PACKAGE LEAFLET: INFORMATION FOR THE USER

Moxifloxacin 400 mg / 250 ml solution for infusion

Moxifloxacin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

The name of your medicine is Moxifloxacin 400 mg / 250 ml solution for infusion.

In the rest of this leaflet this medicine will be called Moxifloxacin.

What is in this leaflet

1. What Moxifloxacin is and what it is used for

The active substance is moxifloxacin which belongs to a group of antibiotics called fluoroquinolones. This medicine works by killing bacteria that cause infections, provided that these bacteria are sensitive to the active substance.
Moxifloxacin is used in adults for treating the following bacterial infections:
- Infection of the lungs (pneumonia) acquired outside the hospital
- Infections of the skin and soft tissue

Moxifloxacin is only used to treat these infections when usual antibiotics cannot be used or have not worked.

2. What you need to know before you use Moxifloxacin

Contact your doctor if you are not sure if you belong to a patient group described below.

Do not use Moxifloxacin
- 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).
- 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 (see sections 2. Warnings and precautions and *4. Possible side effects*).
- If you were born with or have had any condition with abnormal heart rhythm (seen on ECG, electrical recording of the heart)
- If you have salt imbalance in the blood (especially low levels of potassium or magnesium in the blood).
- If you have a very slow heart rhythm (called “bradycardia”).
- If you have a weak heart (heart failure).
- If you have a history of abnormal heart rhythms
- If you are taking other medicines that result in abnormal ECG changes (see section *Other medicines and Moxifloxacin*). This is because Moxifloxacin 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 liver enzymes (transaminases) that are higher than 5 times the upper normal limit.

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before using Moxifloxacin.

Warnings and precautions
Before using Moxifloxacin for the first time
Talk to your doctor, pharmacist or nurse before using 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 using Moxifloxacin.
- If you suffer from **epilepsy** or you are prone to **seizures**, tell your doctor before using Moxifloxacin.
- If you have or have ever had any **mental health problems**, consult your doctor before using Moxifloxacin.
- If you suffer from **myasthenia gravis** using 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 decide whether Moxifloxacin is suitable for you.
- Moxifloxacin should be given intravenously (in the vein) only, and should not be administered into an artery.

If you are not sure if any of the above applies to you, talk to your doctor or nurse, before having Moxifloxacin.

When using Moxifloxacin
- 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 and the speed of the perfusion into your vein. Therefore the recommended dose must not be exceeded.
- There is a rare chance that you may experience a **severe, sudden allergic reaction** (an anaphylactic reaction/shock) even with the first dose, with symptoms that may include tightness in the chest, feeling dizzy, feeling sick or faint, or experience dizziness on standing. **If this happens, treatment with Moxifloxacin solution for infusion has to be discontinued immediately.**
- Moxifloxacin 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*). Please contact your doctor before you continue the treatment if you suddenly start to feel 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 (symptoms of a reduced liver function or a rapidly progressive and severe liver inflammation).
- If you develop a **skin reaction or blistering and/or peeling of the skin and/or mucosal reactions** (see section *4. Possible side effects*) contact your doctor before you continue the treatment.
- Quinolone antibiotics, including Moxifloxacin, may cause **convulsions**. If this happens, treatment with Moxifloxacin has to be discontinued.
- 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** 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-endangering behaviour such as suicide attempts (see section *4. Possible side effects*). If you develop such reactions discontinue treatment with Moxifloxacin and please inform your doctor.
- You may develop **diarrhoea** 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 using 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 must stop using 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 (see sections *2. Do not use Moxifloxacin* and *4. Possible side effects*).
- 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 using Moxifloxacin, consult an eye specialist immediately (see sections *2. 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 using Moxifloxacin.
- There is limited experience on use of sequential intravenous Moxifloxacin for the treatment of infection of the lungs (pneumonia) acquired outside the hospital.
- The efficacy of Moxifloxacin 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
This medicine must not be administered 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 use Moxifloxacin*).

Other medicines and Moxifloxacin
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 using 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), 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. diuretics, laxatives or enemas [large doses] or corticosteroids [anti-inlammatory drugs], amphotericin B), or cause a slow heart rate because these can also increase the risk of serious heart rhythm disturbances while using Moxifloxacin.
- If you are currently taking oral anti-coagulants (e.g. warfarin), it may be necessary for your doctor to monitor your blood clotting times.

Moxifloxacin with food and drink
The effect of Moxifloxacin is not influenced by food including dairy products.

Pregnancy, breast-feeding and fertility
Do not use Moxifloxacin if you are pregnant or breast-feeding.
If you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.
Animal studies do not indicate that your fertility will be impaired by using this medicine.

