

# Moxifloxacin APOTEX

Contains the active ingredient moxifloxacin (as hydrochloride monohydrate)

## Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

### What is in this leaflet

This leaflet answers some common questions about this medicine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

### What this medicine is used for

This medicine contains the active ingredient moxifloxacin, which is an antibiotic belonging to a group of medicines called quinolones. These antibiotics work by killing the bacteria that are causing your infection.

Moxifloxacin will not work against infections caused by viruses such as colds or the flu.

It is used to treat infections of the lungs, airways and sinuses in adults. In certain infections, you may require treatment with moxifloxacin injection followed by a course of moxifloxacin tablets e.g. severe and complicated skin and skin structure infections.

Even if you have read the Consumer Medicine Information for moxifloxacin injection, you should read this leaflet as well as it contains information specific to the tablets.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

This medicine should not be used in children and adolescents under 18 years of age.

### Before you take this medicine

*When you must not take it*

**Do not take this medicine if you have an allergy to:**

- moxifloxacin or other medicines belonging to the quinolone family (e.g. ciprofloxacin, norfloxacin or nalidixic acid)
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

**Do not take this medicine if you have or have had any of the following medical conditions:**

- a condition called "QTc prolongation", which is a type of abnormal heart rhythm
- blood tests that show lower than normal potassium levels

**Do not take this medicine if you are taking medicines to treat arrhythmia - fast, slow or irregular heart beat (e.g. quinidine, procainamide, amiodarone, sotalol).**

**Do not take this medicine if you are pregnant.**

Moxifloxacin is not recommended if you are pregnant.

**Do not breastfeed if you are taking this medicine.**

Moxifloxacin passes into breast milk and may affect your baby.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

*Before you start to take it*

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- you or someone in your family has a history of heart rhythm problems

- you are taking any medicine that might affect heart rhythm (e.g. quinidine, procainamide, amiodarone, sotalol, erythromycin, tricyclic antidepressants or antipsychotics)
- you or someone in your family has a history of aneurysm disease or other vascular diseases
- low potassium levels
- any condition affecting the brain, particularly if you have ever had a seizure ('fit')
- myasthenia gravis (a disease that causes muscle weakness)
- severe liver problems
- mental illness
- diabetes

### *Taking other medicines*

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

Moxifloxacin may affect the electrocardiogram (ECG – an electrical record of the activity of the heart) and may add to the effect of other medicines on the ECG. You should advise your doctor if you are taking any medicine that might affect the heart rhythm.

Tell your doctor if you are taking:

- warfarin, used to stop blood clots – your doctor should perform INR testing and may adjust your warfarin dose
- medicines used to treat abnormal heart rhythm (e.g. quinidine, procainamide, amiodarone or sotalol)
- medicines that can affect the heart rhythm (erythromycin, tricyclic antidepressants or antipsychotics)
- corticosteroids

If you are taking any of these medicines, you may need a different dose, or you may need to take different medicines. Your doctor will advise you if you do.

The following medicines and moxifloxacin may affect each other

or increase the chance of you getting a side effect. These include:

- antacids, multivitamins, mineral supplements and other medicines containing iron, zinc, magnesium, aluminium or calcium
- sucralfate, used to treat duodenal or stomach ulcers
- didanosine, used to treat viral infections

You can still take these medicines while you are taking moxifloxacin.

**However, you must take moxifloxacin at least 2 hours before, or 4 hours after taking any of these medicines to make sure there is no problem with absorption.**

Other medicines not listed above may also interact with moxifloxacin.

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## How to take this medicine

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**Follow carefully all directions given to you by your doctor.**

Their instructions may be different to the information in this leaflet.

### *How much to take*

Your doctor will tell you how much of this medicine you should take.

This will depend on your condition and whether you are taking any other medicines.

The usual adult dosage for most infections is one 400 mg tablet once daily for 5 to 10 days. However, some types of infections may require longer treatment. Your doctor will determine the duration of time that you take the tablets depending on the type of infection you have.

**You should not exceed the dose your doctor has prescribed for you. The risk of heart rhythm problems may increase with an increase in dose.**

### *How to take it*

**Swallow the tablet whole with water. Do not chew the tablet.**

### *When to take it*

Moxifloxacin tablets are usually taken once a day.

**Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

**It does not matter if you take your medicine with or without food. It is advisable to drink plenty of fluids.**

**Do not take moxifloxacin at the same time as taking antacids (containing magnesium, calcium or aluminium), multivitamins (containing iron or zinc), sucralfate (a medicine to treat stomach ulcers) or didanosine (a medicine to treat viral infections).**

Taking these medicines at the same time as moxifloxacin can interfere with the absorption of moxifloxacin tablets and reduce their effectiveness in fighting the infection.

**You must take moxifloxacin at least 2 hours before, or 4 hours after taking any of these medicines.**

### *How long to take it for*

The length of treatment with moxifloxacin tablets may vary depending on the type of infection. The usual duration of treatment is from five to ten days but can be longer. Your doctor will determine the duration of time that you need to take the tablets.

