PANTONE 2738 C

Muxava®

Moxifloxacin

Film coated tablets 400mg

Presentation:

Muxava® 400: Each Film coated tablet contains: Moxifloxacin HCl equivalent to 400 mg Moxifloxacin in packs of 5 & 7 tablets.

Excipients: Microcrystalline cellulose, Croscarmellose sodium, Magnesium Stearate, colloidal anhydrous silica, povidone K30, Opadry pink.

Pharmaceutical form:

Film coated tablets for oral use.

Pharmacotherapeutic group:

Fluoroquinolones antibacterials, ATC code: J01MA14.

Therapeutic indications:

Muxava® is used in patients of 18 years and older for treating the following bacterial infections when caused by bacteria against which Moxifloxacin is active:

- Infection of the sinuses, sudden worsening of long term inflammation of the airways or 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.

Muxava® should only be used to treat these infections when usual antibiotics cannot be used or have not worked.

Muxava® tablets are not sufficient for sole therapy of this kind of infections and therefore another antibiotic in addition to **Muxava®** tablets should be prescribed by your doctor for the treatment of infections of the female upper genital tract.

If the following bacterial infections have shown improvement during initial treatment with Moxifloxacin solution for infusion, **Muxava®** 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.
- **Muxava®** 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.

Posology and method of administration:

Posology

Always take **Muxava®** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure how to take **Muxava®**.

The usual dose for adults is one **Muxava®** 400 mg tablet once daily.

The duration of treatment depends upon the type of infection. Unless otherwise indicated by your doctor the recommended durations of use of **Muxava®** are:

Sudden worsening of chronic bronchitis (acute exacerbation of chronic bronchitis).	5-10 days
Infection of the lungs acquired (pneumonia) outside the hospital, except severe case.	10 days
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 I of the uterus mucous membrane.	14 days

When **Muxava®** 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 **Muxava®** 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 **Muxava®** 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 this medicine too soon your infection may not be completely cured, the infection may return or your condition may get worse, and you may also create a bacterial resistance to the antibiotic.

The recommended dose and duration of treatment should not be exceeded.

Method of administration

Muxava® tablets are for oral use. Swallow the tablet as a whole (to mask the bitter taste) and with plenty of liquid. You can take **Muxava®** with or without food. It is recommended that you take the tablet at approximately the same time each day. No adjustment of the dose is required in elderly patients, patients with a low body weight or in patients with kidney problems.

If you forget to take Muxava® 400 mg tablets

If you forget to take your tablet you should take it as soon as you remember on the same day. If you do not take your tablet on one 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, consult your doctor or pharmacist.

If you stop taking Muxava® 400 mg tablets

If you stop taking this medicine too soon your infection may not be completely cured. Consult 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 product, ask your doctor or pharmacist.

Taking Muxava® 400 mg tablets with food and drink

The effect of **Muxava®** is not influenced by food including dairy products.

Contra-indications:

- If you are allergic (hypersensitive) to the active ingredient Moxifloxacin, any other quinolone antibiotics or any of the other ingredients of Muxava® 400 tablets.
- If you are pregnant or breast-feeding.
- If you are under 18 years of age.
- If you have a history of tendon disease or disorder which was related to treatment with quinolone antibiotics.
- If you were born with or have had any condition with certain abnormal electrocardiogram (ECG, electrical recording of the heart) changes, have salt imbalance in the blood, especially low concentrations of potassium or magnesium in the blood, have a very slow heart rate (bradycardia), have a weak heart (heart failure), have a history of abnormal heart rhythms (arrhythmias) or you are taking other medicines that result in certain abnormal ECG changes. This is because Moxifloxacin can cause a certain change on the ECG), that is a prolongation of the QT-interval i.e. delayed conduction of electrical signals.
- If you have a severe liver disease or increased liver enzymes (transaminases) higher than 5 times the upper normal limit.

Warnings and Precautions for use:

Before taking Muxava® 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 decrease 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, consult 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 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), inform 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.

