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, pharmacist or nurse.
- 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 pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

Moxifloxacin contains the active substance moxifloxacin which belongs to a group of antibiotics called fluoroquinolones. Moxifloxacin works by killing bacteria that cause infections, if they are caused by bacteria that are susceptible to moxifloxacin.
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.

Warnings and precautions
Before taking this medicine
You should not take fluoroquinolone/quinolone antibacterial medicines, including Moxifloxacin, if you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone. In this situation, you should inform your doctor as soon as possible.
Talk to your doctor, pharmacist or nurse before Moxifloxacin is administered for the first time.
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 (see also section *Do not use Moxifloxacin and Other medicines and Moxifloxacin*).
Talk to your doctor before taking Moxifloxacin:
- If you are diabetic because you may experience a risk of change in blood sugar levels with moxifloxacin.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking moxifloxacin.
- 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 been diagnosed with leaking heart valves (heart valve regurgitation).
- If you have a family history of aortic aneurysm or aortic dissection or congenital heart valve disease, or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, or Ehlers- Danlos syndrome, Turner syndrome, Sjögren’s syndrome [an inflammatory autoimmune disease], or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet’s disease, high blood pressure, or known atherosclerosis, rheumatoid arthritis [a disease of the joints] or endocarditis [an infection of the heart]).
- If you suffer from **epilepsy** or a condition which makes you likely to have convulsions, 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.
- If you feel sudden, severe pain in your abdomen, chest or back, which can be symptoms of aortic aneurysm and dissection, go immediately to an emergency room. Your risk may be increased if you are being treated with systemic corticosteroids.
- If you start experiencing a rapid onset of shortness of breath, especially when you lie down flat in your bed, or you notice swelling of your ankles, feet or abdomen, or a new onset of heart palpitations (sensation of rapid or irregular heartbeat), you should inform a doctor immediately.

Moxifloxacin should be given intravenously (in the vein) only, and should not be administered into an artery.
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).
- Quinolone antibiotics, including Moxifloxacin, may cause **convulsions**. If this happens, treatment with Moxifloxacin has to be discontinued.
- 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 and inform your doctor immediately in order to prevent the development of potentially irreversible condition.
- You may experience **mental health problems** even 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-injurious behaviour such as suicide attempts (see section *4. Possible side effects*). If you develop such reactions, treatment with Moxifloxacin has to be discontinued.
- 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.
- 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 Moxifoxacin 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, contact your doctor and rest the painful area.** 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 your eyes seem to be otherwise affected, consult an eye specialist immediately (see sections 2. *Driving and using machines* and 4. *Possible side effects*).
- Fluoroquinolone antibiotics may cause an increase of your blood sugar levels above normal levels (hyperglycaemia), or lowering of your blood sugar levels below normal levels (hypoglycaemia), potentially leading to loss of consciousness (hypoglycaemic coma) in severe cases (see section 4. *Possible side effects*). 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 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.

Serious skin reactions
Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, and acute generalised exanthematous pustulosis (AGEP) have been reported with the use of moxifloxacin.
- SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.
- AGEP appears at the initiation of treatment as a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The most common location: mainly localized on the skin folds, trunk, and upper extremities.

If you develop a serious rash or another of these skin symptoms, stop taking moxifloxacin and contact your doctor or seek medical attention immediately.
Prolonged, disabling and potentially irreversible serious side effects
Fluoroquinolone/quinolone antibacterial medicines, including Moxifloxacin, have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible. This includes tendon, muscle and joint pain of the upper and lower limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, numbness or burning (paraesthesia), sensory disorders including impairment of vision, taste and smell, and hearing, depression, memory impairment, severe fatigue, and severe sleep disorders.
If you experience any of these side effects after taking Moxifloxacin, contact your doctor immediately prior to continuing treatment. You and your doctor will decide on continuing the treatment considering also an antibiotic from another class.
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, have recently taken or might take any other medicines.
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 use 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. some diuretics, some laxatives and enemas [large 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 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 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 using this medicine.
Driving and using machines
Moxifloxacin may make you feel **dizzy or light-headed**, you may experience a **sudden, transient 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
This medicine contains 786.7 mg sodium (main component of cooking/table salt) in each bottle. This is equivalent to 39.35% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Moxifloxacin

Moxifloxacin will always be given to you by a doctor or healthcare professional.
The recommended dose for adults is **one 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 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

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
If the treatment with this medicine is stopped too soon your infection may not be completely cured. 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 **most serious side effects** observed during the 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-threating liver failure (very rare side effect, fatal cases have been observed)
- serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis. These can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms (very rare side effects, potentially life threatening)
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis) (frequency of this side effect is 'not known')
- syndrome associated with impaired water excretion and low levels of sodium (SIADH) (very rare side effect)
- loss of consciousness due to severe decrease in blood sugar levels (hypoglycaemic coma) (very rare side effect)
- inflammation of blood vessels (signs could be red spots on your skin, usually on your lower legs or effects like joint pain) (very rare side effect)
- 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)
- swelling incl. swelling of the airway (rare side effect, potentially life-threatening)
- 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)
- muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell, have a high temperature or have dark urine. They may be caused by an abnormal muscle breakdown which can be life threatening and lead to kidney problems (a condition called rhabdomyolysis) (frequency of this side effect is 'not known')

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 very rare 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 (may affect up to 1 in 10 people)
- nausea
- diarrhoea
- 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 vaginal infections caused by Candida
- pain or inflammation at injection site
- change of the heart rhythm (ECG) in patients with low blood potassium level

