



Information for the patient



FLOXSAFE 400
Moxifloxacin (as hydrochloride) 400 mg Tablets

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 get 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 FLOXSAFE 400 is and what it is used for
2. What you need to know before you take FLOXSAFE 400
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1. What FLOXSAFE 400 is and what it is used for

FLOXSAFE 400 contains moxifloxacin as the active ingredient. This belongs to a group of antibiotics called fluoroquinolones.

FLOXSAFE 400 is indicated in combination with other antituberculosis agents for the treatment of tuberculosis.

FLOXSAFE 400 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 FLOXSAFE 400

Do not take FLOXSAFE 400:

- If you are allergic (hypersensitive) to the active ingredient moxifloxacin, to any other quinolone antibiotics or to any of the other ingredients of FLOXSAFE 400.
- 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 heartrhythms (arrhythmias)
 - Severe liver disease or increased liver enzymes (transaminases) higher than 5 times the upper normal limit.

Warnings and precautions

- FLOXSAFE 400 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 Moxifloxacin 400mg Tablets") 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 FLOXSAFE 400 can cause QT-prolongation, a certain change on the ECG.
- 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 are taking any medicine that decreases your blood potassium levels, talk to your health care provider before taking FLOXSAFE 400.
- If you suffer from epilepsy or a condition which makes you likely to have convulsions, talk to your health care provider before taking FLOXSAFE 400.
- If you have or have ever had any mental health problems, consult your health care provider before taking FLOXSAFE 400.
- If you suffer from myasthenia gravis (abnormal muscle fatigue leading to weakness and in serious cases paralysis), taking FLOXSAFE 400 may worsen the symptoms of your disease. If you think you are affected, consult your health care provider immediately.
- 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).
- If you have a family history of aortic aneurysm or aortic dissection 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, or known atherosclerosis).
- 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 FLOXSAFE 400 is suitable for you.
- If you have a liver disease, consult your health care provider before taking FLOXSAFE 400.
- 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 FLOXSAFE 400 and seek medical help immediately.
- FLOXSAFE 400 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 FLOXSAFE 400, may cause convulsions. If this happens, stop taking Moxifloxacin 400mg 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 FLOXSAFE 400.
- 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 FLOXSAFE 400 and inform your health care provider immediately in order to prevent the development of potentially irreversible condition.
- You may experience mental health problems even when taking quinolone antibiotics, including FLOXSAFE 400, 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

to differentiate between unwanted effects caused by Moxifloxacin 400mg 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.

If you notice

- an abnormal fast heart rhythm (rare side effect)
- 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-threatening liver failure (a very rare side effect, fatal cases have been observed))
- alterations of the skin and mucous membranes like painful blisters in the mouth/nose or at the penis/vagina, called Stevens-Johnson syndrome or toxic epidermal necrolysis (very rare side effects, potentially life threatening)
- 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)

stop taking FLOXSAFE 400 and tell your health care provider immediately as you may need urgent medical advice.

In addition, if you notice transient loss of vision (very rare side effect), contact an eye specialist immediately.

If you have experienced life-threatening irregular heart beat (Torsade de Pointes) or stopping of heart beat while taking FLOXSAFE 400 (very rare side effects), tell your health care provider immediately that you have taken FLOXSAFE 400 and do not restart the treatment.

A worsening of the symptoms of myasthenia gravis has been observed in very rare cases. If this happens, consult your health care provider immediately.

If you suffer from diabetes and you notice that your blood sugar is increased or decreased (rare or very rare side effect), inform your health care provider 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 FLOXSAFE 400 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