

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

Read this leaflet carefully before taking your medicine.

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is Moxifloxacin APOTEX tablets. It 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.

How it works

The antibacterial action of moxifloxacin works by interrupting the pathways that allow bacterial DNA to replicate and repair. At the correct dose moxifloxacin can kill susceptible bacteria.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, moxifloxacin, other medicines belonging to the quinolone family (e.g. ciprofloxacin, norfloxacin, nalidixic acid) or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: 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; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **You have a condition called "QTc prolongation", which is a type of abnormal heart rhythm**
- **You are taking medicines to treat arrhythmia - fast, slow or irregular heart beat (e.g. quinidine, procainamide, amiodarone, sotalol).**
- **You have blood tests that show lower than normal potassium levels**
- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - 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, antipsychotics)
 - you have low potassium levels
 - you have had any condition affecting the brain, particularly if you have ever had a seizure ('fit')
 - you have a condition called myasthenia gravis (a disease causing muscle weakness)
 - you have severe liver problems
 - you have or have had a mental illness

- you have diabetes.
3. You are currently pregnant or you plan to become pregnant. Moxifloxacin is not recommended if you are pregnant.
 4. You are currently breastfeeding or you plan to breast-feed. Moxifloxacin passes into breast milk and may affect your baby.
 5. You are planning to have surgery or an anaesthetic.
 6. You are currently receiving or are planning to receive dental treatment.
 7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Moxifloxacin may have an effect on the electro-cardiogram (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.

- In particular, tell your doctor if you are taking: warfarin, a medicine 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, sotalol)
- medicines that can affect the heart rhythm (erythromycin, tricyclic antidepressants, antipsychotics)
- corticosteroids

If you are taking any of these you may need a different dose or you may need to take different medicines.

Your doctor will advise you.

These medicines and moxifloxacin may affect each other or increase the chance of you getting a side effect.

Some medicines may interfere with the absorption of moxifloxacin tablets. These medicines include:

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

How to take this medicine

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.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

The usual adult dosage for moxifloxacin tablets 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 of the 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 this medicine at the same time each day. Taking it at the same time each day will have the best effect and 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 fluids liberally.

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.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. 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 missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your

pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- 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.
- you get diarrhoea, tell your doctor or pharmacist immediately.
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.
- 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). Elderly patients and those taking a type of medicine called corticosteroids are more at risk.

- you experience palpitations (fast or irregular heart beat) or fainting spells during the period of treatment, tell your doctor immediately.
- you experience symptoms of depression or self-endangering behaviour. This medicine should be discontinued.
- 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.
- you develop pain, burning, tingling, numbness or weakness in any part of the body.
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

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.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking moxifloxacin or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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.

These may be serious side effects and you may need medical attention:

- allergic reactions such as skin rashes, swelling of the face, lips, mouth or throat
- 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)

- 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

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and 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
- hearing impairment
- temporary visual impairment

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.

Allergic reactions

If you think you are having an allergic reaction to moxifloxacin, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- 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
- fainting
- hay fever-like symptoms.

Storage and disposal

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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

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.

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
- silica colloidal
- 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.

Australian Registration Numbers

Moxifloxacin APOTEX 400 mg:
Blister pack of 5 tablets, AUST R 223564.

Sponsor

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