

MOXIFCIN FILM COATED TABLET

Moxifloxacin (400mg)

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What MOXIFCIN is used for

MOXIFCIN is used in patients aged 18 years old and above for the treatment of bacterial infections caused by bacteria susceptible to moxifloxacin.

How MOXIFCIN works

MOXIFCIN works by killing bacteria that cause infections.

Before you use MOXIFCIN

- When you must not use it

Do not take this medicine if:

- You are allergic to Moxifloxacin, other quinolone antibiotics or any other ingredients of this medicine (listed in Product Description)
- You are under 18 years of age
- You have previously had problems with your tendons related to quinolone antibiotics treatment
- You have severe liver disease or increased liver enzymes
- You are born with or have:
 - ✓ Any condition with abnormal heart rhythm (as in ECG)
 - ✓ Salt imbalance in the blood (especially low levels of potassium in the blood)
 - ✓ A very slow heart rhythm (bradycardia)
 - ✓ A weak heart (heart failure)
 - ✓ A history of abnormal heart rhythm or if you are taking other medicines that result in abnormal ECG changes.

Pregnancy and lactation

- Do not take MOXIFCIN if you are pregnant, trying to get pregnant or think you may be pregnant.
- Do not take MOXIFCIN if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows sign of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

- Before you start to use it

Tell your doctor before taking MOXIFCIN

- If you have abnormal heart rhythm
- If you have allergic reactions to quinolone antibiotics
- If you have severe liver disorders
- If you have severe bullous skin reactions
- If you suffer from seizure or a condition which makes you likely to have convulsions
- If you experience neuropathy symptoms such as pain, burning, tingling or numbness
- If you have or have ever had any mental health problems
- If you suffer from antibiotic-associated diarrhea
- If you suffer from myasthenia gravis (abnormal muscle fatigue and weakness)
- If you have tendon inflammation & rupture
- Glucose-6-phosphate dehydrogenase deficiency (G6PD)
- Complicated infection of the female upper genital tract (pelvic inflammatory disease)
- High blood glucose level (diabetic)
- Kidney problem (renal disorder in elderly patients)

Tell your healthcare providers:

- if you have been diagnosed with an enlargement or “bulge” of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm) or 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-Dantos syndrome, or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet’s disease, high blood pressure, or known atherosclerosis).

You should not take fluoroquinolone antibacterial, including MOXIFCIN, if you have experienced any serious adverse reaction in the past when taking a fluoroquinolone (see section Things to be careful of and Side effects). In this situation, you should inform your healthcare providers as soon as possible.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Beware if there is concurrent usage with:

- Anti-arrhythmics that affect your heart rhythm (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide)
- Any antipsychotics medications (e.g. phenothiazines, pimozide, sertindole, haloperidol, sultopride)
- Tricyclic antidepressants medicines
- Other medicines that can lower your blood potassium levels (eg: loop and thiazide diuretics, laxatives, enemas, corticosteroids, amphotericin B) or slow down your heart rate
- Certain antimicrobial agents (sparfloxacin, intravenous erythromycin, pentamidine)
- Antimalarial (halofantrine)
- Certain antihistamine agents (terfenadine, astemizole and mizolastine)
- Any medicine containing magnesium or aluminium (such as antacids for indigestion), iron, zinc or sucralfate as these drugs can interfere with the action of MOXIFCIN. Take MOXIFCIN about 6 hours before or after taking those medicines.
- Charcoal as it reduces the action of MOXIFCIN. These two medicines should not be taken together.
- If you are currently taking blood thinning medicine such as warfarin, your doctor may need to monitor your blood clotting time.
- Other medicines (e.g. cisapride, intravenous vincamine, bepridil and diphemanil).

How to use MOXIFCIN

- How much to use

Adults: One 400mg tablet once daily.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in

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this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

MOXIFCIN should be used for the following treatment durations:

Treatment	Durations
Sudden worsening (acute exacerbation) of chronic bronchitis	5 days
Infection of the lungs (pneumonia) except for pneumonia which starts during a stay in hospital	10 days
Acute infection of the sinuses	7 days
Mild to moderately severe inflammatory pelvic diseases (infections of the female genital tract)	14 days

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

- 7-21 days for infection of the skin and soft tissue
- 5-14 days for intraabdominal infection

The recommended duration of treatment for the indication being treated should not be exceeded.

Geriatric patients: No adjustment of dosage is required in the elderly.

Pediatric patients: The efficacy of Moxifloxacin in children and adolescents has not been established. No recommendation on posology can be made. The safety of Moxifloxacin in children below the age of 6 years has not been established.

Ethnic differences: No adjustment of dosage is required in ethnic groups.

Patients with hepatic impairment: No dosage adjustment is required in patients with impaired liver function.

Patients with renal impairment: No dose adjustment is required in patients with renal impairment and in patients on chronic dialysis.