Uncommon (may affect up to 1 in 100 people)
- rash
- stomach upset (indigestion/heartburn)
- changes in taste (in very rare cases loss of taste)
- sleep problems (predominantly sleeplessness)
- increase of a special liver enzyme in the blood (gamma-glutamyl-transferase and/or alkaline phosphatase)
- low number of special white blood cells (leukocytes, neutrophils)
- constipation
- itching
- sensation of dizziness (spinning or falling over)
- sleepiness
- wind
- change of the heart rhythm (ECG)
- impaired liver function (incl. increase of a special liver enzyme in the blood (LDH))
- decreased appetite and food intake
- low white blood cells count
- aches and pains such as back, chest, pelvic and extremities pains
- increase of special blood cells necessary for blood clotting
- sweating
- increased specialised white blood cells (eosinophils)
- anxiety
- feeling unwell (predominantly weakness or tiredness)
- shaking
- joint pain
- palpitations
- irregular and fast heart beat
- difficulty in breathing incl. asthmatic conditions
- increase of a special digestive enzyme in the blood (amylase)
- restlessness / agitation
- tingling sensation (pins and needles) and/or numbness
- skin hives
- widening of blood vessels
- confusion and disorientation
- decrease of special blood cells necessary for blood clotting
- visual disturbances incl. double and blurred vision
- decreased blood clotting
- increased blood lipids (fats)
- low red blood cell count
- muscle pain
- allergic reaction
- increase of bilirubin in the blood
- inflammation of a vein at the injection site
- inflammation of the stomach
- dehydration
- severe heart rhythm abnormalities
- dry skin
- angina pectoris (chest pain caused by lack of blood to the heart muscle)

Rare (may affect up to 1 in 1,000 people)
- increased blood sugar
- muscle twitching
- muscle cramp
- hallucination
- high blood pressure
- swelling (of the hands, feet, ankles, lips, mouth, throat)
- low blood pressure
- kidney impairment (incl. increase in special kidney laboratory test results like urea and creatinine)
- inflammation of the liver
- inflammation of the mouth
- ringing/noise in the ears
- jaundice (yellowing of the whites of the eyes or skin)
- impairment of skin sensation
- abnormal dreams
- disturbed concentration
- difficulty in swallowing
- changes in smell (incl. loss of smell)
- balance disorder and poor co-ordination (due to dizziness)
- partial or total loss of memory
- hearing impairment including deafness (usually reversible)
- increased blood uric acid
- emotional instability
- impaired speech
- fainting
- muscle weakness

Very rare (may affect up to 1 in 10,000 people)
- inflammation of joints
- abnormal heart rhythms
- increase of skin sensitivity
- a feeling of self-detachment (not being yourself)
- increased blood clotting
- muscle rigidity
- significant decrease of special white blood cells (agranulocytosis)
- a drop in the number of red and white blood cells and platelets (pancytopenia)

The following symptoms have been observed more frequently in patients treated intravenously:
Common (may affect up to 1 in 10 people)
- increase of a special liver enzyme in the blood (gamma-glutamyl-transferase)

Uncommon (may affect up to 1 in 100 people)
- severe diarrhoea containing blood and/or mucus (antibiotic associated colitis) which in very rare circumstances, may develop into complications that are life-threatening
- abnormal fast heart rhythm
- hallucination
- low blood pressure
- kidney impairment (incl. increase in special kidney laboratory test results like urea and creatinine)
- kidney failure
- swelling (of the hands, feet, ankles, lips, mouth, throat)
- convulsions

Very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as tendon inflammations, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, burning, numbness or pain (neuropathy), depression, fatigue, sleep disorders, memory impairment, as well as impairment of hearing, vision, and taste and smell have been associated with administration of quinolone and fluoroquinolone antibiotics, in some cases irrespective of pre-existing risk factors.
Cases of an enlargement and weakening of the aortic wall or a tear in the aortic wall (aneurysms and dissections), which may rupture and may be fatal, and of leaking heart valves have been reported in patients receiving fluoroquinolones. See also section 2. Furthermore, 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 Moxifloxacin: increased blood sodium levels, increased blood calcium levels, a special type of reduced red blood cell count (haemolytic anaemia), increased sensitivity of the skin to sunlight or UV light.
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 Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
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 ºC.
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, hydrochloric acid (for pH-adjustment), sodium hydroxide (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 cartons containing 250 mL polypropylene bottles. Packs of 1, 5, 10 and 12 bottles.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder: Noridem Enterprises Limited, Evagorou & Makariou, Mitsi Building 3, Office 115, 1065 Nicosia, Cyprus.
Manufacturer: DEMO S.A. PHARMACEUTICAL INDUSTRY, 21st km National Road Athens-Lamia, 14568 Krioneri, Attiki, Greece,
T: +30 210 8161802, **F:** +30 210 8161587.

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

Austria	Moxifloxacin Noridem 400 mg Infusionslösung
Cyprus	Moxifloxacin 400 mg / 250 mL Διάλυμα για έγχυση
Germany	MOXIfloxacin Noridem 400 mg / 250 mL Infusionslösung
Greece	MOXIFALON 400 mg / 250 mL Διάλυμα για έγχυση
Poland	Moxifloxacin Noridem
United Kingdom	Moxifloxacin 400 mg / 250 mL Solution for infusion

This leaflet was last revised in 04/2021.