

MOVELOX

(Moxifloxacin 0.5 % w/v Ophthalmic Solution USP)

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What MOVELOX is used for

MOVELOX 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.

How MOVELOX works

Moxifloxacin, a fourth-generation fluoroquinolone, inhibits the DNA gyrase and topoisomerase IV required for bacterial DNA replication, repair, and recombination.

Before you use MOVELOX

When you must not use it

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

WARNINGS AND PRECAUTIONS

- **If you experience an allergic reaction to MOVELOX:** Allergic reactions occur uncommonly and serious reactions occur rarely. If you experience any allergic (hypersensitivity) reaction or any side effect, inform your doctor.
- **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

MOVELOX if you develop pain or swelling of the tendons (tendinitis). As with any antibiotic, use of MOVELOX for a long time may lead to other infections.

Other medicines and MOVELOX

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and lactation

Ask your doctor before using MOVELOX eye drops.

Do not take MOVELOX if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

How to use MOVELOX

- How much to use

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

The usual 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).

- Get the MOVELOX 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 '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
- Don't 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 MOVELOX, 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

When to use it

MOVELOX 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 MOVELOX for dropping in your eyes. The infection normally improves within 5 days.

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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.

If you forget to use it

Continue with the next dose as planned. Do not use a double dose to make up for a forgotten dose.

If you use too much (overdose)

rinse it all out with warm water. Don't put in any more drops until it's time for your next regular dose.

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking MOVELOX eye drops.

Tell your doctor immediately if you become pregnant while taking this medication.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give MOVELOX eye drops to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

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

Side effects

Like all medicines MOVELOX 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 MOVELOX 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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490 or visiting the website npra.moh.gov.my [Public→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of MOVELOX

- Storage

Keep out of the reach and sight of children.

Store below 30 °C. Protect from light.

Do not store any medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

- Disposal

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.

Product Description

- What it looks like

A yellow coloured clear solution, free from visible particles of foreign matter.

- Ingredients

- Active ingredient(s)

Each ml contains:

Moxifloxacin Hydrochloride USP

.....5.45 mg

Equivalent to Moxifloxacin .. 5 mg.

- Inactive ingredients

Sterile aqueous vehicle q.s.

- MAL number:

MAL19016006AZ

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(Moxifloxacin 0.5 % w/v Ophthalmic Solution USP)

Manufacturer

INDOCO REMEDIES LTD
L-32, 33 & 34, Verna Industrial Area,
Verna, Goa – 403 722, INDIA.

Regd. Office: 166, C.S.T. Road,
Mumbai 400 098, INDIA

Product Registration Holder

Arms Pharma Sdn. Bhd,
22-1, Jalan PJU 5/20D, The Strand,
47810 Kota Damansara, Selangor.

Date of revision

11/06/2019

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