

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

Information for the patient

[TB315 trade name][†]
Moxifloxacin (hydrochloride)

*The warnings and instructions in this leaflet are intended for the person taking the medicine.
If you are a parent or carer responsible for giving the medicine to someone else such as a child,
you will need to apply the instructions accordingly.*

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 questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [TB315 trade name] is and what it is used for
2. What you need to know before you take [TB315 trade name]
3. How to take [TB315 trade name]
4. Possible side effects
5. How to store [TB315 trade name]
6. Contents of the pack and other information

1. What [TB315 trade name] is and what it is used for

[TB315 trade name] is a medicine used to treat tuberculosis (TB), an infection caused by bacteria called *Mycobacterium tuberculosis*. It is always given together with other medicines to treat tuberculosis. Your health care provider has chosen the combination that is right for you.

[TB315 trade name] contains the active substance moxifloxacin. It belongs to a group of antibiotics called quinolones and fluoroquinolones.

2. What you need to know before you take [TB315 trade name]

Do not take [TB315 trade name] if you:

- are allergic (hypersensitive) to the active ingredient moxifloxacin, to any other quinolone antibiotics or to any of the other ingredients of [TB315 trade name] (listed in section 6).
- have previously had problems with your tendons related to treatment with quinolone antibiotics (see 'Warnings and precautions' and section 4, 'Possible side effects').
- were born with or have
 - abnormal heart rhythm (often seen on ECG, a recording of your heart's electrical activity), or if you have had such a condition in the past
 - a salt imbalance in the blood, especially if you have low levels of potassium or magnesium
 - a very slow heart rate (bradycardia)
 - a weak heart (heart failure)

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

- severe liver disease or blood tests that show that your liver is not working properly

Warnings and precautions

Talk to your health care provider before taking [TB315 trade name] if:

- you are taking any medicine that decreases your blood potassium levels
- you have had a serious reaction when taking a quinolone or fluoroquinolone. In this situation, you should not take [TB315 trade name] or another fluoroquinolone or quinolone antibiotic.
- you suffer from epilepsy or a condition which makes you likely to have convulsions (fits)
- you have or have ever had any mental health problems
- you suffer from myasthenia gravis (abnormal muscle fatigue leading to weakness and, in serious cases, paralysis). Taking [TB315 trade name] may worsen your disease. If you think you are affected, talk with your health care provider immediately.
- you or a member of your family have had heart disease, heart valve disease, or weakness or a tear of a large blood vessel
- you or a member of your family have glucose-6-phosphate dehydrogenase deficiency (G6PD, a rare hereditary disease)
- you have liver disease

Ask your health care provider if you are not sure if any of the above apply to you.

Stop taking [TB315 trade name] and contact your health care provider immediately if you:

- get sudden, severe pain in your belly, chest or back, or you have breathlessness, palpitations or swelling (fluid build-up) in your belly or legs. These may be signs of aortic dissection or heart valve disease. If you get any of these, immediately go to an emergency room.
- feel tightness in the chest, dizzy, sick or faint, or feel dizzy when standing up. These may be symptoms of a severe allergic reaction (anaphylactic reaction). Such reactions may occur even with the first dose. If you get any of these, seek medical help immediately.
- have convulsions (fits)
- get mental health problems including depression, memory problems, and severe sleep problems (see 'Prolonged, disabling and potentially irreversible serious side effects', below). 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').
- lose your appetite, or get nausea (feel sick), or feel persistently tired, or have a rash

and have any of the following

- belly pain, usually on the right side and near the chest
- unexplained itching
- yellowing of the white parts of your eyes, your nails or your skin or
- passing dark urine
- passing stools that are very pale

These are signs of a problem with your liver, which can become serious.

- a skin reaction or blistering or peeling of the skin and effects on moist body surfaces such as the lining of the mouth (see section 4, 'Possible side effects'). You may also get fever or flu-like symptoms with these skin reactions.