### *If you forget to take it*

**If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

**Do not take a double dose to make up for the dose that you missed.**

This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

*If you take too much (overdose)*

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that 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.

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## While you are taking this medicine

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### *Things you must do*

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

It may affect other medicines used during surgery.

**If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.**

**If you develop an allergic reaction (e.g. skin rash) while taking this medicine, even following a single dose, stop taking it and tell your doctor.**

**Tell your doctor immediately if you get diarrhoea.**

Do this even if it occurs several weeks after you have stopped taking this medicine. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any medications for diarrhoea without checking with your doctor.

**Tell your doctor immediately if you feel any discomfort, pain, swelling or inflammation of a tendon.**

Medicines like moxifloxacin have been reported to cause tendon damage (especially the Achilles tendon). This may occur even within the first 48 hours of treatment and up to several months after completing treatment with moxifloxacin. Elderly patients, patients taking a type of medicine called corticosteroids, patients with reduced kidney function or that have received solid organ transplants are more at risk.

**Tell your doctor immediately if you experience palpitations (fast or irregular heart beat) or fainting spells during the period of treatment.**

**Tell your doctor if you experience symptoms of depression or self-endangering behaviour. This medicine should be discontinued.**

**Tell your doctor if you develop photosensitivity (getting sunburnt very easily).**

Avoid exposure to ultraviolet radiation and sunlight. Protect your skin when you are in the sun, especially between 10am and 3pm. If you are outdoors, wear protective clothing and use a 30+ sunscreen.

**Tell your doctor if you develop pain, burning, tingling, numbness or weakness in any part of the body.**

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.**

It may interfere with the results of some tests.

**Keep all your doctor's appointments so that your progress can be checked.**

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

### *Things you must not do*

**Do not take this medicine to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or lower the dosage without checking with your doctor first, especially if you are feeling better.**

If you do not complete the full course prescribed by your doctor, some of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear up completely or it may return.

### *Things to be careful of*

**Be careful when driving or operating machinery until you know how this medicine affects you.**

Moxifloxacin tablets may cause dizziness or faintness in some patients. The ability to drive and/or operate machinery may be impaired. If you drink alcohol, dizziness or faintness may be worse.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.**

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**Tell your doctor if you notice any of the following and they worry you:**

- headache
- dizziness or light headedness
- nausea, vomiting
- stomach pains, diarrhoea
- thrush in the mouth (sore creamy yellow raised patches in mouth) or in the vagina (itching, burning or thick white discharge)

These are the more common side effects of this medicine. They are usually mild and short-lived.

**Tell your doctor as soon as possible if you notice any of the following:**

- palpitations or fainting spells
- watery or bloody diarrhoea, even if it occurs several weeks after finishing your tablets
- pain, swelling or rupture of a tendon
- fits (seizures, convulsions)
- visual disturbances or changes in vision (specialist consult needed)
- pain, burning, tingling, numbness or weakness that starts or worsens on this medicine
- changes in your mood or thoughts that worry you

The above list includes serious side effects and you may need medical attention.

In isolated instances, some serious side effects may be long-lasting (greater than 30 days) and disabling, such as tendonitis, tendon rupture, musculoskeletal disorders and other reactions affecting the nervous system including mental health disorders and disturbances of sense.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- hearing impairment
- temporary visual impairment
- sudden abdominal, chest or back pain
- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

**This medicine may cause rapid and severe inflammation of the liver, which can lead to life-threatening liver failure including fatal cases. Tell your doctor immediately if you suddenly feel unwell or sick and develop symptoms such as:**

- yellowing of the skin and in the whites of your eyes, also called jaundice
- pain in liver area
- dark urine
- itchy skin
- tendency to bleed

**If you develop a skin reaction or blistering and/or peeling of the skin and/or mucosal reactions contact your doctor immediately before you continue the treatment.**

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may occur in some patients.

**Some of these side-effects may also be long-lasting and disabling in some patients. If this occurs, speak to your doctor or pharmacist.**

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## Storage and disposal

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### Storage

**Keep your medicine in its original packaging until it is time to take it.**

If you take your medicine out of its original packaging it may not keep well.

**Keep your medicine in a cool dry place where the temperature will stay below 30°C.**

**Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep this medicine where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Disposal

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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## Product description

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### *What Moxifloxacin APOTEX tablets looks like*

400 mg film coated tablets: Reddish brown coloured, modified capsule-shaped, biconvex, film coated tablet engraved "APO" one side and "MX 400" on the other side. AUST R 223564.

Blister pack of 5 tablets.

### *Ingredients*

Each tablet contains 400 mg moxifloxacin as the active ingredient.

It also contains the following inactive ingredients:

- powdered cellulose
- pregelatinised maize starch
- croscarmellose sodium
- silicon dioxide
- magnesium stearate
- polyvinyl alcohol
- macrogol 8000
- purified talc
- titanium dioxide
- iron oxide red

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

### *Sponsor*

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