

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Moxifloxacin 400 mg Tablets* moxifloxacin (as hydrochloride)

Read all of this leaflet carefully before you start taking 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 health care provider.
- 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 health care provider. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Moxifloxacin 400 mg Tablets is and what it is used for
2. What you need to know before you take Moxifloxacin 400 mg Tablets
3. How to take Moxifloxacin 400 mg Tablets
4. Possible side effects
5. How to store Moxifloxacin 400 mg Tablets
6. Contents of the pack and other information

1. WHAT MOXIFLOXACIN 400 MG TABLETS IS AND WHAT IT IS USED FOR

Moxifloxacin 400 mg Tablets contains moxifloxacin as the active ingredient. This belongs to a group of antibiotics called fluoroquinolones. Moxifloxacin 400 mg Tablets works by killing bacteria that cause infections, including the bacteria that cause tuberculosis (TB).

Moxifloxacin 400 mg Tablets is used to treat TB caused by *Mycobacterium tuberculosis*. It is always given together with other medicines for TB.

To help clear up your TB completely, you must keep taking this medicine for the full time of treatment, even if you begin to feel better before. This is very important. It is also important that you do not miss any doses.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MOXIFLOXACIN 400 MG TABLETS

Do not take Moxifloxacin 400 mg Tablets:

- If you are allergic (hypersensitive) to the active ingredient moxifloxacin, to any other quinolone antibiotics or to any of the other ingredients of Moxifloxacin 400 mg Tablets.
- If you have previously had problems with your tendons related to treatment with quinolone antibiotics (see section ‘Warnings and precautions’ and section 4, ‘Possible side effects’).
- If you were born with or have
 - a condition with certain abnormalities in the electrocardiogram (ECG, electrical recording of the heart), so called QT-prolongation
 - a salt imbalance in the blood, especially low concentrations of potassium in the blood (hypokalaemia)
 - a very slow heart rate (bradycardia)
 - a weak heart (heart failure)
 - a history of abnormal heart rhythms (arrhythmias)or
 - if you are taking other medicines that result in certain ECG abnormalities (see section “Other medicines and Moxifloxacin 400 mg Tablets”). This is because Moxifloxacin 400 mg Tablets can cause QT-prolongation, a certain change on the ECG.

Warnings and precautions

- Moxifloxacin 400 mg Tablets can change your heart’s ECG, especially if you are female or elderly. If you experience palpitations or an irregular heartbeat during treatment, you should tell your health care provider immediately. He/she may wish to perform an ECG to measure your heart rhythm.
- If you are taking any medicine that decreases your blood potassium levels, talk to your health care provider before taking Moxifloxacin 400 mg Tablets.
- If you suffer from epilepsy or a condition which makes you likely to have convulsions, talk to your provider before taking Moxifloxacin 400 mg Tablets.
- If you have or have ever had any mental health problems, consult your health care provider before taking Moxifloxacin 400 mg Tablets.
- If you suffer from myasthenia gravis (abnormal muscle fatigue leading to weakness and in serious cases paralysis), taking Moxifloxacin 400 mg Tablets may worsen the symptoms of your disease. If you think you are affected, consult your health care provider immediately.
- If you or any member of your family have glucose-6-phosphate dehydrogenase deficiency (a rare hereditary disease), tell your health care provider, who will advise whether Moxifloxacin 400 mg Tablets is suitable for you.
- If you have a liver disease, consult your health care provider before taking Moxifloxacin 400 mg Tablets.
- The risk of heart problems may increase with higher doses. Therefore, you should keep to the prescribed dose.
- There is a small risk that you may experience a severe, sudden allergic reaction (an anaphylactic reaction/shock) even with the first dose. Symptoms include tightness in the chest, feeling dizzy, feeling sick or faint, or dizziness when standing up. If so, stop taking Moxifloxacin 400 mg Tablets and seek medical help immediately.
- Moxifloxacin 400 mg Tablets may cause a rapid and severe inflammation of the liver which could lead to life-threatening liver failure (including fatal cases, see section 4, ‘Possible side effects’). If you suddenly feel unwell and/or are being sick and also have yellowing of the whites of the eyes (jaundice), dark urine, itching of the skin, a tendency to bleed or liver induced disease of the brain (symptoms of a reduced liver function or a rapid and severe inflammation of the liver) please contact your health care provider before taking any more tablets.