- pain, burning, tingling, numbness and weakness especially in the feet and legs or hands and arms (see also ‘Prolonged, disabling and potentially irreversible serious side effects’, below). These may be symptoms of nerve damage (neuropathy).
- severe or persistent diarrhoea, or your stool contains blood or mucus. Speak with your health care provider before taking any medicines to treat the diarrhoea because some medicines that stop diarrhoea may be harmful in this situation.
- pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), pain and swelling in the joints (see also ‘Prolonged, disabling and potentially irreversible serious side effects’, below). [TB315 trade name] may damage your joints or tendons, especially if you are elderly, have kidney problems, or take corticosteroids. If you get such problems, rest the affected limb and avoid any unnecessary exercise, as this might increase the risk of a tendon rupture. Inflammation and tendon rupture may even occur several months after you stop taking [TB315 trade name].

Take special care with [TB315 trade name]

Tell your health care provider immediately if during treatment you get:

- palpitations (forceful, rapid heartbeat) or an irregular heartbeat. [TB315 trade name] can cause abnormal heart rhythm, especially if you are female or elderly.
 - if you are taking other medicines that can cause ECG abnormalities (see section ‘Other medicines and [TB315 trade name]’) your health care provider may adjust the dose of your medicine and will closely monitor your heart rhythm and your blood potassium levels. This is because [TB315 trade name] can cause QT-interval prolongation, a disorder that can be seen on the ECG.
 - the risk of heart problems may increase with higher doses. Therefore, you should keep to the prescribed dose.
- problems with your blood sugar if you have diabetes. Check your blood sugar regularly as [TB315 trade name] can make it harder to keep your blood sugar under control.
- problems with your eyesight. See an eye specialist if you have problems with your eyesight whilst taking [TB315 trade name].

[TB315 trade name] may make your skin become more sensitive to sunlight. You should avoid strong sunlight or being in sunlight for a long time and you should not use a sunbed or any other UV lamp while taking [TB315 trade name].

If you are elderly and have kidney problems, make sure that you drink plenty whilst taking [TB315 trade name]. If you get dehydrated, this may increase the chance of kidney damage.

Prolonged, disabling and potentially irreversible serious side effects

Medicines like [TB315 trade name] are associated with very rare but serious side effects, some of these side effects may be disabling and continue for a long time. These side effects include tendon, muscle and joint pain of the upper and lower limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, numbness or burning (paraesthesia), disorders of vision, taste, smell, and hearing, depression, memory problems, severe tiredness, and severe sleep disorders. If you get any of these side effects after taking [TB315 trade name], contact your health care provider immediately. You and your health care provider will need to decide on how to continue your treatment.

Children and adolescents

In children, [TB315 trade name] may cause damage to the cartilage. Therefore, children should only take [TB315 trade name] when the health care provider considers the benefit to outweigh the risks.

Other medicines and [TB315 trade name]

Tell your health care provider if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. They may affect the action of [TB315 trade name] or [TB315 trade name] may affect their action.

You must tell your health care provider if you are taking;

- Medicines that can affect your heart rhythm, such as:
 - medicines to treat heart rhythm problems (e.g. *amiodarone, disopyramide, dofetilide, ibutilide, hydroquinidine, quinidine, sotalol*),
 - medicines used to treat severe mental disorders such as schizophrenia,
 - antidepressants (e.g. *amitriptyline, clomipramine, doxepin, imipramine, nortriptyline*),
 - medicines for treating other infections (e.g. *antimalarials*, particularly *halofantrine*, intravenous *erythromycin, pentamidine, saquinavir, sparfloxacin*),
 - some antihistamines (e.g. *astemizole, mizolastine, terfenadine*),
 - other medicines (e.g. *bepidil, cisapride*).
- Medicines that lower your blood potassium levels (e.g. some diuretics [medicines that make you pass water], some laxatives and enemas [high doses], corticosteroids [anti-inflammatory drugs], amphotericin B).
- 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 amount of [TB315 trade name] entering your body. Take your tablet of [TB315 trade name] 6 hours before or 6 hours after taking the other medicine.
- Any medicine containing *charcoal* can reduce the amount of [TB315 trade name] entering your body. It is recommended that these medicines are not used together.
- If you are taking an anticoagulant such as *warfarin* (a medicine that prevent your blood from clotting), your health care provider may need to check how well the anticoagulant is working.

