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In vitro resistance to moxifloxacin develops via multiple-step mutations. Resistance to moxifloxacin occurs in vitro at a general frequency of between  $1.8 \times 10^{-10}$  to less than  $1 \times 10^{-11}$  for Gram-positive bacteria. Moxifloxacin has been shown to be active against most strains of the following microorganisms, both in vitro and in clinical infections as described in the indications and usage section:

#### Aerobic Gram-positive microorganisms:

*Listeria monocytogenes*, *Staphylococcus saprophyticus*, *Streptococcus agalactiae*, *Streptococcus mitis*, *Streptococcus pyogenes*, *Streptococcus Group C, G and F*

#### Aerobic Gram-negative microorganisms:

*Acinetobacter baumannii*, *Acinetobacter calcoaceticus*, *Citrobacter freundii*, *Citrobacter koseri*, *Enterobacter aerogenes*, *Enterobacter cloacae*, *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Moraxella catarrhalis*, *Morganella morganii*, *Neisseria gonorrhoeae*, *Proteus mirabilis*, *Proteus vulgaris*, *Pseudomonas stutzeri*

#### Aerobic Microorganism:

*Clostridium perfringens*, *Fusobacterium species*, *Prevotella species*, *Propionibacterium acnes*,

#### Other microorganisms:

*Chlamydia pneumoniae*, *Legionella pneumophila*, *Mycobacterium avium*, *Mycobacterium marinum*, *Mycoplasma pneumoniae*

#### Preclinical Safety data:

Carcinogenesis, Mutagenesis, Impairment of Fertility

#### Carcinogenesis:

Long-term studies in animals to determine the carcinogenic potential of moxifloxacin have not been performed. However, in an accelerated study with initiators and promoters, moxifloxacin was not carcinogenic in rats following up to 38 weeks of oral dosing at 500 mg/kg/day (3224 times the highest recommended total daily human ophthalmic dose for a 60 kg person, based on body surface area).

#### Mutagenesis:

Moxifloxacin was not mutagenic in four bacterial strains used in the Ames Salmonella reversion assay. As with other quinolones, the positive response observed with moxifloxacin in strain TA 102 using the same assay may be due to the inhibition of DNA gyrase. Moxifloxacin was not mutagenic in the CHO/HGPRT mammalian cell gene mutation assay. An equivocal result was obtained in the same assay when v79 cells were used. Moxifloxacin was clastogenic in the v79 chromosome aberration assay, but it did not induce unscheduled DNA synthesis in cultured rat hepatocytes. There was no evidence of genotoxicity in vivo in a micronucleus test or a dominant lethal test in mice.

#### Impairment of Fertility:

Moxifloxacin had no effect on fertility in male and female rats at oral doses as high as 500 mg/kg/day, approximately 3224 highest recommended total daily human ophthalmic dose, based on body surface area. At 500 mg/kg orally there were slight effects on sperm morphology (head-tail separation) in male rats and on the estrous cycle in female rats.

#### Pharmaceutical particulars

**Incompatibilities:** Not applicable

**Shelf life:** 3 Years (Unopened), One month after first opening.

**Special Precautions for storage:** Do not store above 30°C, Protect from direct sunlight.

#### **Nature and contents of container:**

Opaque low-density polyethylene of 5 ml or 3ml bottle with open translucent open nozzle, plastic closure and HDPE cap packed in carton along with pack insert.

#### **Marketing Authorization Holder:**

Manufacturing Site :  
Ajanta Pharma Ltd,  
Mirza-Palashbari Road,  
Village Kokhjar, Kamrup (R),  
Guwahati, Assam – 781128

#### **Registered office:**

Ajanta House,  
Charkop, Kandiali (W),  
Mumbai 400 067  
India.

**Marketing Authorization Numbers:** Not Applicable

**Date of first authorization/ renewal of the authorization:**  
Not Applicable

**Date of revision of text:** Jan 2022

## apdrops

Eye Drops

### Moxifloxacin Hydrochloride Eye Drops

#### Patient Information Leaflet

**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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

#### **What is in this leaflet:**

1. What Apdrops is and what it is used for
2. What you need to know before you are given Apdrops
3. How to use Apdrops
4. Possible side effects
5. How to store Apdrops
6. Contents of the pack and other information

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

APDROPS 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. What you need to know before you use Apdrops**

- 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 APDROPS. Allergic reactions occur uncommonly and serious reactions occur rarely. If you experience any allergic (hypersensitivity), reaction or any side effect.
- 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 APDROPS if you develop pain or swelling of the tendons (tendinitis).

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

#### **Driving and using machines**

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

#### **Other medicines and Apdrops**

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 APDROPS eye drops.

#### **3. How to use Apdrops**

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 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). APDROPS 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 APDROPS 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.

Get the APDROPS 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 APDROPS, 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, APDROPS 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 APDROPS 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, APDROPS 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 APDROPS 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**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

#### **5. How to store Apdrops**

1. Keep this medicine out of the sight and reach of children.
2. Do not use this medicine after the expiry date, which is stated on the bottle label and carton after "EXP". The expiry date refers to the last day of that month.
3. This medicine does not need any special storage conditions.
4. Stop using the bottle 4 weeks after first opening. This is to prevent infections.
5. 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 Apdrops contains:**

The active substance is: Moxifloxacin Hydrochloride BP

#### **List of Excipients:**

Boric Acid BP, Borax BP (Disodium Tetraborate Dehydrate), Sodium Chloride BP, Water for Injection IP / BP / IH / USP

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

Pale yellow coloured, clear solution, free from visible particles.

Opaque low-density polyethylene of 5 mL or 3mL bottle with open translucent open nozzle, plastic closure and HDPE cap packed in carton along with pack insert.

LDPE vial containing 5 mL of solution along with patient information leaflet.

#### **SUPPLIER AND MANUFACTURER**

Supplier	Manufacturer
Ajanta Pharma Limited Ajanta House, Charkop Kandiali (West) Mumbai - 400 067 India.	Ajanta Pharma Limited Mirza-Palashbari Road, Village Kokhjar, Kamrup (R), Guwahati, Assam - 781128.

For any information about this medicinal product, Please contact the Supplier.

#### **DATE OF PUBLICATION OR REVISION**

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