- If you develop a skin reaction or blistering / peeling of the skin and/or mucosal reactions (see section 4, 'Possible side effects'), contact your health care provider immediately before you continue treatment.
- Quinolone antibiotics, including Moxifloxacin 400 mg Tablets, may cause convulsions. If this happens, stop taking Moxifloxacin 400 mg Tablets and contact your health care provider immediately.
- You may experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or weakness. If this happens, inform your health care provider immediately prior to continuing treatment with Moxifloxacin 400 mg Tablets.
- You may experience mental health problems even when taking quinolone antibiotics, including Moxifloxacin 400 mg Tablets, for the first time. In very rare cases depression or mental health problems have led to suicidal thoughts and self-endangering behaviour such as suicide attempts (see section 4, 'Possible side effects'). If you develop such reactions, stop taking Moxifloxacin 400 mg Tablets and inform your health care provider immediately.
- You may develop diarrhoea whilst or after taking antibiotics including Moxifloxacin 400 mg Tablets. If this becomes severe or persistent or you notice that your stool contains blood or mucus you should stop taking Moxifloxacin 400 mg Tablets immediately and consult your health care provider. In this situation you should not take medicines that stop or slow down bowel movement.
- Moxifloxacin 400 mg Tablets may cause pain and inflammation of your tendons, particularly if you are elderly or if you are also taking corticosteroids. At the first sign of any pain or inflammation you should stop taking Moxifloxacin 400 mg Tablets, rest the affected limb and consult your health care provider immediately. Avoid any unnecessary exercise, as this might increase the risk of a tendon rupture. Inflammation and ruptures of tendons may occur even up to several months after discontinuing therapy with Moxifloxacin 400 mg Tablets.
- If you are elderly and have kidney problems, make sure that you drink plenty whilst taking Moxifloxacin 400 mg Tablets. If you get dehydrated, this may increase the risk of kidney failure.
- If your eyesight becomes impaired or if your eyes seem to be affected whilst taking Moxifloxacin 400 mg Tablets, consult an eye specialist immediately (see sections 2, 'Driving and using machines' and 4, 'Possible side effects').
- Quinolone antibiotics may make your skin become more sensitive to sunlight or UV light. You should avoid prolonged exposure to sunlight or strong sunlight and should not use a sunbed or any other UV lamp while taking Moxifloxacin 400 mg Tablets.

Children and adolescents

In children, Moxifloxacin 400 mg Tablets may cause damage to the cartilage. Therefore, children should only take Moxifloxacin 400 mg Tablets when his/her health care provider considers the benefit to outweigh the risks.

Other medicines and Moxifloxacin 400 mg Tablets

Please tell your health care provider if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. These may affect the action of Moxifloxacin 400 mg Tablets or Moxifloxacin 400 mg Tablets may affect their action.

For Moxifloxacin 400 mg Tablets be aware of the following:

- Do not take Moxifloxacin 400 mg Tablets with the following medicines as there is an increased risk that your heartbeat may be altered:
 - medicines that affect your heart rate or rhythm (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide),
 - medicines used to treat severe mental disorders (e.g. phenothiazines, pimozide, sertindole, haloperidol, sultopride),
 - tricyclic antidepressants,
 - other drugs used to treat infections (e.g. sparfloxacin, intravenous erythromycin, pentamidine, antimalarials, particularly halofantrine),
 - some antihistamines (e.g. terfenadine, astemizole, mizolastine),

- other medicines (e.g. cisapride, bepridil).
- Any medicine containing magnesium or aluminium (such as antacids for indigestion), iron, zinc or didanosine or any medicine containing sucralfate (to treat stomach disorders) can reduce the action of Moxifloxacin 400 mg Tablets. Take your tablet of Moxifloxacin 400 mg Tablets 6 hours before or after taking the other medicine.
- If you are currently taking drugs to thin your blood (oral anticoagulants such as warfarin), it may be necessary for your health care provider to monitor your blood clotting time.

Moxifloxacin 400 mg Tablets with food

You can take Moxifloxacin 400 mg Tablets with or without food.

Pregnancy and breastfeeding

If you become pregnant, or are planning to become pregnant, you must contact your health care provider to discuss the potential benefits and risks of your tuberculosis therapy to you and your child.

Since the safety of taking Moxifloxacin 400 mg Tablets during pregnancy has not been investigated in humans, you should avoid becoming pregnant during treatment. You or your partner need to use a reliable form of barrier contraception (for example, a condom), or oral (pill) or other hormonal contraceptives (for example, implant or injection).

Since moxifloxacin passes over into the mother's milk and might hurt the development of your child's skeleton, you should not breast-feed while taking Moxifloxacin 400 mg Tablets.