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 health care provider for advice before taking this medicine.

Tuberculosis can be particularly dangerous in pregnancy and it is important that you get the right treatment.

Driving and using machines

[TB315 trade name] may make you feel dizzy or light-headed, you may have a sudden, temporary loss of vision, or you may faint for a short period. If you get these side effects, do not drive, operate machinery or do anything that requires you to be alert. Remember that if you are unwell your ability to drive or operate machinery may be affected.

3. How to take [TB315 trade name]

Always take [TB315 trade name] exactly as your health care provider told you. Check with your health care provider if you are not sure.

This medicine is used as part of tuberculosis treatment. The treatment will include other medicines as well as [TB315 trade name] and may need to continue for many months.

Your healthcare provider will explain to you how to take your medicines and how long your treatment should last. It is important to take the full course of treatment, even if you feel better.

Adults and adolescents

Standard-dose treatment

The usual recommended dose for people weighing at least 24 kg is one 400-mg tablet once daily.

High-dose treatment

In certain cases your health care provider may prescribe a higher dose, as in the table below:

Body weight	Number of 400-mg tablets
30 to less than 36 kg	1 <i>or</i> 1½* tablets once daily
36 to less than 46 kg	1½* tablets once daily
46 to less than 56 kg	1½* <i>or</i> 2 tablets once daily
56 kg and over	2 tablets daily
* [TB315 trade name] cannot be used if you need to take 1½ tablets. Your health care provider will prescribe a suitable medicine.	

Children

[TB315 trade name] is not suitable for children weighing less than 24 kg. Medicines containing a smaller amount of moxifloxacin are more appropriate.

However, [TB315 trade name] can be used in children 24 kg if a suitable medicine is not available. See Instructions for giving [TB315 trade name] to a child, below.

How to take [TB315 trade name]

Take the tablet with some water and swallow it whole. Do not crush or chew the tablet before swallowing as it has a bitter taste.

Try to take the tablet at around the same time each day. You can take the tablets with food or between meals.

If you take more [TB315 trade name] than you should

Immediately contact your health care provider or your nearest hospital emergency department. 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 [TB315 trade name] or if you vomit

If you forget to take a dose and it is still less than 12 hours after you should have taken it, take the dose at once and take the next dose at the usual time.

If more than 12 hours have passed since you missed the dose, do not take the missed dose and instead take the next one at the usual time.

Do not take a double dose to make up for a missed dose.

If you vomit within 1 hour of taking [TB315 trade name], take an extra dose. If you vomit more than an hour after taking the dose, you don't need to take an extra dose and you can take the next dose at the time.

If you are not sure what to do, ask your health care provider.

If you stop taking [TB315 trade name]

It is important to continue taking this medicine.

If you feel unwell again after you have stopped taking this medicine, speak to your health care provider at once to check that the tuberculosis has not come back.

If you have any questions on the use of this medicine, ask your health care provider.

Instructions for giving [TB315 trade name] to a child

Use [TB315 trade name] for a child **only** if a medicine suitable for children is not available.

Mix [TB315 trade name] tablet in water and give the right amount of the mixture to your child (see table, below).

To make the mixture, you need:

- one [TB315 trade name] tablet
 - two small bowls
 - drinking water
 - a 10-mL oral syringe, showing measurements of 0.5 mL.
1. Use the oral syringe to measure 10 mL of drinking water into the first bowl.
 2. Add one [TB315 trade name] tablet to the drinking water in the bowl and mix well until the tablet breaks down completely.
 3. Use the oral syringe to measure a proportion of the mixture according to the child's dose (see table below). Throw away the mixture that remains in the bowl.
 4. Squirt the measured mixture into the second bowl and add a small amount (no more than a teaspoonful) of sweet semi-solid food and mix thoroughly.
 5. Give this to the child immediately. Rinse the bowl with a small amount of water and the child should drink this also.
 6. Give the child a drink after taking the medicine to help wash away the medicine's taste.

