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 or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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 (sensitive) 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 are administered 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 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 *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 level of potassium or magnesium in the blood),
- If you have a very slow heart rhythm (called 'bradycardia'), have a weak heart (heart failure), have a history of abnormal heart rhythms, or 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, that is, 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 before Moxifloxacin is administered to you for the first time. It is important you know that:

- 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 Moxifloxacin is administered to you (also see sections *Do not use Moxifloxacin* and *Other medicines and 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 suffer from **epilepsy** or a condition which makes you likely to have **convulsions**, tell your doctor before Moxifloxacin is administered to you.
- If you have or have ever had any **mental health problems**, consult your doctor before Moxifloxacin is administered to you.
- If you suffer from **myasthenia gravis** (rare disease leading to muscle weakness) because using Moxifloxacin may worsen the symptoms of your disease. If you think you are affected consult your doctor immediately.
- 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]).

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- If you or any member of your family have **glucose-6-phosphate dehydrogenase deficiency** (a rare hereditary disease), inform your doctor, who will advise whether Moxifloxacin is suitable for you.
- Moxifloxacin should be given intravenously (in the vein) only, and should not be administered into an artery.

Treatment with Moxifloxacin should be stopped immediately in the following cases:

- There is a rare chance that you may experience a **severe, sudden allergic reaction** (an anaphylactic reaction/shock) even with the first dose. Tell your doctor if you experience symptoms that may include tightness in the chest, feeling dizzy, feeling sick or faint, or experience dizziness on standing.
- 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.
- Quinolone antibiotics, including Moxifloxacin, may cause **convulsions**. If this happens, treatment with Moxifloxacin has to be discontinued.
- 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.
- 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 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 *Do not use Moxifloxacin* and *4. Possible side effects*).

During treatment with Moxifloxacin you should inform your doctor immediately:

- If you experience **palpitations or irregular heart beat** during the period of treatment. He/she may wish to perform an ECG to measure your heart rhythm.
- Serious skin reactions
  Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalised exanthematous pustulosis (AGEP) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) 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.
- DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

If you develop a serious rash or another of these skin symptoms, stop taking moxifloxacin and contact your doctor or seek medical attention immediately.

- 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 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.
- 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.
- If your eyesight becomes impaired or if you have any other **eye disturbances** whilst using Moxifloxacin, consult an eye specialist immediately (see sections *Driving and using machines* and *4. Possible side effects*).
- Fluoroquinolone antibiotics may cause an increase of your blood sugar levels above normal levels (hyperglycemia), or lowering of your blood sugar levels below normal levels (hypoglycaemia), potentially leading to loss of consciousne**ss** (hypoglycaemic coma) in severe cases (see section 4. Possible side effects). If you suffer from diabetes, your blood sugar should be carefully monitored.

When using Moxifloxacin you should be aware that:

- The risk of heart problems may increase with increase of the dose and the speed of the perfusion into your vein.
- 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.
- 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 (see section 4. Possible side effects)..
- There is limited experience on use of sequential intravenous/oral 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.

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.

When receiving treatment with Moxifloxacin be aware of the following
If you are using Moxifloxacin together with 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 (such as quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide),
- Antipsychotics (such as phenothiazines, pimozide, sertindole, haloperidol, sultopride),
- Tricyclic antidepressants,
- Some antimicrobials (such as saquinavir, sparfloxacin, intravenous erythromycin, pentamidine, antimalarials particularly halofantrine),
- Some antihistamines (such as terfenadine, astemizole, mizolastine),
- Other medicines such as cisapride, intravenous vincamine, bepridil and diphemanil.

You must tell your doctor:

- if you are taking other medicines that can lower your blood potassium levels (for instance some diuretics, some laxatives and enemas [large doses] or corticosteroids [anti-inflammatory medicines], amphotericin B),
- if you are taking other medicines that can 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 (for instance warfarin); it may be necessary for your doctor to monitor your blood clotting times.

