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.

[*] https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[TB230 trade name][†]
Moxifloxacin (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 questions about the medicine, 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 seem 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 [TB230 trade name] is and what it is used for

[TB230 trade name] contains moxifloxacin as the active ingredient. This belongs to a group of antibiotics called fluoroquinolones.

[TB230 trade name] is indicated in combination with other antituberculosis agents for the treatment of tuberculosis.

[TB230 trade name] is only indicated as a second-line antimycobacterial drug when use of first line drugs is not appropriate due to resistance or intolerance.

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.

2. What you need to know before you take [TB230 trade name]

Do not take [TB230 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 [TB230 trade name].
- 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)

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

- a weak heart (heart failure)
- a history of abnormal heart rhythms (arrhythmias)
- Severe liver disease or increased liver enzymes (transaminases) higher than 5 times the upper normal limit.

Warnings and precautions

- [TB230 trade name] 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 other medicines that result in certain ECG abnormalities (see section "Other medicines and [TB230 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 [TB230 trade name] can cause QT-prolongation, a certain change on the ECG.
    - If you are taking any medicine that decreases your blood potassium levels, talk to your health care provider before taking [TB230 trade name].
- The risk of heart problems may increase with higher doses. Therefore, you should keep to the prescribed dose.
- You should not take fluoroquinolone/quinolone antibacterial medicines, including moxifloxacin, **if you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone**. In this situation, you should inform your health care provider as soon as possible.
- If you suffer from **epilepsy** or a condition which makes you likely to have convulsions, talk to your health care provider before taking [TB230 trade name]. Quinolone antibiotics, including [TB230 trade name], may cause convulsions. If this happens, stop taking [TB230 trade name] and contact your health care provider immediately.
- You may experience **mental health problems** even when taking quinolone antibiotics, including [TB230 trade name], 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 [TB230 trade name] and inform your health care provider immediately.
- If you have or have ever had any mental health problems, consult your health care provider before taking [TB230 trade name].
- If you suffer from **myasthenia gravis** (abnormal muscle fatigue leading to weakness and in serious cases paralysis), taking [TB230 trade name] may worsen the symptoms of your disease. If you think you are affected, consult your health care provider immediately.
- Tell your health care provider:
    - If you have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic **aneurysm** or large vessel peripheral aneurysm).
    - If you have experienced a previous episode of **aortic dissection** (a tear in the aorta wall) or **heart valve disease**.
    - If you have a family history of aortic aneurysm or aortic dissection, heart valve disease, or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, or vascular Ehlers-Danlos syndrome, or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet´s disease, high blood pressure, rheumatoid arthritis, or known atherosclerosis).

      Sudden, severe pain in your abdomen, chest or back, or developing breathlessness, palpitations or swelling (fluid build-up) in your belly or legs may be signs of aortic dissection or heart valve disease. **If you get any of these, go immediately to an emergency room**.
- If you or any member of your family have glucose-6-phosphate dehydrogenase deficiency (**G6PD**, a rare hereditary disease), tell your health care provider, who will advise whether [TB230 trade name] is suitable for you.
- 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 [TB230 trade name] and seek medical help immediately.

- If you have a **liver disease**, consult your health care provider before taking [TB230 trade name].
- [TB230 trade name] 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 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 [TB230 trade name].
- You may rarely experience symptoms of **nerve damage** (neuropathy) such as pain, burning, tingling, numbness and/or weakness especially in the feet and legs or hands and arms. If this happens, stop taking [TB230 trade name] and inform your health care provider immediately in order to prevent the development of potentially irreversible condition.
- You may develop **diarrhoea** whilst or after taking antibiotics including [TB230 trade name]. If this becomes severe or persistent or you notice that your stool contains blood or mucus you should stop taking [TB230 trade name] immediately and consult your health care provider. In this situation you should not take medicines that stop or slow down bowel movement.
- Pain and swelling in the **joints** and inflammation or rupture of **tendons** may occur rarely. Your risk is increased if you are elderly (above 60 years of age), have received an organ transplant, have kidney problems or if you are being treated with corticosteroids. Inflammation and ruptures of tendons may occur within the first 48 hours of treatment and even up to several months after stopping of moxifloxacin therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking [TB230 trade name], contact your health care provider and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.
- If you are elderly and have **kidney problems**, make sure that you drink plenty whilst taking [TB230 trade name]. If you get dehydrated, this may increase the risk of kidney failure.
- If you have **diabetes**, fluoroquinolone antibiotics such as [TB230 trade name] can make it harder to keep your blood sugar under control. Check your blood sugar regularly and speak to your health care provider if you get any problems.
- If your **eyesight** becomes impaired or if your eyes seem to be affected whilst taking [TB230 trade name], consult an eye specialist.

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone/quinolone antibacterial medicines, including [TB230 trade name], have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible. This includes 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), sensory disorders including impairment of vision, taste and smell, and hearing, depression, memory impairment, severe fatigue, and severe sleep disorders. If you experience any of these side effects after taking [TB230 trade name], contact your health care provider immediately prior to continuing treatment. You and your health care provider will decide on continuing the treatment.