Driving and using machines
Moxifloxacin may make you feel **dizzy or light-headed**, you may experience a **sudden, temporary loss of vision**, or you might **faint for a short period**. If you are affected in this way do not drive or operate machinery.

Moxifloxacin contains sodium
Moxifloxacin contains 356mg (approximately 16mmol) **sodium** per vial. If you are on a controlled-salt diet, please inform your doctor immediately.

3. How to use Moxifloxacin

Moxifloxacin will always be given to you by a doctor or healthcare professional.

The usual dose for adults is **1 bottle, once daily**. Moxifloxacin is for **intravenous use**. Your doctor should ensure that the infusion is given at a **constant flow, over 60 minutes**.

No adjustment of the dose is required in elderly patients, patients with a low bodyweight or in patients with kidney problems.

Duration of treatment
Your doctor will decide on the duration of your treatment with Moxifloxacin. In some cases your doctor may start your treatment with Moxifloxacin solution for infusion and then continue your treatment with Moxifloxacin tablets. The duration of treatment depends upon the type of infection, and how well you respond to treatment but 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 Moxifloxacin tablets within 4 days.

– Infections of the skin and soft tissue **7 – 21 days.** For patients with complicated skin and skin structure infections the mean duration of intravenous treatment was approximately 6 days and the average overall duration of treatment (infusion followed by tablets) was 13 days.

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

If you use more Moxifloxacin than you should
If you are concerned that you may have received too much Moxifloxacin, contact your doctor immediately.

If you forget to use Moxifloxacin
If you are concerned that you may have missed a dose of Moxifloxacin, contact your doctor immediately.

If you stop using Moxifloxacin
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 / using 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. Consult your doctor if you wish to stop the treatment with Moxifloxacin solution for infusion or Moxifloxacin tablets before the end of the course of treatment.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

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 Moxifloxacin.

Serious side effects
If you experience the following side effects you may need **urgent medical treatment**. You must tell your doctor or go to the nearest hospital immediately if you notice:
– Severe, sudden **generalised allergic reaction** including very rarely life-threatening shock (such as difficulty in breathing, drop of blood pressure, fast pulse), swelling (including potentially life-threatening swelling of the airway). Rare side effect: affects 1 to 10 users in 10,000.
– severe diarrhoea containing blood and/or mucus (**antibiotic associated colitis** including pseudomembranous colitis), which in very rare circumstances, may develop into complications that are life-threatening. Rare side effect: affects 1 to 10 users in 10,000.
– A feeling of self-detachment (not being yourself), insanity (potentially leading to self-harm, such as **suicidal thoughts**, or suicide attempts).
– Jaundice, and feeling unwell, which may be a sign of a fulminant inflammation of the liver potentially leading to life-threatening liver failure (including fatal cases). Very rare side effect: affects 1 user in 10,000.
– Alterations of the skin and mucous membranes (painful blisters in the mouth / nose or at the level of penis / vagina), potentially life-threatening (**Stevens-Johnson Syndrome**, toxic epidermal necrolysis). Very rare side effect: affects 1 user in 10,000.

Common (affects 1 to 10 users in 100)
– Infections caused by resistant bacteria or fungi; for instance, oral and vaginal infections caused by Candida.
– Headache, dizziness.
– Change of the heart rhythm (ECG) in patients with low blood potassium level.
– Nausea, vomiting, stomach and abdominal ache, diarrhoea.
– Increase of a special liver enzyme in the blood (transaminases).
– Pain or inflammation at injection site.

Uncommon (affects 1 to 10 users in 1,000)
– 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 specialised white blood cells (eosinophils), decreased blood clotting.
– Allergic reaction
– Increased blood lipids (fats).
– Anxiety, restlessness / agitation.
– Tingling sensation (pins and needles) and/or numbness, changes in taste (in very rare cases loss of taste), confusion and disorientation, sleep problems (predominantly sleeplessness), shaking, sensation of dizziness (spinning or falling over), sleepiness.
– Visual disturbances including double and blurred vision.
– Change of the heart rhythm (ECG), palpitations, irregular and fast heart beat, severe heart rhythm abnormalities, angina pectoris (chest pain caused by lack of blood to the heart muscle).
– Widening of blood vessels.
– Difficulty in breathing including asthmatic conditions.
– Loss of appetite, wind and constipation, stomach upset (indigestion / heartburn), inflammation of the stomach, increase of a special digestive enzyme in the blood (amylase).
– 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).
– Itching, rash, skin hives, dry skin.
– Joint pain, muscle pain.
– Dehydration.
– Feeling unwell (predominantly weakness or tiredness), aches and pains such as back, chest, pelvic and extremities pains, sweating.
– Inflammation of a vein at the injection site.