Child's weight	Amount of mixture to give
3 to less than 5 kg	1 mL
5 to less than 7 kg	2 mL
7 to less than 10 kg	3 mL
10 to less than 16 kg	5 mL
16 to less than 24 kg	5 mL or 7.5 mL
24 kg and over	Use tablet

4. Possible side effects

Like all medicines, [TB315 trade name] can cause side effects, although not everybody gets them.

If you notice any of the following symptoms, **stop taking [TB315 trade name] and tell your health care provider immediately** as you may need urgent medical advice:

- abnormal heart rhythms including heart beating too fast (rare side effect) or irregular heart beat or very slow heart beat (both very rare and potentially life-threatening side effects)
- lose your appetite, or get nausea (feel sick), or feel tired all the time, or have a rash *and have any of the following*
 - belly pain, usually on the right side and near the chest
 - unexplained itching
 - yellowing of the white parts of your eyes, your nails or your skin or
 - passing dark urine
 - passing stools that are very pale

These are signs of a problem with your liver, which can become serious.

- rashes, reddening, peeling or blistering of the skin and mucous membranes (the lining of eyes, nose, mouth and genitals), especially with fever or chills, which could be due to very rare and potentially life-threatening side effects called Stevens-Johnson syndrome, toxic epidermal necrolysis (both very rare and potentially life-threatening), and acute generalised exanthematous pustulosis, which mainly affects armpits, groin and face (frequency of this side effect is unknown).

- reduced urine and low levels of sodium in the blood (caused by a very rare side effect called syndrome of inappropriate secretion of antidiuretic hormone, SIADH).
- signs of reduced blood sugar (such as feeling shaky, confused, irritable, going pale, having palpitations, fast pulse and blurred vision, headache, and blurred vision), very rarely leading to hypoglycaemic coma
- inflammation of blood vessels, signs of which could be red spots on your skin, usually on your lower legs or effects like joint pain (very rare side effect)
- a severe, sudden allergic reaction including very rarely a life-threatening shock, e.g. difficulty in breathing, drop of blood pressure, fast pulse (rare side effect)
- swelling including swelling of the airway (rare side effect, potentially life-threatening)
- convulsions or fits (rare side effect)
- problems associated with nerves such as pain, burning, tingling, numbness and weakness in arms and legs (rare side effect)
- depression, in very rare cases leading to self-harm, such as suicidal thoughts, or suicide attempts (rare side effect)
- severe mental disorders and disordered thinking, potentially leading to self-harm, such as suicidal thoughts, or suicide attempts (very rare side effect)
- severe diarrhoea containing blood or mucus, so-called antibiotic-associated colitis including pseudomembranous colitis, which may be life-threatening (rare side effects)
- pain and swelling of the tendons, i.e. tendinitis (rare side effect) or a tendon rupture (very rare side effect)
- muscle weakness and tenderness or pain, especially with high temperature and passing dark urine, which may be due to muscle breakdown (frequency not known)

If you get loss of vision or bright light causes you pain or discomfort (rare or very rare side effects), see an eye specialist immediately.

If you are elderly and have kidney problems and you notice decrease in urine, swelling in your legs, ankles or feet, fatigue, nausea, drowsiness, shortness of breath or confusion (these can be signs of kidney failure, a rare side effect), see your health care provider immediately.

Other side effects of [TB315 trade name] are listed below. Tell your health care provider if you get any of those side effects, especially if it gets serious, or if you notice any other unexpected or unusual symptoms not listed in this leaflet.