- When to use it

May be taken with or without food. Use as directed by your doctor or pharmacist.

- How long to use it

Use MOXIFCIN for the duration that the doctor recommends.

It is important that you complete the course of treatment even if your symptoms start to improve. If you stop taking MOXIFCIN before the full prescribed length of time or if you skip doses, your infection may not be completely treated and the bacteria may become resistant to antibiotics.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using MOXIFCIN.

Tell your doctor immediately if you become pregnant while using this medication.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not give MOXIFCIN to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

If you feel sudden, severe pain in your abdomen, chest or back, go immediately to the emergency department.

Driving or using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a

headache, do not drive or use machines and contact your doctor immediately.

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone antibacterial medicines, including MOXIFCIN, have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible.

Stop taking your fluoroquinolone antibiotic and contact your healthcare providers immediately if you have the following signs of a side effect:

- Tendon pain or swelling, often beginning in the ankle or calf. If this happens, rest the painful area until you can see your healthcare providers.
- Pain in your joints or swelling in your shoulder, arms, or legs.
- Abnormal pain or sensations (such as persistent pins and needles, tingling, tickling, numbness, or burning), weakness in your body, especially in the legs or arms, or difficulty walking.
- Severe tiredness, depressed mood, anxiety, problems with your memory, or severe problems sleeping.
- Changes in your vision, taste, smell, or hearing.

Tell your healthcare providers if you have had one of the above effects during or shortly after taking a fluoroquinolone – this means you should avoid them in the future. You and your healthcare providers will decide on continuing the treatment considering also an antibiotic from another class.

Tendinitis and tendon rupture

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 therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking MOXIFCIN, contact your healthcare providers and rest the painful area. Avoid any unnecessary exercise as this might

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increase the risk of a tendon rupture.

Peripheral neuropathy

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 and inform your healthcare providers immediately in order to prevent the development of potentially irreversible condition.

You may experience mental health problems even when taking/ using fluoroquinolone antibiotics, including MOXIFCIN 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. If you develop such reactions, stop taking/ using MOXIFCIN and inform your doctor immediately.

Side effects

Like all medicines, MOXIFCIN can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

Fluoroquinolones have been reported to cause serious side effects involving tendons, muscles, joints, and the nerves – in a small proportion of patients, these side effects caused long-lasting or permanent disability (see section Before you start to use it and Things to be careful of).

Common side effects include:

- Oral or vaginal fungal infections
- Headache, dizziness
- Change of the heart rhythm (ECG) in patients with low blood potassium level
- Nausea, vomiting, stomach pain, diarrhea
- Increase of a special liver enzyme in the blood (transaminases)

Uncommon side effects:

- 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)
- Change in heart rhythm
- 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
- 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

Rare side effects:

- Severe, sudden allergic reaction including very rarely life-threatening shock
- Swelling (including potentially life-threatening swelling of the airway)
- Severe diarrhoea containing blood and/or mucus
- Jaundice (yellowing of the whites of the eyes or skin), inflammation of the liver
- Pain and swelling of the tendons
- Increased blood sugar
- Increased blood uric acid
- Feeling particularly emotional
- Depression (in very rare cases may lead to self-harm, such as suicidal ideations/thoughts, or suicide attempts)
- Hallucinations
- Problems with skin sensations
- Changes in smell (including loss of smell)
- Unusual dreams
- Problems with balance and coordination (due to dizziness)
- Convulsions
- Disturbed concentration
- Problems with speech
- Partial or total loss of memory
- Troubles associated with the nervous system such as pain, burning, tingling, numbness and/or weakness in extremities
- 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), kidney failure
- Swelling (of the hands, feet, ankles, lips, mouth or throat)

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Very rare:

- Severe inflammation of the liver potentially leading to life threatening liver failure (including fatal cases)
- Changes to 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)
- Rupture of tendons
- Increased blood clotting, significant decrease of special white blood cells
- 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)
- Psychotic reactions (potentially leading to self-harm, such as suicidal ideations/ thoughts (desire to kill oneself), or suicide attempts)

Product Description

- What it looks like

A pink color film coated tablet, one side impressed with the letter "Y".



- Ingredients

- Active ingredient:

Moxifloxacin Hydrochloride

- Inactive ingredients:

Lactose

Polyvinylpyrrolidone

Croscarmellose Sodium

Colloidal Silicone Dioxide

Magnesium Stearate

Opadry Pink

- MAL number

MAL21096009AZ

Manufacturer and Product Registration Holder

Y.S.P Industries (M) Sdn. Bhd.

Lot 3, 5, 7, 12 & 14, Jalan P/7, Section 13,

Kawasan Perindustrian Bandar Baru

Bangi, 43000 Kajang, Selangor,

Malaysia.

Date of revision

28/03/2024

Serial Number

NPRA (R2) 20/130

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of MOXIFCIN

- Storage

Store below 30°C, protect from moisture.

- Disposal

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.