

MOXIFLOXACIN HEC 400MG FILM-COATED TABLET

Moxifloxacin (400mg)

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What *Moxifloxacin HEC* is used for

Moxifloxacin HEC is used in patients 18 years of age and older for treatment of bacterial infections caused by bacteria susceptible to moxifloxacin.

How *Moxifloxacin HEC* works

Moxifloxacin HEC works by killing bacteria that cause infections.

Before you use *Moxifloxacin HEC*

- When you must not use it

Do not take *Moxifloxacin-HEC*:

- If you are allergic to moxifloxacin, any other quinolone antibiotics or any of the other ingredients of this medicine.
- If you are under 18 years of age.
- If you have previously had problems with your tendons related to treatment with quinolone antibiotics
- If you were born with or have any condition with abnormal heart rhythm, a salt imbalance in the blood (especially low levels of potassium in the blood), a very slow heart rhythm, heart failure, a history of abnormal heart rhythms, or you are taking other medicines that result in abnormal ECG changes.
- If you have a severe liver disease or increased liver enzymes.

- Pregnancy and lactation

Do not take *Moxifloxacin HEC* if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take *Moxifloxacin HEC* if you are breast-feeding. Ask your doctor

or pharmacist for advice before taking any medicine.

- Before you start to use it

Talk to your doctor before taking *Moxifloxacin-HEC*

- If you have any heart rhythm conditions.
- If you suffer from epilepsy or a condition which makes you likely to have convulsions.
- If you have or have ever had any mental health problems.
- If you suffer from myasthenia gravis (abnormal muscle fatigue leading to weakness and in serious cases paralysis).
- If you or any member of your family have glucose-6-phosphate dehydrogenase deficiency (a rare hereditary disease).
- 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).
- If you have kidney problem.

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).

Tell your healthcare providers if you have experienced a previous episode of aortic dissection (a tear in the aorta wall).

Tell your healthcare providers 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).

You should not take fluoroquinolone antibacterial medicines, including *Moxifloxacin HEC*, 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.

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, such as:

- Anti-arrhythmics (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide)- for treating of heart condition.
- Antipsychotics (e.g. phenothiazines, pimozide, sertindole, haloperidol, sultopride),
- Tricyclic antidepressants medicines
- Antibiotics (sparfloxacin, intravenous erythromycin, pentamidine)
- Antimalarials particularly (halofantrine)
- Some antihistamines (terfenadine, astemizole and mizolastine)
- Other medicines (e.g. cisapride, intravenous vincamine, bepridil and diphemanil).
- Medicines that can lower your blood potassium levels (eg: loop and thiazide diuretics, laxatives, enemas, corticosteroids, amphotericin B) or cause a slow heart rate
- Any medicine containing magnesium or aluminium (such as antacids for indigestion), iron, zinc or didanosine or any medicine containing sucralfate (to treat stomach disorders). Take your *Moxifloxacin-HEC* 6 hours before or after taking the other medicine.
- If you are currently taking drugs to thin your blood (oral anti-coagulants such as warfarin).

How to use Moxifloxacin HEC

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

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

Moxifloxacin HEC 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 Moxifloxacin HEC 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

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Moxifloxacin-HEC for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do 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.

Taking too many tablets may cause change in heart rhythm.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Moxifloxacin HEC.

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

- Things you must not do

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

Do not take any new medicines without consulting your doctor.

Do not give Moxifloxacin HEC 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 and 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 Moxifloxacin HEC, 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 *Moxifloxacin HEC* therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking *Moxifloxacin HEC*, contact your healthcare providers and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.

Nerve damage (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 *Moxifloxacin HEC* and inform your healthcare providers immediately in order to prevent the development of potentially irreversible condition.

Psychiatric reactions

You may experience mental health problems even when taking/ using fluoroquinolone antibiotics, including *Moxifloxacin HEC* 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 *Moxifloxacin HEC* and inform your doctor immediately.

Side effects

Like all medicines, *Moxifloxacin HEC* can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking 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 leading to self-harm, such as suicidal ideations/thoughts (desire to kill oneself), or suicide attempts)
- Hallucination
- Problems with skin sensations
- Changes in smell (including loss of smell)
- Unusual dreams
- Problems with balance and co-ordination (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).

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)
- Psychotic reactions (potentially leading to self-harm, such as suicidal ideations/ thoughts (desire to kill oneself), 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)

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

Storage and Disposal of Moxifloxacin HEC

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

- 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.

Product Description

- What it looks like

White or off-white oblonged film-coated tablets, debossed “S9” on one side while blank on the other.

- Ingredients

- Active ingredient

Moxifloxacin

- Inactive ingredients

Microcrystalline cellulose

Mannitol

Croscramellose sodium

Magnesium stearate

Opadry Y-1-7000

- MAL number:

MAL19116036ACZ

Manufacturer

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Product Registration Holder

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Date of revision

13/06/2024

Serial number

NPRA(R2/1)240613/1287