Rare (affects 1 to 10 users in 10,000)
– Increased blood sugar, increased blood uric acid.
– Emotional instability, depression (in very rare cases leading to self-harm, such as suicidal ideations / thoughts, or suicide attempts), hallucination.
– 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.
– Ringing / noise in the ears, hearing impairment, including deafness (usually reversible)
– fainting.
– High blood pressure, low blood pressure.
– Jaundice (yellowing of the whites of the eyes or skin), inflammation of the liver.
– Pain and swelling of the tendons (tendonitis), muscle cramp, muscle twitching, muscle weakness.
– Kidney impairment (including increase in special kidney laboratory test results like urea and creatinine), kidney failure.
– Swelling (of the hands, feet, ankles, lips, mouth, throat).
– Difficulty in swallowing, inflammation of the mouth,

Very rare (affects less than 1 user in 10,000)
– Increased blood clotting, significant decrease of special white blood cells (agranulocytosis).
– Increase in skin sensitivity.
– Temporary loss of vision.
– Abnormal heart rhythms, life-threatening irregular heart beat, stopping of heart beat.
– Rupture of tendon, inflammation of joints, muscle rigidity, worsening of the symptoms of myasthenia gravis.

The following symptoms have been observed more frequently in patients treated intravenously:
Common (affects 1 to 10 users in 100)
– Increase of a special liver enzyme in the blood (gamma-glutamyl-transferase).
Uncommon (affects 1 to 10 users in 1,000)
– Abnormally fast heart rhythm, low blood pressure, swelling (of the hands, feet, ankles, lips, mouth, throat), severe diarrhoea containing blood and/or mucus (antibiotic associated colitis) which in very rare circumstances may develop into complications that are life-threatening, convulsions, hallucination, kidney impairment (including increase in special kidney laboratory test results, like urea and creatinine), kidney failure.

Furthermore, there have been very rare cases of the following side effects reported **after 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 (haemolytic anaemia), muscle reactions with muscle cell damage, increased sensitivity of the skin to sunlight or UV light, troubles associated with the nervous system such as pain, burning, tingling, numbness and/or weakness in extremities.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. Please tell your doctor or pharmacist immediately to get advice before receiving / taking the next dose.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via via Yellow Card Scheme,
Website: www.mhra.gov.uk/yellowcard .
By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Moxifloxacin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label on the bottle and carton after EXP. The expiry date refers to the last day of that month.

Do not store below **15°C**.

Use immediately after first opening and/or dilution. This product is for single use only. Any unused solution should be discarded.
At cool storage temperatures precipitation may occur, which will re-dissolve at room temperature.

Do not use this medicine if you notice any visible particulate matter or if the solution is cloudy.

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. Contents of the pack and other information

What Moxifloxacin contains
– The active substance is moxifloxacin. Each bottle contains 400 mg moxifloxacin (as hydrochloride). 1 ml contains 1.6 mg moxifloxacin (as hydrochloride).
– The other ingredients are sodium chloride, glycine, disodium edetate, hydrochloric acid (for pH-adjustment) and water for injections.

What Moxifloxacin looks like and contents of the pack
Moxifloxacin is a clear, yellow solution for infusion.
Moxifloxacin is packaged in carton boxes containing 250 ml polypropylene bottles. Packs of 1, 5, 10 and 12 bottles.
Not all pack sizes may be marketed.

Medicinal product subject to medical prescription.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder: Noridem Enterprises Ltd., Evagorou & Makariou, Mitsi Building 3, Office 115, 1065 Nicosia, Cyprus.
Manufacturer: DEMO S.A., 21st km National Road Athens-Lamia, 14568 Krioneri, Athens, Greece.

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom: Moxifloxacin 400mg/250ml Solution for Infusion
Germany: Moxifloxacin Noridem 400mg/250ml Infusionslösung
Austria: Moxifloxacin Noridem 400mg Infusionslösung
Spain: Moxifloxacino KERN PHARMA 400mg/250ml solución para perfusion
Cyprus: Moxifloxacin 400mg/250ml Διάλυμα για έγχυση
Poland: Moxifloxacin Noridem
Greece: MOXIFALON 400mg/250ml διάλυμα για έγχυση

This leaflet was last revised in 03/2014

The following information is intended for healthcare professionals only:
Moxifloxacin can be administered via a T-tube together with the following solutions:
Water for injections, sodium chloride 0.9%, sodium chloride 1 molar, glucose 5%/10%/40%,
Xylitol 20%, Ringer's solution, compound sodium lactate solution (Hartmann's solution,
Ringer-lactate solution).
Moxifloxacin should not be co-infused with other drugs.
The following solutions were incompatible with Moxifloxacin:
Sodium chloride 10% and 20% solutions,
Sodium bicarbonate 4.2% and 8.4% solutions

If this leaflet is difficult to see or read, please contact the following address for help:
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