

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Moxifloxacin 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 any further questions about this medicine, ask your healthcare 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 Moxifloxacin 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
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6. Contents of the pack and other information

1. WHAT MOXIFLOXACIN IS AND WHAT IT IS USED FOR

Moxifloxacin contains the active substance moxifloxacin which belongs to a group of antibiotics called fluoroquinolones. Moxifloxacin works by killing bacteria that cause infections.

Moxifloxacin is used in patients 18 years of age and older for treating the following bacterial infections when caused by bacteria against which Moxifloxacin is active. Moxifloxacin should only be used to treat these infections when usual antibiotics cannot be used or have not worked:

- Infection of the sinuses
- Sudden worsening of long term inflammation of the airways
- Infection of the lungs (pneumonia) acquired outside the hospital (except severe cases)
- Mild to moderate infections of the female upper genital tract (pelvic inflammatory disease), including infections of the fallopian tubes and infections of the uterus mucous membrane.

Moxifloxacin is not sufficient on its own for treating this kind of infection. Therefore, another antibiotic in addition to Moxifloxacin should be prescribed by your doctor for the treatment of infections of the female upper genital tract (see section 2).

If the following bacterial infections have shown improvement during initial treatment with Moxifloxacin solution for infusion, Moxifloxacin tablets may also be prescribed by your doctor to complete the course of therapy:

- Infection of the lungs (pneumonia) acquired outside the hospital,
- Infections of the skin and soft tissue.

Moxifloxacin tablets should not be used to initiate therapy for any type of infections of the skin and soft tissue or in severe infections of the lungs.

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

Do not take Moxifloxacin 400 mg tablets

- If you are **allergic** to moxifloxacin, any other quinolone antibiotics or any of the other ingredients of this medicine (listed in section 6).
- If you are **pregnant or breast-feeding**.
- If you are **younger than 18 years of age**.
- If you have previously had **problems with your tendons** related to treatment with quinolone antibiotics (see ‘Warnings and Precautions’ and section ‘4. Possible side effects’).
- If you have a **severe liver disease** or **increased liver enzymes** (transaminases) higher than 5 times the upper normal limit.
- If you were born with or have any condition with **abnormal heart rhythm** (seen on ECG, electrical recording of the heart).
- If you have a **salt imbalance** in the blood (especially low levels of potassium or magnesium in the blood).
- If you have a **very slow heart rhythm** (called ‘bradycardia’).
- If you have a **weak heart** (heart failure).
- If you have a history of **abnormal heart rhythms**.
- If you are **taking other medicines** that result in abnormal ECG changes (see ‘Other medicines and Moxifloxacin’). This is because Moxifloxacin can cause changes on the ECG, that is a prolongation of the QT-interval, i.e., delayed conduction of electrical signals.

Warnings and precautions

Talk to your health care provider before taking Moxifloxacin 400 mg tablets.

- Moxifloxacin **can change your heart's ECG**, especially if you are female, or if you are elderly. If you are currently taking any medicine that decreases your blood potassium levels, consult your doctor before taking Moxifloxacin.
- If you suffer from **epilepsy** or a condition which makes you likely to have convulsions, tell your doctor before taking Moxifloxacin.
- If you have or have ever had any **mental health problems**, consult your doctor before taking Moxifloxacin.
- If you suffer from **myasthenia gravis** (abnormal muscle fatigue leading to weakness and in serious cases paralysis), taking Moxifloxacin may worsen the symptoms of your disease. If you think you are affected consult your doctor immediately.
- If you or any member of your family have **glucose- 6-phosphate dehydrogenase deficiency** (a rare hereditary disease), tell your doctor, who will advise whether Moxifloxacin is suitable for you.
- If you have a **complicated infection of the female upper genital tract** (e.g. associated with an abscess of the fallopian tubes and ovaries or of the pelvis), for which your doctor considers an intravenous treatment necessary, treatment with Moxifloxacin tablets is not appropriate.
- For the treatment of **mild to moderate infections of the female upper genital tract** your doctor should prescribe another antibiotic in addition to Moxifloxacin. If there is no improvement in symptoms after 3 days of treatment, please consult your doctor.
- 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 feel **sudden, severe pain in your abdomen, chest or back**, go immediately to an emergency room.

When taking Moxifloxacin

Be aware of this important information while taking this medicine:

- If you experience **palpitations or irregular heart beat** during the period of treatment, you should inform your doctor immediately. He/she may wish to perform an ECG to measure your heart rhythm.
- The **risk of heart problems** may increase with increase of the dose. Therefore, the recommended dosage should be followed.
- There is a rare chance 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 and seek medical advice immediately.
- Moxifloxacin may cause a **rapid and severe inflammation of the liver** which could lead to life-threatening liver failure (including fatal cases, see section 4). If you suddenly feel unwell and/ or are being sick and also have yellowing of the whites of the eyes, 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 doctor before taking any more tablets.
- If you develop a **skin reaction** or **blistering** and/ or **peeling of the skin** and/or **mucosal reactions** (see section '4. Possible side effects') contact your doctor immediately before you continue treatment.
- **Quinolone antibiotics**, including Moxifloxacin, may cause convulsions. If this happens, stop taking Moxifloxacin and contact your doctor immediately.
- You may 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, inform your doctor immediately prior to continuing treatment with Moxifloxacin.
- You may experience **mental health problems** even when taking quinolone antibiotics, including Moxifloxacin, for the first time. In very rare cases depression or mental health problems have led to suicidal thoughts and self-injurious behaviour such as suicide attempts (see section 4). If you develop such reactions, stop taking Moxifloxacin and inform your doctor immediately.
- You may develop **diarrhoea** whilst or after taking antibiotics including Moxifloxacin. If this becomes severe or persistent or you notice that your stool contains blood or mucus you