Driving and using machines

Moxifloxacin 400 mg Tablets may make you feel dizzy or light-headed, you may experience a sudden, transient loss of vision, or you may faint for a short period. If you are affected, do not drive or operate machines.

3. HOW TO TAKE MOXIFLOXACIN 400 MG TABLETS

Always take Moxifloxacin 400 mg Tablets exactly as your health care provider told you. You should check with your health care provider if you are not sure.

The recommended dose for adults and children weighing 33 kg or more is one 400 mg film-coated tablet once daily. You can take Moxifloxacin 400 mg Tablets with or without food.

Moxifloxacin 400 mg Tablets are for oral use. Swallow the tablet whole (to mask the bitter taste) and with plenty of liquid. Try to take the tablet at approximately the same time each day.

It is important that you complete the course of treatment even if you begin to feel better. If you stop taking Moxifloxacin 400 mg Tablets too soon, your infection may not be completely cured and the infection may return or your condition may get worse. The bacteria causing your infection may become resistant to Moxifloxacin 400 mg Tablets.

Children weighing less than 33 kg should not take Moxifloxacin 400 mg Tablets as appropriate dose adjustments cannot be made.

If you take more Moxifloxacin 400 mg Tablets than you should

If you take more than the prescribed one tablet a day, get **medical help immediately**. Try to take any remaining tablets, the packaging or this leaflet with you to show the health care provider what you have taken.

If you forget to take Moxifloxacin 400 mg Tablets

If you forget to take your tablet, you should **take it as soon as you remember on the same day**. If you do not remember on the same day, take your normal dose (one tablet) on the next day. Do not take a double dose to make up for a forgotten dose.

If you stop taking Moxifloxacin 400 mg Tablets

Keep taking the medicine for as long as your health care provider has told you, even if you are feeling better. If you stop the medicine too soon, your infection may not be completely cured. You should not stop treatment unless your health care provider tells you to. If you have any further questions on the use of this product, ask your health care provider.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Moxifloxacin 400 mg Tablets can cause side effects, although not everybody gets them. When treating tuberculosis, it is not always possible to differentiate between unwanted effects caused by Moxifloxacin 400 mg Tablets, or those caused by any other medicines you may be taking at the same time, or by the disease itself. For this reason, it is important that you inform your health care provider of any change in your health.

Common side effects (may affect up to 1 in 10 people):

- Infections caused by resistant bacteria or fungi, e.g. thrush or vaginitis (oral and vaginal infections caused by Candida)
- Headache
- Dizziness
- Feeling sick (nausea)
- Being sick (vomiting)
- Stomach ache
- Diarrhoea
- Increase of special liver enzymes in the blood (transaminases)

Uncommon side effects (may affect up to 1 in 100 people):

- Allergic reactions
- Changes in the electrical activity of the heart (ECG), palpitations, irregular and fast heartbeat
- Low red blood cell count (anaemia)
- Low white blood cells count
- Low numbers of special white blood cells (neutrophils)
- Decrease or increase of special blood cells necessary for blood clotting (platelets)
- Increased specialised white blood cells (eosinophils)
- Decreased blood clotting
- Increased blood lipids (fats)
- Feeling anxious, restless, or agitated
- Tingling sensation (pins and needles) and/or numbness
- Changes in taste (in very rare cases loss of taste)
- Feeling confused and disorientated
- Sleep problems (e.g. sleeplessness or sleepiness)
- Shaking
- Sensation of dizziness (spinning or falling over)
- Problems with vision (including double or blurred vision)
- Chest pain (angina)
- Widening of the blood vessels (flushing)
- Difficulty in breathing (including asthmatic conditions)
- Loss of appetite
- Wind and constipation

- Stomach upset (indigestion or heartburn)
- Inflammation of the stomach
- Increase of a special digestive enzyme in the blood (amylase)
- Problems with liver function (increase of bilirubin in the blood, increase of special liver enzymes in the blood, such as gamma-glutamyl-transferase and/or alkaline phosphatase)
- Itching, rash, skin hives, dry skin
- Joint pain, muscle pain
- Dehydration
- Feeling unwell (usually weakness or tiredness), aches and pains such as back, chest, pelvic pains and pains in the extremities
- Sweating.

