

Package leaflet: Information for the patient

[Invented name], 5 mg/ml, eye drops, solution
Moxifloxacin

Read all of this leaflet carefully before you start taking 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 [Invented name] is and what it is used for
2. What you need to know before you use [Invented name]
3. How to use [Invented name]
4. Possible side effects
5. How to store [Invented name]
6. Contents of the pack and other information

1. What [Invented name] is and what it is used for

[Invented name] eye drops are used for the treatment of infections of the eye (conjunctivitis, or “pink eye”) caused by bacteria.

2. What you need to know before you take [Invented name]

Do not use [Invented name]:

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using [Invented name]

- **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 [Invented name] if you develop pain or swelling of the tendons (tendinitis).

As with any antibiotic, use of [Invented name] for a long time may lead to other infections.

Other medicines and [Invented name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are using other eye drops, leave at least 5 minutes between putting in [Invented name] and the other drops. Eye ointments should be administered last.

Pregnancy, breastfeeding and fertility

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

Driving and using machines

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

3. How to use [Invented name]

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

The usual dose is:

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

[Invented name] 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 [Invented name] 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.

Instructions for use

- Get the [Invented name] bottle and a mirror.
- Wash your hands.
- Twist off the cap.
- After cap is removed, if tamper evident snap collar is loose, remove it before using the medicine.
- 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.
- Don't touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops.
- Gently press with your thumb and forefinger in the middle of the bottle to release one drop of medicine at a time.
- After using [Invented name], 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 [Invented name] 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 have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine 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 [Invented name] and seek for medical help 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 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, 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, nausea, increased allergic symptoms, itching, rash, skin redness 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 listed in Appendix V**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

This medicinal product does not require any special storage conditions.

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 carton and label after EXP. The expiry date refers to the last day of that month.

After first opening of the bottle - store for 28 days at a temperature below 30°C.

Stop using the bottle 28 days after the first opening of the bottle. 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 [Invented name] contains

- The active substance is moxifloxacin.
Each ml of solution contains 5.45 mg moxifloxacin hydrochloride equivalent to 5 mg moxifloxacin base.
Each eye drop contains 0.2 mg of moxifloxacin.
- The other ingredients are sodium chloride, boric acid, sodium hydroxide (for pH-adjustment), water purified.

What [Invented name] looks like and contents of the pack

The medicine is a liquid (green-yellow transparent solution) supplied in a pack containing one 5 ml plastic bottle with a screw cap.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This leaflet was last revised in