When taking Muxava® 400 mg tablets

- 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 cardiac abnormalities may increase with increase of the dose. Therefore, you should adhere to the dosage.
- There is a rare chance that you may experience a severe, sudden allergic reaction (an anaphylactic reaction/shock) even with the first dose, with the following symptoms: tightness in the chest, feeling dizzy, feeling sick or faint, or experience dizziness on standing. 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. Please contact your doctor before you continue the treatment if you develop signs such as rapidly feeling unwell and/or being sick associated with 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).
- If you develop a skin reaction or blistering and/or peeling of the skin and/or mucosal reactions contact your doctor immediately before you continue the treatment.
- You may experience symptoms of neuropathy such as pain, burning, tingling, numbness and/or weakness. 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 behavior such as suicide attempts. If you develop such reactions, stop taking Moxifloxacin and inform your doctor immediately.
- You may develop diarrhea whilst taking, 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. In this situation, 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 currently being treated with 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.
- If you are elderly with existing kidney problems take care that your fluid intake is sufficient because dehydration may increase the risk of kidney failure.
- If your eyesight becomes impaired or if you have any other eye disturbances whilst taking Moxifloxacin, consult an eye specialist immediately.
- 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.
- Peripheral neuropathy (serious nerve damage) is an identified risk of fluoroquinolone drugs taken by mouth or by injection. (peripheral neuropathy symptoms in the arms or legs such as pain, burning, tingling, numbness, weakness or a change in sensation to light touch, pain or temperature).

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• Peripheral neuropathy can occur at any time during treatment with fluoroquinolones (may occur soon after these drugs are taken) and can last for months to years after the drug is stopped or be permanent.
• If you develop symptoms of peripheral neuropathy inform your doctor immediately, the fluoroquinolone should be stopped and you should be switched to another non-fluoroquinolone antibacterial drug, unless the benefit of continued treatment with a fluoroquinolone outweighs the risk.
• The efficacy of moxifloxacin solution for infusion 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.
• **Driving and using machines:** Moxifloxacin may make you feel dizzy or lightheaded, you may experience a sudden, transient loss of vision, or you might faint for a short period. If you are affected in this way do not drive or operate machinery.

Use during Pregnancy and Lactation:
Do not take Moxifloxacin if you are pregnant or breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Drug Interactions:
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines besides Moxifloxacin, including medicines obtained without a prescription. For 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 heartbeat. Therefore, do not take Moxifloxacin together with the following medicines: Medicines that belong to the group of anti-arrhythmic (e.g. Quinidine, Hydroquinidine, Disopyramide, Amiodarone, Sotalol, Dofetilide, Ibutilide), antipsychotics (e.g. Phenothiazines, Pimozide, Sertindole, Haloperidol, Sultopride), tricyclic antidepressants, some antimicrobial (e.g. Sparfloxacin, intravenous Erythromycin, Pentamidine, antimalarials particularly Halofantrine), some antihistamines (e.g. Terfenadine, Astemizole, Mizolastine), and 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 aluminum such as antacids for indigestion, or any medicine containing iron or zinc, medicine containing Didanosine or medicine containing Sucralfate to treat gastrointestinal disorders can reduce the action of Moxifloxacin tablets. Therefore, take your Moxifloxacin tablet 6 hours before or after taking the other medicine.
• Taking oral medicinal charcoal at the same time as Moxifloxacin tablets reduces the action of Moxifloxacin. Therefore it is recommended that these medicines are not used together.
• If you are currently taking oral anti-coagulants (e.g. warfarin), it may be necessary for your doctor to monitor your blood clotting times.

Undesirable Effects:
Like all medicines, Moxifloxacin can cause side effects, although not everybody gets them.
The following side effects have been observed during treatment with Moxifloxacin. Evaluation of side effects has been based on the following frequency data:
Common: in less than 1 per 10 patients but in more than 1 per 100 patients.
Uncommon: in less than 1 per 100 patients but in more than 1 per 1000 patients.
Rare: in less than 1 per 1000 patients but in more than 1 per 10000 patients.
Very rare: in less than 1 per 10000 patients, including isolated cases.

Infections
Common: Infections caused by resistant bacteria or fungi e.g. oral and vaginal infections caused by Candida.

Blood and Lymph System
Uncommon: Low red blood cell count, 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 specialized white blood cells (eosinophils), decreased blood clotting.
Very rare: Increased blood clotting, significant decrease of special white blood cells (agranulocytosis).

Allergic Reactions
Uncommon: Allergic reaction.
Rare: Severe, sudden generalized 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).

Changes in laboratory Test Results
Uncommon: Increased blood lipids (fats).
Rare: Increased blood sugar, increased blood uric acid.