should stop taking Moxifloxacin immediately and consult your doctor. You should not take medicines that stop or slow down bowel movement.

- Moxifloxacin may cause **pain and inflammation** of your tendons, even within 48 hours of starting treatment and up to several months after discontinuing Moxifloxacin therapy. The risk of inflammation and rupture of tendons is increased 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, rest the affected limb(s) and consult your doctor immediately. Avoid any unnecessary exercise, as this might increase the risk of a tendon rupture (see section 2 and section 4).
- If you are elderly and have **kidney problems** make sure that you drink plenty whilst taking Moxifloxacin. 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, consult an eye specialist immediately (see ‘Driving and using machines’ and section 4).
- 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.
- The efficacy of Moxifloxacin in the treatment of severe burns, infections of deep tissue and diabetic foot infections with osteomyelitis (infections of the bone marrow) has not been established.

Children and adolescents

Do not give this medicine to children and adolescents under the age of 18 because efficacy and safety have not been established for this age group (see section 2).

Other medicines and Moxifloxacin

Tell your doctor or pharmacist if you are taking, have recently taken or might take other medicines. In particular, when taking Moxifloxacin, be aware of the following:

- If you are taking Moxifloxacin and **other medicines that affect your heart** there is an increased risk for altering your heart rhythm. Therefore, do not take Moxifloxacin together with the following medicines: medicines that belong to the group of anti-arrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), antipsychotics (e.g. phenothiazines, pimozide, sertindole, haloperidol, sultopride), tricyclic

antidepressants, some antimicrobials (e.g. saquinavir, sparfloxacin, intravenous erythromycin, pentamidine, antimalarials particularly halofantrine), some antihistamines (e.g. terfenadine, astemizole, mizolastine), other medicines (e.g. cisapride, intravenous vincamine, bepridil and diphemanil).

- You must tell your doctor if you are taking other medicines that can lower your blood potassium levels (e.g. some diuretics, some laxatives and enemas (high doses) or corticosteroids (anti-inflammatory drugs), amphotericin B) or cause a slow heart rate because these can also increase the risk of serious heart rhythm disturbances while taking Moxifloxacin.
- 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 tablets. Take your Moxifloxacin tablet 6 hours before or after taking the other medicine.
- Taking any medicine containing charcoal at the same time as Moxifloxacin tablets reduces the action of Moxifloxacin. It is recommended that these medicines are not used together.
- If you are currently taking medicines to thin your blood (oral anti-coagulants such as warfarin), it may be necessary for your doctor to monitor your blood clotting time.

Moxifloxacin with food and drink

Moxifloxacin may be taken with or without food (including dairy products).

Pregnancy, breast-feeding and fertility

Do not take Moxifloxacin if you are pregnant or breast-feeding. If you are pregnant or breast - feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Animal studies do not indicate that your fertility will be impaired by taking this medicine.

Driving and using machines

Moxifloxacin 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 machinery.

3. HOW TO TAKE MOXIFLOXACIN 400 mg TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults is one 400mg film-coated tablet once daily.

Moxifloxacin tablets are for oral use. Swallow the tablet whole (to mask the bitter taste) and with plenty of liquid. You can take Moxifloxacin with or without food. Try to take the tablet at approximately the same time each day.

The same dose can be taken by elderly patients, patients with a low bodyweight or in patients with kidney problems.

The length of time you will take Moxifloxacin for depends on your infection. Unless your doctor tells you otherwise, your treatment will be as follows:

- for sudden worsening (acute exacerbation) of chronic bronchitis 5 - 10 days
- for infection of the lungs (pneumonia) acquired outside the hospital except severe cases 10 days
- for acute infection of the sinuses (acute bacterial sinusitis) 7 days
- Mild to moderate infections of the female upper genital tract (pelvic inflammatory disease), including infection of the fallopian tubes and infection of the uterus mucous membrane 14 days.

When Moxifloxacin film-coated tablets are used to complete a course of therapy started with Moxifloxacin solution for infusion, the recommended durations of use are:

- Infection of the lungs (pneumonia) acquired outside the hospital 7 - 14 days Most patients with pneumonia were switched to oral treatment with (Moxifloxacin) film-coated tablets within 4 days.
- Infections of the skin and soft tissue 7 - 21 days Most patients with infections of the skin and soft tissue were switched to oral treatment with Moxifloxacin film-coated tablets within 6 days.

It is important that you complete the course of treatment even if you begin to feel better after a few days. If you stop taking Moxifloxacin 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.