Children and adolescents

In children, [TB230 trade name] may cause damage to the cartilage. Therefore, children should only take [TB230 trade name] when the health care provider considers the benefit to outweigh the risks.

Other medicines and [TB230 trade name]

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 [TB230 trade name] or [TB230 trade name] may affect their action.

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

- Other medicines that can affect your heart rhythm, such as:
  - 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 (treatments for depression such as *amitriptyline, clomipramine, doxepin, imipramine, nortriptyline*),
  - 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*).
- Other 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 action of [TB230 trade name]. Take your tablet of [TB230 trade name] 6 hours before or after taking the other medicine.
- Any medicine containing *charcoal* at the same time as [TB230 trade name]. Charcoal reduces the action of [TB230 trade name]. It is recommended that these medicines are not used together.
- 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.

[TB230 trade name] with food

You can take [TB230 trade name] with food or between meals.

Pregnancy and breast-feeding

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 [TB230 trade name] 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 breastfeed while taking [TB230 trade name].

Driving and using machines

[TB230 trade name] 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.

[TB230 trade name] contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor or health care provider before taking this medicinal product.

3. How to take [TB230 trade name]

Always take [TB230 trade name] 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 at least 30 kg is one 400 mg tablet once daily.

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

Body weight	**Number of 400-mg tablets**	**Daily dose**
30 to less than 36 kg	1 or 1.5	400–600 mg
36 to less than 46 kg	1.5	600 mg
46 to less than 56 kg	1.5 or 2	600–800 mg
56 kg and over	2	800 mg

You can take [TB230 trade name] with food or between meals.

[TB230 trade name] is for oral use .You may split a tablet in 2 along the score line to obtain a dose of 1.5 tablets, but do not crush the tablet or chew it when swallowing as it has a bitter taste; swallow it with plenty of liquid. Try to take the tablet at approximately the same time each day.

Children weighing 24 to 30 kg may be given one 400-mg tablet of [TB230 trade name] daily.

Children weighing less than 24 kg should be given other formulations, e.g. dispersible tablets containing 100 mg moxifloxacin. If these formulations are not available, you may prepare a mixture for the child using a 400-mg tablet of [TB230 trade name] in 10 mL of liquid as explained below, to achieve the following doses:

Child's weight	**How much mixture to draw up**
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* to 7.5 mL
24 kg and over	*(Use tablet)*

*For children needing a 5 mL dose you can split the tablet in half along the score line and give half a tablet instead.

For preparing this mixture you need:
- Two small bowls
- drinking water
- a teaspoon and
- a 10 mL oral syringe (dispenser), showing measurements of 0.5 mL

The following steps should be applied:
1. Measure out 10 mL drinking water using the dispenser and put it in the first bowl.
2. Add one [TB230 trade name] tablet.
3. Stir gently until dispersed.
4. Look up the child's weight on in the above table (left hand column).

5. Then look to the right under "How much mixture to draw up", which shows how much of the liquid mixture you need to draw up.
6. Use the dispenser to draw up the correct amount of liquid mixture from the first bowl. Make sure there are no bubbles in the mixture when you measure the amount drawn up.
7. Add a small amount of sweet food—no more than one teaspoon—to the second bowl. This is to hide the bitter taste of the medicine.
8. Mix the sweet food and medicine-containing liquid well.
9. Give the whole contents of the second bowl (medicine in the sweet food) to the child straight away.
10. If there is anything left in the second bowl, rinse the bowl with a small amount of water and get the child to drink it all. If the child cannot drink from the bowl, use a spoon or use a bottle to feed the child the remaining liquid. This is to make sure that the child gets the full dose.
11. Give the child something to drink after taking the medicine.
12. Throw away any liquid left in the first bowl.

Repeat these steps every time you need to give the medicine.

If you take more [TB230 trade name] than you should

If you take more than the prescribed dose, 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 [TB230 trade name]

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 are unsure about what to do ask your health care provider.

If you stop taking [TB230 trade name]

It is important that you complete the course of treatment even if you begin to feel better. If you stop taking [TB230 trade name] 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 [TB230 trade name].

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

4. Possible side effects

Like all medicines, [TB230 trade name] can cause side effects, although not everybody gets them. When treating tuberculosis, it is not always possible to differentiate between unwanted effects caused by [TB230 trade name], 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.

