

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

**MOXIFLOXACIN 0.5%W/V EYEDROPS**

Moxifloxacin

**Read this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

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**1. WHAT MOXIFLOXACIN 0.5% EYEDROPS IS AND WHAT IT IS USED FOR** Moxifloxacin 0.5% eye drops are used for the treatment of infections of the eye (conjunctivitis) when caused by bacteria. The active ingredient is moxifloxacin, an ophthalmological anti-infective.

**2. BEFORE YOU USE MOXIFLOXACIN 0.5% EYEDROPS**

**Do not use Moxifloxacin 0.5% Eyedrops if:**

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

**Caution with Moxifloxacin 0.5% Eyedrops**

Before treatment with Moxifloxacin 0.5% Eyedrops, talk to your healthcare provider: • **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.
  - 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 moxifloxacin if you develop pain or swelling of the tendons (tendinitis).
  - As with any antibiotic, use of moxifloxacin for a long time may lead to other infections
- If you are not sure if any of the above applies to you, talk to your doctor, nurse, or pharmacist before being given moxifloxacin

**Taking other medicines**

**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 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 before using moxifloxacin 0.5% eye drops.

### **Driving and 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 TAKE MOXIFLOXACIN 0.5% EYE DROPS**

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:

**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).

Moxifloxacin 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 new-born and its use is not recommended in the new-born.

Only use the medicine in both eyes if your doctor told you to. Only use moxifloxacin eye drops for 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 if your doctor told you to. • Get the moxifloxacin 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.
- 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.
- After using moxifloxacin, press a finger into the corner of your eye, by the nose for 2 - 3 minutes. 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.

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 moxifloxacin, 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 moxifloxacin 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 moxifloxacin 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 moxifloxacin 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.

**Rare side effects** *(May affect up to 1 in 1000 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, headache and bad taste, decreased iron in blood, abnormal liver blood tests, abnormal skin sensation, pain, throat irritation

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

**Reporting of side effects**

If you experience any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to Fidson Healthcare Plc. By reporting side effects, you can help provide more information on the safety of this medicine.

**5. HOW TO STORE MOXIFLOXACIN 0.5% EYE DROPS**

Keep all medicines out of the reach of children.

Store below 30°C, in a dry place.

Do not use Moxifloxacin 0.5% Eye drops after the expiry date 'Exp. Date' which is stated on the label. The expiry date refers to the last day of that month.

Do not use Moxifloxacin 0.5% Eye drops if you notice leaking or visible particles in the product or if the solution is unclear or discoloured.

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

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.

**6. FURTHER INFORMATION**

**What Moxifloxacin 0.5% Eye drops contains:**

The active pharmaceutical ingredient is Moxifloxacin

**What Moxifloxacin 0.5% Eye drops looks like and contents of the**

**pack:** Moxifloxacin 0.5% Eye drops is a solution with no visible particles.

It comes in 5ml and 10ml solution for Eye drops in an LDPE bottle, placed in an outer carton with an insert.

**SUPPLIER AND MANUFACTURER**

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