getting into the rest of the body and is important in young children.
- If you need 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.
- Use up one bottle before opening the next bottle.

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

**If you use more Moxifloxacin than you should**

Rinse all the medicine out of your eye with warm water. Do not put in any more drops until it is time for your next regular dose.

**If you accidentally swallow Moxifloxacin**

Contact your doctor or pharmacist for advice.

**If you forget to use Moxifloxacin**

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 Moxifloxacin and the other drops.

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

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everyone gets them. You can usually carry on using the drops, unless the effects are serious or if you suffer a severe allergic reaction.

**Common:** may affect up to 1 in 10 people

*Effects in the eye:* eye pain, eye irritation, dry eye, itchy eye, redness of the eye

*General side effects:* bad taste

**Uncommon:** may affect up to 1 in 100 people

*Effects in the eye:* corneal disorder, eye surface inflammation or scarring, broken blood vessel in eye, inflammation or infection of the conjunctiva, abnormal eye sensation, blurred or reduced vision, eye swelling, eyelid abnormality, itching, redness or swelling.

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

**Additional side effects that have been reported for which the frequency is unknown:**

*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

### **Reporting of side effects**

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

## **5. How to store Moxifloxacin**

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

Do not use this medicine after the expiry date which is stated on the bottle and box after “EXP”. The expiry date refers to the last day of the month.

This medicine does not require 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 Moxifloxacin 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 Boric Acid, sodium chloride, sodium hydroxide for pH adjustment and water for injection.

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

The medicine is a liquid (a clear, greenish-yellow solution) supplied in a pack containing 1 plastic bottle with a screw cap which includes 5ml solution.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

<to be completed nationally>

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

<to be completed nationally>

**This leaflet was last revised in MM/YYYY.**