If you notice

- abnormal heart rhythms including heart beating too fast (rare side effect) or irregular heart beat (torsade de pointes) or stopping of heart beat (both very rare and potentially life-threatening side effects)
- that you suddenly start feeling unwell or notice yellowing of the whites of the eyes, dark urine, itching of the skin, a tendency to bleed or disturbances of thought or wakefulness (these can be signs and symptoms of fulminant inflammation of the liver potentially leading to life-threating liver failure (a very rare side effect, fatal cases have been observed))
- 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 and toxic epidermal necrolysis, or another condition of unknown frequency called acute generalised exanthematous pustulosis which mainly affects armpits, groin and face.
- 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 generalised allergic reaction incl. 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 (rare side effect)
- troubles associated with the nervous system such as pain, burning, tingling, numbness and/or weakness in extremities (rare side effect)
- depression, in very rare cases leading to self-harm, such as suicidal ideations/thoughts, or suicide attempts (rare side effect)
- insanity, potentially leading to self-harm, such as suicidal ideations/thoughts, or suicide attempts (very rare side effect)
- severe diarrhoea containing blood and/or mucus, so called antibiotic associated colitis incl. pseudomembranous colitis, which in very rare circumstances, may develop into complications that are 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) **stop taking [TB230 trade name] and tell your health care provider immediately** as you may need urgent medical advice.

Also inform your healthcare provider immediately if:

- you suffer from myasthenia gravis and notice a worsening of the symptoms (very rare
- you suffer from diabetes and you notice that your blood sugar is increased or decreased (rare or very rare side effect).

If you get transient loss of vision (very rare side effect) see an eye specialist immediately.

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

Other side effects which have been observed during treatment with [TB230 trade name] are listed below by how likely they are:

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 and abdominal ache
- Diarrhoea
- Increase of special liver enzymes in the blood (transaminases)
- change of 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 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 (leukocytes, 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)
- Decreased appetite and food intake
- 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
- Confusion and disorientation
- 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 (tendinitis)
- 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 [TB230 trade name])
- Severe inflammation of the liver, potentially leading to life-threatening liver failure (including fatal cases)
- rashes, reddening, peeling or blistering of the skin and mucous membranes (the lining of eyes, nose, mouth and genitals), especially with fever or chills, (Stevens-Johnson-Syndrome, toxic epidermal necrolysis)
- Rupture of tendons
- Increased blood clotting, significant decrease of special white blood cells (agranulocytosis), low levels of all blood cells (pancytopenia)
- abnormally low sodium levels in the blood due to retaining too much water (syndrome of inappropriate ADH secretion, SIADH)
- Low blood sugar, sometimes severe enough to lead to coma
- 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)

Side effects whose frequency is not known:

- Red skin with many small pustules, especially in armpits, groin and face (acute generalised exanthematous pustulosis)
- muscle breakdown associated with muscle weakness and tenderness or pain, especially with high temperature and passing dark urine (rhabdomyolysis)

Very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as tendon inflammations, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, burning, numbness or pain (neuropathy), depression, fatigue, sleep disorders, memory impairment, as well as impairment of hearing, vision, and taste and smell have been associated with administration of quinolone and fluoroquinolone antibiotics, in some cases irrespective of pre-existing risk factors.

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 [TB230 trade name]:

- 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

Reporting of side effects

If you get any side effects,talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects, you can help improve understanding about the safety of this medicine.

5. How to store [TB230 trade name]

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

Store below 30°C in a dry place. Protect from light. 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 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 [TB230 trade name] 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, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate and microcrystalline cellulose.
Film coat: Hydroxypropyl methylcellulose, iron oxide red, polyethylene glycol, purified talc and titanium dioxide.

What [TB230 trade name] looks like and contents of the pack

Moxifloxacin 400mg tablets is a brick red coloured, capsule shaped, biconvex film coated tablets having lip break line on one side and plain on the other side.

Moxifloxacin 400mg tablets is provided in Alu-Alu blister pack made of blister aluminium foil and cold blister foil. Each blister pack contains 5 tablets and 1 or 20 such blister packs are packed in a carton along with the leaflet.

Moxifloxacin 400mg tablets is also provided in Alu-Alu strip pack made of plain and printed aluminium foil. Each strip pack contains 5 tablets and 1 or 20 such strip packs are packed in a carton along with the leaflet.

Moxifloxacin 400mg tablets is provided in Alu-Alu blister pack made of blister aluminium foil and cold blister foil. Each blister pack contains 7 tablets and 10 such blister packs are packed in a carton along with the leaflet.

Moxifloxacin 400mg tablets is also provided in Alu-Alu strip pack made of plain and printed aluminium foil. Each strip pack contains 7 tablets and 10 such strip packs are packed in a carton along with the leaflet.

Moxifloxacin 400mg tablets is provided in Alu-Alu blister pack made of blister aluminium foil and

cold blister foil. Each blister pack contains 10 tablets and 10 such blister packs are packed in a carton along with the leaflet.

Moxifloxacin 400mg tablets is also provided in Alu-Alu strip pack made of plain and printed aluminium foil. Each strip pack contains 10 tablets and 10 such strip packs are packed in a carton along with the leaflet.

Moxifloxacin 400mg tablets is provided in Alu-PVC blister pack made of blister aluminium foil and PVC blister . Each blister pack contains 10 tablets and 10 such blister packs are packed in a carton along with the leaflet.

Supplier and Manufacturer

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For any information about this medicine, contact the local representative of the supplier.

This leaflet was last revised in June 2021

Detailed information on this medicine is available on the World Health Organization (WHO) website: https://extranet.who.int/pqweb/medicines