MOXIVE®

Package leaflet: Information for the patient
Moxive 400 mg film-coated tablets
Active substance: Moxifloxacin

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 more questions, ask your doctor or pharmacist.
- 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 are the same as yours. Do not re-use this medicine without medical prescription, even if you want to treat a similar illness.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. WHAT MOXIVE IS AND WHAT IT IS USED FOR

Moxive contains the active substance moxifloxacin, which belongs to a group of antibiotics called fluoroquinolones. Moxive works by killing bacteria that cause infections.
Moxive is used in patients aged 18 years and above for treating the following bacterial infections when caused by bacteria against which moxifloxacin is active. Moxive 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.
Moxive tablets are not sufficient on their own for treating this kind of infection. Therefore, another antibiotic in addition to Moxive tablets should be prescribed by your doctor for the treatment of infections of the female upper genital tract (see section 2. What you need to know before you take Moxive, Warnings and precautions, Talk to your doctor before taking Moxive).
If the following bacterial infections have shown improvement during initial treatment with Moxive solution
For infusion, Moxive 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.
Moxive 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. BEFORE YOU TAKE MOXIVE

Contact your doctor if you are not sure if you belong to a patient group described below.
Do not take Moxive
- If you are allergic to the active substance moxifloxacin, any other quinolone antibiotics or any of the other ingredients of this medicine (listed in section 6. Further information).
- If you are pregnant or are breast-feeding.
- If you are under 18 years of age.
- If you have previously had problems with your tendons related to treatment with quinolone antibiotics (see section Warnings and Precautions … and section 4. Possible side effects).
- If you were born with or have
  - any condition with abnormal heart rhythm (seen on ECG, electrical recording of the heart)
  - a salt imbalance in the blood (especially low levels of potassium or magnesium in the blood)
  - a very slow heart rhythm (called 'bradycardia')
  - a weak heart (heart failure)
  - a history of abnormal heart rhythms or
- if you are taking other medicines that result in abnormal ECG changes (see section Other medicines and Moxive). This is because Moxive can cause changes 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.

Take special care with Moxive
Talk to your doctor before taking Moxive
- 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.
- Moxive 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 Moxive (see also sections Do not take and Other medicines and Moxive).
- If you suffer from epilepsy or a condition which makes you likely to have convulsions talk to your doctor before taking Moxive.
- You have ever had mental health problems (as all fluoroquinolones may cause mental health changes such as disturbances in attention, disorientation, agitation, nervousness, memory impairment and delirium).
- You are diabetic (Hypoglycemia - including hypoglycemic coma- has been reported. If this happens, contact your doctor immediately.)
- If you suffer from myasthenia gravis (abnormal muscle fatigue leading to weakness and in serious cases paralysis), taking Moxive 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 Moxive 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 Moxive 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 Moxive. If there is no improvement in symptoms after 3 days of treatment, please consult your doctor.

When taking Moxive
- 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 Moxive and seek medical advice immediately.
- Moxive may cause a rapid and severe inflammation of the liver which could lead to life-threatening liver failure (including fatal cases, see section 4. Possible side effects). 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 / 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 Moxive, may cause convulsions. If this happens, stop taking Moxive and contact your doctor immediately.
- 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 Moxive.
- You may experience mental health problems even when taking quinolone antibiotics, including Moxive, 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. Possible side effects). If you develop such reactions, stop taking Moxive and inform your doctor immediately.
- You may develop diarrhoea whilst or after taking antibiotics including Moxive. If this becomes severe or persistent or you notice that your stool contains blood or mucus you should stop taking Moxive immediately and consult your doctor. You should not take medicines that stop or slow down bowel movement.
- Moxive may cause pain and inflammation of your tendons, even within 48 hours of starting treatment and up to several months after discontinuing Moxive 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 Moxive, 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 sections Do not take Moxive… and 4. Possible side effects). .
- If you are elderly and have kidney problems make sure that you drink plenty whilst taking Moxive. 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 Moxive, consult an eye specialist immediately (see sections Driving and using machines and 4. Possible side effects).
- 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 Moxive.
- The efficacy of Moxive 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 Do not take Moxive).
Taking other medicines
Tell your doctor or pharmacist about any other medicines that you are taking, took recently or might take.
For Moxive, be aware of the following:
- If you are taking Moxive and other medicines that affect your heart there is an increased risk for altering your heart rhythm. Therefore, do not take Moxive 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 Moxive.
- 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 Moxive tablets. Take your Moxive tablet 6 hours before or after taking the other medicine.
- Taking any medicine containing charcoal at the same time as Moxive tablets reduces the action of Moxive. It is recommended that these medicines are not used together.
- If you are currently taking drugs to thin your blood (oral anti-coagulants such as warfarin), it may be necessary for your doctor to monitor your blood clotting time.