Psychiatric Effects
Uncommon: Anxiety, restlessness/agitation.
Rare: Emotional instability, depression (in very rare cases leading to self-harm, such as suicidal ideations/thoughts, or suicide attempts), hallucination.
Very rare: A feeling of self-detachment (not being yourself), insanity (potentially leading to self-harm, such as suicidal ideations/thoughts, or suicide attempts).

Nervous System
Common: Headache, dizziness.
Uncommon: Tingling sensation (pins and needles) and/or numbness, chances in taste (in very rare cases loss of taste), confusion and disorientation, sleep problems (predominately sleeplessness), shaking, sensation of dizziness (spinning or falling over), sleepiness.
Rare: Impairment of skin sensation, changes in smell (including loss of smell), abnormal dreams, balance disorder and poor co-ordination (due to dizziness), convulsions, disturbed concentration, impaired speech, partial or total loss of memory, troubles associated with the nervous system such as pain, burning, tingling, numbness and/or weakness in extremities.
Very rare: Increase of skin sensitivity.

Eye
Uncommon: Visual disturbances incl. double and blurred vision.
Very rare: Transient loss of vision.

Ear
Rare: Ringing/noise in the ears, hearing impairment including deafness (usually reversible).

Cardiac System
Common: Change of the heart rhythm (ECG) in patients with low blood potassium level.
Uncommon: Change of the heart rhythm (ECG), palpitations, irregular and fast heart beat, severe heart rhythm abnormalities, angina pectoris.
Rare: Abnormal fast heart rhythm, fainting.
Very rare: Abnormal heart rhythms, life-threatening irregular heart beat, stopping of heart beat.

Vascular System
Uncommon: Widening of blood vessels.
Rare: High blood pressure, low blood pressure.

Respiratory System
Uncommon: Difficulty in breathing including asthmatic conditions.

Gastrointestinal System
Common: Nausea, vomiting, stomach and abdominal ache, diarrhea.
Uncommon: Loss of appetite, wind and constipation, stomach upset (indigestion/heartburn), inflammation of the stomach, increase of a special digestive enzyme in the blood (amylase).
Rare: Difficulty in swallowing, inflammation of the mouth, severe diarrhea containing blood and/or mucus (antibiotic associated colitis including pseudomembranous colitis), which in very rare circumstances, may develop into complications that are life-threatening.

Liver
Common: Increase of a special liver enzyme in the blood (transaminases).
Uncommon: Impaired 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-glutamyl-transferase and/or alkaline phosphatase).
Rare: Jaundice (yellowing of the whites of the eyes or skin), inflammation of the liver.
Very rare: Fulminant inflammation of the liver potentially leading to life-threatening liver failure (including fatal cases).

Skin
Uncommon: Itching, rash, skin hives, dry skin.
Very rare: Alterations of the skin and mucous membranes (painful blisters in the mouth/nose or at the penis/vagina), potentially life threatening (Stevens-Johnson Syndrome, toxic epidermal necrolysis).

Muscular and Joint System
Uncommon: Joint pain, muscle pain.
Rare: Pain and swelling of the tendons (tendonitis), muscle cramp, muscle twitching
Very rare: Rupture of tendon, inflammation of joints, muscle rigidity, worsening of the symptoms of myasthenia gravis.

Kidney
Uncommon: Dehydration.
Rare: Kidney impairment (including increase in special kidney laboratory test results like urea and creatinine), kidney failure.

General Side Effects
Uncommon: Feeling unwell (predominantly weakness or tiredness), aches and pains such as back, chest, pelvic and extremities pains, sweating.
Rare: Swelling (of the hands, feet, ankles, lips, mouth, throat) Furthermore, 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 (hemolytic anemia), 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 gets 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.

Overdose:
If you take more than the prescribed one tablet a day, seek medical advice immediately and, if possible, take any remaining tablets, the packaging or this leaflet with you to show the doctor or pharmacist what you have taken.

Pharmacodynamic Properties:
Muxava® (Moxifloxacin) belongs to a group of antibiotics called fluoroquinolones.
Muxava® works by killing bacteria that cause infections.

Special Precautions for storage:
Store below 30°C.

This is a medicament
• A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
• Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
• The doctor and the pharmacist are experts in medicine, its benefits and risks.
• Do not by yourself interrupt the period of treatment prescribed for you.
• Do not repeat the same prescription without consulting your doctor.
• Keep medicament out of the reach of children.

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