

PACKAGE LEAFLET: INFORMATION FOR THE USER

Moxifloxacin 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.

Whats in this leaflet:

1. What Moxifloxacin 0.5 % w/v eye drops, solution is and what it is used for
2. What you need to know before you use Moxifloxacin 0.5 % w/v eye drops, solution
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4. Possible side effects
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1. What Moxifloxacin 0.5 % w/v eye drops, solution is and what it is used for

Moxifloxacin 0.5 % w/v eye drops, solution 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. What you need to know before you use Moxifloxacin 0.5 % w/v eye drops, solution

Do not use Moxifloxacin 0.5 % w/v eye drops, solution

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

Warnings and Precautions

- Talk to your doctor or pharmacist:
- **If you experience an allergic reaction to Moxifloxacin 0.5 % w/v eye drops, solution.** 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 0.5 % w/v eye drops, solution if you develop pain or swelling of the tendons (tendinitis).

As with any antibiotic, use of Moxifloxacin 0.5 % w/v eye drops, solution for a long time may lead to other infections.

Other medicines and Moxifloxacin 0.5 % w/v eye drops, solution

Tell your doctor or pharmacist if you are taking or 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 Moxifloxacin 0.5 % w/v eye drops, solution eye drops.

Driving and using machines

You may find that your vision is blurred for a short time just after you use Moxifloxacin 0.5 % w/v eye drops, solution. Do not drive or use machines until this has worn off.

3. How to use Moxifloxacin 0.5 % w/v eye drops, solution

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 for -

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 0.5 % w/v eye drops, solution 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 Moxifloxacin 0.5 % w/v eye drops, solution for dropping in your eyes.

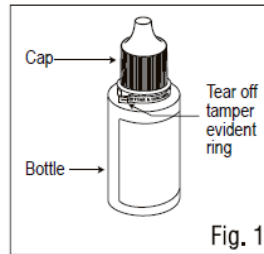
The infection normally improves within 5 days. If no improvement is seen, contact your doctor. You should continue to use the drops for a further 2-3 days or as long as your doctor told you to.

INSTRUCTIONS FOR USE

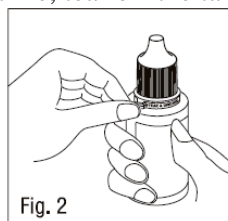
Using the three piece container for the first time:

Opening the bottle before first use

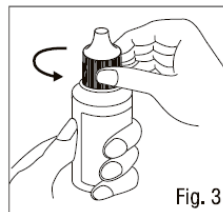
1. Before using the medication for the first time, be sure the tamper evident ring between the bottle and the cap is unbroken (Fig.1). You must not use the bottle if the tamper evident ring on the bottle neck is broken.



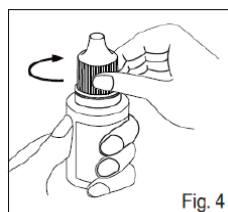
2. Before opening the bottle for the first time, tear off the tamper evident ring to break the seal (Fig.2).



3. To open the bottle, remove the cap by turning it in the counterclockwise direction (Fig.3).



4. Tighten the cap on the container after every use (Fig.4).



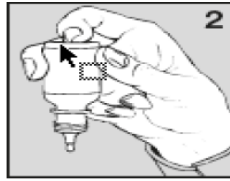
Using your eye drops

1. **Wash your hands.**
2. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and eye (**picture 1**)



3. Bring the bottle tip close to the eye. **Don't touch your eye or eyelid, surrounding areas or other surfaces with the dropper.** It could infect the drops

4. Gently press the bottom of the bottle to release one drop of medicine at a time (**picture 2**).



5. After using Moxifloxacin eye drops, 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.



6. 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.
7. 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. Don't put in any more drops until it's time for your next regular dose.

If you accidentally swallow Moxifloxacin 0.5 % w/v eye drops, solution 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 0.5 % w/v eye drops, solution 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 0.5 % w/v eye drops, solution 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 0.5 % w/v eye drops, solution 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 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, increased allergic symptoms, itching, rash, skin redness, nausea and urticaria

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of benefit/risk balance of the medicinal product. Health care professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Moxifloxacin 0.5 % w/v eye drops, solution

Keep out of the sight and reach of children.

Don't use the drops 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 dispose of medicines into the water supply or in household waste. Ask your pharmacist how to dispose of medicines you no longer need. This will help protect the environment.

6. Contents of the pack and other Information

What Moxifloxacin 0.5% w/v eye drops, solution contains

The active substance is moxifloxacin.

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

The other ingredients are: sodium chloride, boric acid, sodium hydroxide, hydrochloric acid and water for injections

What Moxifloxacin 0.5 % w/v eye drops, solution looks like and the contents of the pack

The medicine is a clear, greenish yellow solution supplied in a 5 ml plastic bottle with a screw cap.

Each bottle contains 5 ml of this medicine.

Marketing Authorisation Holder and Manufacturer

Brown & Burk UK Ltd
5 Marryat Close
Hounslow West
Middlesex
TW4 5DQ
United Kingdom

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