Taking Moxive with food and drink
Moxive can be taken with or without food (including dairy products).
Pregnancy, breast-feeding and fertility
Do not take Moxive 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
Moxive 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.
Moxive contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, speak to your doctor before taking Moxive.

3. HOW TO TAKE MOXIVE

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The recommended dose for adults is one 400 mg film-coated tablet once daily.
Moxive tablets are for oral use. Swallow the tablet whole and with plenty of liquid. You can take Moxive 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 time you will take Moxive 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) except for pneumonia which starts during a stay in hospital 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 Moxive film-coated tablets are used to complete a course of therapy started with Moxive 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 Moxive 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 Moxive 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 Moxive 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 Moxive.
The recommended dose and duration of treatment should not be exceeded (see section 2. What you need to know before you take Moxive, Warnings and precautions).
If you take more Moxive than you should
If you take more than the prescribed one tablet a day, get medical help immediately. Try to 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 Moxive
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 Moxive
If you stop taking this medicine too soon 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 about 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 Moxive. The frequency of possible side effects listed below is defined using the following convention:
Common: may affect up to 1 in 10 people
Uncommon: may affect up to 1 in 100 people
Rare: may affect up to 1 in 1,000 people
Very rare: may affect up to 1 in 10,000 people
Cardiac System (see section 2. What you need to know before you take Moxive)
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 heartbeat, severe heart rhythm abnormalities, chest pain (angina pectoris)
Rare: Abnormal fast heart rhythm, fainting
Very rare: Abnormal heart rhythms, life-threatening irregular heartbeat, stopping of heartbeat
Common side effects:
- 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 ache
- Diarrhoea
- 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)
- Widening of the blood vessels (flushing)
- Difficulty in breathing (including asthmatic conditions)
- Decreased appetite
- 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-glutamyl-transferase 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.

Rare side effects:
- Severe, sudden 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)
- Severe diarrhoea containing blood and/or mucus (antibiotic associated colitis including pseudomembranous colitis), which very rarely, may develop into complications that are life-threatening
- Jaundice (yellowing of the whites of the eyes or skin), inflammation of the liver
- Pain and swelling of the tendons (tendonitis)
- Increased blood sugar
- Increased blood uric acid
- Feeling particularly emotional
- Depression (which in very rare cases may lead to self-harm, such as suicidal ideations/thoughts, 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 side effects:
- 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 (agranulocytosis)
- 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)

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 Moxive:
- 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 get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. HOW TO STORE MOXIVE

Keep out of the reach and sight of children.
Do not use this medicine after the expiry date stated on the blister and carton. The expiry date refers to the last day of the month.
Do not store above 30°C.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What Moxive contains
- The active substance is moxifloxacin. Each film-coated tablet contains 400 mg moxifloxacin as hydrochloride.
- The other ingredients are: Lactose anhydrous NF D.C., Povidon 30, Croscarmellose sodium Type A, Colloidal silicon dioxide, Magnesium stearate, Hydroxypropyl methylcellulose, Titanium dioxide, purified talc, Polyethylene Glycol MW 6000 and Iron oxide red.

What Moxive looks like and contents of the pack
A dull red, bevelled edge, oblong biconvex film-coated tablets, engraved with "223" on one side and plain on the other side.
Available in packs of 5 and 7 tablets
1 blister (5 tablet/blister)
1 blister (7 tablet/blister)

Marketing Authorisation Holder and Manufacturer
SPIMACO
Al-Qassim Pharmaceutical Plant
Saudi Arabia.

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To report any side effect(s):

For Saudi Arabia:
• The National Pharmacovigilance and Drug Safety Centre (NPC)
• Fax: +966-11-205-7662
• Call NPC at +966-11-2038222, Exts: 2317-2356-2340.
• Reporting hotline: 19999.
• E-mail: npc.drug@sfda.gov.sa
• Website: https://ade.sfda.gov.sa

For UAE
• Pharmacovigilance & Medical Device section
• P.O.Box: 1853
• Tel: 80011111
• Email: pv@moh.gov.ae
• Drug Department
Ministry of Health & Prevention
Dubai

For Oman
• Department of Pharmacovigilance & Drug Information
• Directorate General of Pharmaceutical Affairs & Drug Control
• Ministry of Health, Sultanate of Oman
• Phone Nos. 22357687 / 22357686
• Fax: 22358489
• Email: dg-padc@moh.gov.om
• Website: www.moh.gov.om

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 pharmacists who sold the medicament.
- The doctor and the pharmacists 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 medicaments out of the reach of children
Council of Arab Health Ministers
Union of Arab Pharmacists