Rare side effects (may affect up to 1 in 1,000 people):

- Severe, sudden allergic reaction including very rarely life-threatening shock (e.g. difficulty in breathing, drop of blood pressure, fast pulse), swelling (including potentially life-threatening swelling of the airway)
- Severe diarrhoea containing blood and/or mucus (antibiotic associated colitis including pseudomembranous colitis), which very rarely, may develop into complications that are life-threatening
- Jaundice (yellowing of the whites of the eyes or skin), inflammation of the liver
- Pain and swelling of the tendons (tendonitis)
- Increased blood sugar
- Increased blood uric acid
- Feeling particularly emotional
- Depression (which in very rare cases may lead to self-harm, such as suicidal ideations/thoughts, or suicide attempts)
- Hallucination
- Problems with skin sensations
- Changes in smelling
- Unusual dreams
- Problems with balance and co-ordination (due to dizziness)
- Convulsions
- Disturbed concentration
- Problems with speech
- Partial or total loss of memory
- Ringing or noise in the ears, hearing impairment including deafness (usually reversible)
- Faster heart rate than normal
- Fainting
- High or low blood pressure
- Difficulty in swallowing
- Inflammation of the mouth
- Muscle cramps or twitching
- Muscle weakness
- Kidney problems (including an increase in special kidney laboratory test results like urea and creatinine), kidney failure
- Swelling (of the hands, feet, ankles, lips, mouth or throat).

Very rare side effects (may affect up to 1 in 10,000 people):

- Severe heart rhythm problems (Torsade de Pointes), stopping of heart (cardiac arrest) (see section 2, What you need to know before you take Moxifloxacin 400 mg Tablets)
- Severe inflammation of the liver, potentially leading to life-threatening liver failure (including fatal cases)

- Changes to the skin and mucous membranes (painful blisters in the mouth/nose or at the penis/vagina), potentially life-threatening (Stevens-Johnson-Syndrome, toxic epidermal necrolysis)
- Rupture of tendons
- Increased blood clotting, significant decrease of special white blood cells (agranulocytosis)
- A feeling of self-detachment (not being yourself)
- Feeling mentally unwell (potentially leading to self-harm, such as suicidal ideations/thoughts, or suicide attempts)
- Transient loss of vision
- Skin feeling more sensitive
- Inflammation of joints
- Muscles feeling stiff
- Worsening of the symptoms of myasthenia gravis (abnormal muscle fatigue leading to weakness and in serious cases paralysis)

Also, there have been very rare cases of the following side effects reported following treatment with other quinolone antibiotics, which might possibly also occur during treatment with Moxifloxacin 400mg tablet:

- Increased blood sodium levels
- Increased blood calcium levels
- A special type of reduced red blood cell count (haemolytic anaemia)
- Muscle reactions with muscle cell damage
- Increased sensitivity of the skin to sunlight or UV light
- Troubles associated with the nervous system such as pain, burning, tingling, numbness and/or weakness in extremities

If you feel you are suffering from a side effect, especially if any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider immediately to get advice before taking the next dose.

5. HOW TO STORE MOXIFLOXACIN 400 MG TABLETS

Keep this medicine out of the sight and reach of children.

Do not store above 30°C. Store in the original container.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your health care provider 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 Moxifloxacin 400 mg Tablets contains

The active ingredient is moxifloxacin (as hydrochloride). Each tablet contains moxifloxacin hydrochloride equivalent to 400 mg moxifloxacin.

The other ingredients are:

Core tablet: Croscarmellose sodium, copovidone, magnesium stearate and microcrystalline cellulose

Film coat: Hypromellose, iron oxide red, macrogol, titanium dioxide.

What Moxifloxacin 400 mg Tablets looks like and contents of the pack

Moxifloxacin 400 mg Tablets is a pink, film-coated, capsule shaped, biconvex, bevelled edge tablet debossed with 'M' on one side of the tablet and 'MO2' on other side.

Moxifloxacin 400 mg Tablets is provided in following packs:

Blister packs

Clear transparent PVC/PVDC-Al blister pack of 10 tablets.

HDPE bottle

White opaque HDPE bottle with white opaque screw cap. The HDPE bottle is kept in a carton box.

Pack size: 100 Tablets.

Supplier and Manufacturer

Supplier	Manufacturer
Mylan Laboratories Limited Plot No. 564/A/22, Road No.92, Jubilee Hills Hyderabad - 500096, Telangana, India Tel No: +91 40 39258109 Email: imtiyaz.basade@mylan.in	Mylan Laboratories Limited F-4, F-12, Malegaon M.I.D.C. Sinnar, Nashik – 422113 Maharashtra State India

For any information about this medicinal product, please contact the supplier:

This leaflet was last approved in July 2017.

Detailed information on this medicine is available on the World Health Organization (WHO) web site:
<https://extranet.who.int/prequal>.