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

- infections caused by resistant bacteria or fungi, e.g. vaginal or oral thrush (oral and vaginal infections caused by Candida)
- headache
- dizziness
- feeling sick (nausea)
- being sick (vomiting)
- stomach and abdominal (belly) pain
- diarrhoea
- changes in blood test results measuring your liver function
- change in the heart rhythm (ECG) in patients with low blood potassium level

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

- allergic reactions
- changes in the heart rhythm (ECG), palpitations (forceful, rapid heartbeat), irregular and fast heartbeat
- chest pain (angina)
- anaemia (low red blood cell count which can make skin pale and cause weakness or breathlessness)
- low numbers of white blood cells (cells that help the body to fight infections)

- increased numbers of specialised white blood cells (eosinophils)
- changes in the number of blood cells that affect blood clotting (platelets)
- increased blood lipids (fats)
- feeling anxious, restless, or agitated
- feeling confused and disorientated
- sleep problems (e.g. sleeplessness or sleepiness)
- tingling sensation (pins and needles) and numbness
- changes in taste (in very rare cases loss of taste)
- shaking
- sensation of dizziness (spinning or falling over)
- problems with vision (including double or blurred vision)
- widening of the blood vessels (flushing)
- difficulty in breathing (including asthmatic conditions)
- decreased appetite and food intake
- gas and constipation
- stomach upset (indigestion or heartburn)
- inflammation of the stomach
- increase of an enzyme in the blood (amylase), which may be a sign of pancreas damage
- blood test results indicating your liver is not working properly
- itching, rash, skin hives, dry skin
- joint pain, muscle pain
- dehydration
- feeling unwell (usually weakness or tiredness), aches and pains such as back, chest, belly and pains in the arms and legs
- sweating

Rare side effects (may affect up to 1 in 1000 people):

- jaundice (yellowing of the whites of the eyes or skin), inflammation of the liver
- pain and swelling of the tendons (tendinitis)
- increased blood sugar
- increased blood uric acid
- emotional abnormalities
- depression (which in very rare cases may lead to self-harm, such as suicidal ideations/thoughts, or suicide attempts)
- seeing, hearing or feeling things that are not there (hallucination)
- problems with skin sensations
- changes in the sense of smell and loss of the sense of smell
- abnormal 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 problems including deafness
- faster heart rate than normal
- fainting
- high or low blood pressure
- difficulty swallowing
- inflammation of the mouth
- muscle cramps or twitching
- muscle weakness

- kidney problems including blood test results indicating your kidneys are not working properly
- swelling (of the hands, feet, ankles, lips, mouth or throat)

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

- Blood disorders including low levels of all blood cells (pancytopenia)
- feeling of self-detachment (not being yourself)
- 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 [TB315 trade name]:

- raised pressure in the skull (causing headache, blurred vision, blind spots, double vision, loss of vision)
- increased blood sodium levels
- increased blood calcium levels
- haemolytic anaemia (excessive breakdown of red blood cells)
- increased sensitivity of the skin to sunlight or UV light

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [TB315 trade name]

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

Do not store above 30°C. Store in the original package in order to protect from light.

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

Do not use this medicine if you notice description of the visible signs of deterioration that it is different from the description below.

Do not throw away any medicines in 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 [TB315 trade name] contains

- The active ingredient is moxifloxacin (as hydrochloride).
- The other ingredients of [TB315 trade name] are:
 - *Core tablet*: Croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, microcrystalline cellulose and povidone
 - *Film coat* : Hypromellose, iron oxide red, iron oxide yellow, macrogol (PEG) and titanium dioxide.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [TB315 trade name] looks like and contents of the pack

[TB315 trade name] is a pink coloured, capsule shaped, biconvex, film coated tablet debossed with "80" on one side and '1' on the other side.

The primary packs are blister cards of 10 tablets (comprised of aluminium foil-aluminium foil). Each blister card is packed in a carton.

Supplier and Manufacturer

Supplier

Hetero Labs Ltd, Hetero Corporate,
7-2-A2, Industrial Estates,
Sanath Nagar,
Hyderabad,
Ranga Reddy District,
Telangana – 500 018,
India
Tel: +91 40 23704923
E-mail: contact@heterodrugs.com

Manufacturer

Hetero Labs Limited, Unit 5
Survey No 439,440,441 & 458.TSIIC
Formulation SEZ,
Polepally Village,Jadcherla (M)
Mahaboob Nagar District
Telangana – 509 301,
India

“For any information about this medicinal product, please contact the supplier”.

This leaflet was last revised in March 2024

Detailed information on this medicine is available on the World Health Organization (WHO) website:
<https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>