The recommended dose and duration of treatment should not be exceeded (see section 2).

If you take more Moxifloxacin than you should

If you take more than the prescribed one tablet a day, get medical help immediately. Take any remaining tablets, the packaging or this leaflet with you to show the doctor or pharmacist what you have taken.

If you forget to take Moxifloxacin

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 doctor or pharmacist.

If you stop taking Moxifloxacin

If you stop taking this medicine before your prescription is finished your infection may not be completely cured. Talk to your doctor if you wish to stop taking your tablets before the end of the course of treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects have been observed during treatment with Moxifloxacin.

Stop taking Moxifloxacin and tell your doctor immediately if you notice the following (as you may need urgent medical advice):

- Alterations of the skin and mucous membranes like painful blisters in the mouth/nose or at the penis/vagina (Stevens-Johnson syndrome or toxic epidermal necrolysis) (very rare side effects, potentially life threatening)
- Inflammation of blood vessels (signs could be red spots on your skin, usually on your lower legs or effects like joint pain) (very rare side effect)
- Abnormal fast heart rhythm (rare side effect)
- Pain and swelling of the tendons (tendonitis) (rare side effect)
- Rupture of tendons (very rare side effect)
- Severe diarrhoea containing blood and/or mucus (antibiotic associated colitis including pseudomembranous colitis), which very rarely, may develop into complications that are life-threatening (rare 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-threatening liver failure (including fatal cases) (very rare side effect)
- Severe, sudden allergic reaction including very rarely life-threatening shock (e.g. difficulty in breathing, drop of blood pressure, fast pulse) (rare side effect)
- Swelling (including potentially life-threatening swelling of the airway) (rare side effect)
- 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 (which in very rare cases may lead to self-harm, such as suicidal ideations/thoughts, or suicide attempts) (rare side effect)
- Abnormal heart rhythms, life-threatening irregular heartbeat, stopping of heartbeat (very rare side effects)
- Worsening of the symptoms of myasthenia gravis (abnormal muscle fatigue leading to weakness and in serious cases paralysis) (very rare side effect)
- If you are elderly with existing kidney problems and you notice a 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) (rare side effect)
- Feeling mentally unwell (potentially leading to self-harm, such as suicidal ideations/thoughts, or suicide attempts) (very rare side effect)
- Your blood sugar is increased and you suffer from diabetes (rare side effect)

Stop taking Moxifloxacin and contact an eye specialist immediately if you notice:

- Transient loss of vision

Other side effects

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

- Infections caused by resistant bacteria or fungi, e.g. oral and vaginal infections caused by Candida (thrush)
- Headache
- Dizziness
- Feeling sick (nausea)

- Being sick (vomiting)
- Stomach and abdominal ache
- Diarrhoea
- Increase of a special liver enzyme in the blood (transaminases)
- Change of the heart rhythm (ECG) in patients with low blood potassium level

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

- Allergic reaction
- 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
- 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)
- 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 (including increase of a special liver enzyme in the blood (LDH)), increase of bilirubin in the blood, increase of a special liver enzyme in the blood (gamma-glutamyltransferase 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
- Change of the heart rhythm (ECG)
- Palpitations
- Irregular and fast heartbeat
- Severe heart rhythm abnormalities
- Chest pain (angina pectoris)

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

- Jaundice (yellowing of the whites of the eyes or skin), inflammation of the liver
- Increased blood uric acid
- Feeling particularly emotional
- Hallucination
- Problems with skin sensations
- Changes in smell (including loss of smell)
- Unusual dreams
- Problems with balance and co-ordination (due to dizziness)
- Disturbed concentration
- Problems with speech
- Partial or total loss of memory
- Ringing or noise in the ears, hearing impairment including deafness (usually reversible)
- 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)
- Swelling (of the hands, feet, ankles, lips, mouth or throat)
- Fainting

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

- Increased blood clotting, significant decrease of special white blood cells (agranulocytosis)
- A feeling of self-detachment (not being yourself)
- Skin feeling more sensitive
- Inflammation of joints
- Muscles feeling stiff

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:

- 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.

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 doctor or pharmacist immediately to get advice before taking the next dose.

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 provide more information on the safety of this medicine.

5. HOW TO STORE MOXIFLOXACIN 400 mg TABLETS

Do not store above 30⁰C. Store in the original container protect from light and humidity

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Moxifloxacin 400 mg Film-coated Tablets contains

The active substance is Moxifloxacin.

The other ingredients are Microcrystalline cellulose (NF/EP), Lactose monohydrate (NF/EP), Croscarmellose sodium (NF/EP), Magnesium stearate (NF/EP), Opadry 06B540021 Pink

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

Peach colored capsule shaped, biconvex film coated tablets having score line on one side and plain other side.

- 10 tablets per blister using clear PVC/PVdC 90 GSM foil as a base material and 0.025mm thick hard tampered heat seal lacquer coated Plain Aluminium foil as a lidding material.
- 10 tablets per blister using Clear PVC foil as a base material and 0.025mm thick hard tampered heat seal lacquer coated Plain Aluminium foil as a lidding material

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