

MOXIMAC 400MG TABLETS

Moxifloxacin Tablets

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What **MOXIMAC** is used for

Moxifloxacin is used in patients aged 18 years and above 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 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.

You must use Moxifloxacin together with other antibacterial agent.

How **MOXIMAC** works

Moxifloxacin works by killing bacteria that cause infections.

Before you use **MOXIMAC**

- When you must not use it

- If you are allergic to the active substance moxifloxacin, any other quinolone antibiotics or any of the other ingredients of this medicine.
- 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. Avoid taking moxifloxacin if you suffer from myasthenia gravis.

- Before you start to use it

Talk to your doctor before taking Moxifloxacin

- 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 talk to your doctor before taking Moxifloxacin.

- 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.

- You should not take fluoroquinolone antibacterial medicines, including **MOXIMAC**, 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 or pharmacist about any other medicines that you are taking, took recently or might take.

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 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).

How to use **MOXIMAC**

-How much to use it

Take this medication exactly as it was prescribed for you.

- The recommended dose for adults is one 400mg 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

-When to use it

It should be taken as Prescribed by the Doctor

-How long to use it

You should continue to take Moxifloxacin for as long as instructed by your doctor

- If you forget to use it

If you accidentally miss a dose, then simply use your normal dose when the next one is due. Do not use a double dose to make up for a missed or forgotten dose.

- If you use too much (Overdose)

If you use too many **MOXIMAC**, or if someone accidentally swallows some of your **MOXIMAC**, there is no immediate danger. However, you should contact your doctor, health care provider, or the nearest hospital emergency department for further advice.

While you are using **MOXIMAC**

- Things you must do

Swallow the tablets whole with some water. If someone else takes your medicine by mistake, tell your doctor at once. Because your medicine controls and does not cure your condition, you will normally need to take it continuously.

- Things you must not do

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. 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.

- 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.

Things to be careful of:

- Fluoroquinolone antibiotics may cause disturbances in blood sugar, including both a decrease in blood sugar below normal levels (hypoglycemia) and an increase in blood sugar above normal levels (hyperglycemia). In patients treated with

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moxifloxacin, disturbances in blood sugar occurred predominantly in elderly patients receiving concomitant treatment with oral antidiabetic medicines that lower blood sugar (e. g. sulfonylurea) or with insulin. If you suffer from diabetes, your blood sugar should be carefully monitored.

- 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.

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone antibacterial medicines, including Moximac, 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 Moximac therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Moximac, contact your healthcare providers and rest the painful area. Avoid any unnecessary exercise as this might 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 Moximac and inform your healthcare providers immediately in order to prevent the development of potentially irreversible condition.

Side Effects

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

The most serious side effects observed during treatment with Moxifloxacin are listed below:

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 (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 (Stevens-Johnson syndrome or toxic epidermal necrolysis) (very rare side effects, potentially life threatening)
- 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)
- 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 (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 (tendonitis) (rare side effect) or a tendon rupture (very rare side effect)

stop taking moxifloxacin and tell your doctor 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 moxifloxacin (very rare side effects), tell your treating doctor immediately that you have taken moxifloxacin and do not restart the treatment.

A worsening of the symptoms of myasthenia gravis has been observed in post marketing cases. If this happens, consult your doctor 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 doctor 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 doctor immediately.

Other side effects which have been observed during treatment with moxifloxacin are listed below by how likely they are:

Common

- nausea
- diarrhea
- dizziness
- stomach and abdominal ache
- vomiting
- headache
- increase of a special liver enzyme in the blood (transaminases) infections caused by resistant bacteria or fungi e.g. oral and

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vaginal infections caused by Candida
- change of the heart rhythm (ECG) in patients with low blood potassium level

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).

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 MOXIMAC

Store below 30°C in a dry place, protected from light
Keep out of the reach and sight of children.

-Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away the medicines you no longer use. These measures will help to protect the environment.

Product Description

-What it looks like

Brick red colored, capsule shaped, biconvex, film coated tablets with plain surface on both the sides.

-Ingredients

Active ingredient:

Moxifloxacin Hydrochloride

Inactive Ingredients:

Microcrystalline Cellulose (pH 101); Lactose Monohydrate; L Hydroxy propyl Cellulose (LH21); Purified Water; Microcrystalline Cellulose (pH 102); Croscarmellose Sodium; Magnesium Stearate; Hydroxy propyl methyl cellulose (E5) Macrogol 6000; Titanium dioxide (E171); Purified Talc & Ferric oxide red (E172).

MAL Number:

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Manufacturer

MACLEODS

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Product Registration Holder

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