Moxifloxacin with food, drink and alcohol
The effect of Moxifloxacin is not influenced by food, including dairy products.
You should not drink alcohol while using Moxifloxacin.

Pregnancy, breast-feeding and fertility
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 using this medicine.

Do not use Moxifloxacin if you are pregnant or breast-feeding.

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, brief (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
The maximum recommended daily dose of this medicinal product contains 1206 mg sodium (found in table salt). This is equivalent to 60% of the adult recommended maximum daily dietary intake for sodium.

3. How to use Moxifloxacin

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

The recommended dose for adults is **1 bottle** once daily.

Moxifloxacin is for intravenous (into a vein) 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 respective 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:

Indication	Duration of treatment
Infection of the lungs (pneumonia) acquired outside the hospital Most patients with pneumonia were switched to oral treatment with respective tablets within 4 days.	7 - 14 days
Infections of the skin and soft tissue For patients with complicated skin and skin structure infections the average duration of intravenous treatment was approximately 6 days and the average overall duration of treatment (infusion followed by respective tablets) was 13 days.	7 - 21 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 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.

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

If you receive more Moxifloxacin than you should
If you are concerned that you may have received more Moxifloxacin than prescribed, contact your doctor immediately.

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

If you stop using Moxifloxacin
If your treatment with this medicine is stopped too soon your infection may not be completely cured. Consult your doctor if you wish to stop your treatment with Moxifloxacin before the end of your course of treatment.

If you have any further questions on the use of 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.

Tell your doctor immediately and treatment should be stopped if you experience the side effects listed below, because they may be life-threatening:
Rare side effects (may affect up to 1 in 1,000 people)

- Severe, sudden generalised allergic reaction including very rarely life-threatening shock (for instance difficulty in breathing, drop of blood pressure, fast pulse), swelling (including potentially life-threatening swelling of the airway).
- Depression (in very rare cases leading to self-harm, such as suicidal thoughts or suicide attempts).
- 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.
- Increased blood sugar.
- 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).

Very rare side effects (may affect up to 1 in 10,000 people)

- A feeling of self-detachment (not being yourself), insanity (potentially leading to self-harm, such as suicidal thoughts or suicide attempts).
- Life-threatening irregular heartbeat (Torsade de Pointes) or stopping of heartbeat.
- Fulminant (dangerous) inflammation of the liver potentially leading to life-threatening liver failure (including fatal cases)
- 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 (potentially life threatening)
- Syndrome associated with impaired water excretion and low levels of sodium (SIADH)

- Inflammation of blood vessels (signs could be red spots on your skin, usually on your lower legs or effects like joint pain).
- Rupture of tendon, inflammation of joints, muscle rigidity.
- A worsening of the symptoms of *myasthenia gravis* has been observed.
- Decreased blood sugar.
- Loss of consciousness due to severe decrease in blood sugar levels (hypoglycaemic coma)

Not known (frequency cannot be estimated from the available data)
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis)
- Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (drug reaction with eosinophilia and systemic symptoms which is also known as DRESS or drug hypersensitivity syndrome)
- 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)

The following side effects have been observed during treatment with Moxifloxacin.

Common side effects (may affect up to 1 in 10 people)
- Infections caused by resistant bacteria or fungi, for instance, oral and vaginal infections caused by *Candida*
- Headache, dizziness
- Change of the heart rhythm (as seen on the ECG) in patients with low blood potassium level (see section *2. What you need to know before you are using Moxifloxacin*)
- Nausea, vomiting, stomach and abdominal ache, diarrhoea
- Increase of a special liver enzyme in the blood (transaminases)
- Pain or inflammation at injection site

Uncommon side effects (may affect up to 1 in 100 people)
- 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 (thrombocytes), 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 (mainly sleeplessness), shaking, sensation of dizziness (spinning or falling over), sleepiness
- Visual disturbances including double and blurred vision
- Change of the heart rhythm (as seen on the ECG), palpitations, irregular and fast heartbeat, severe heart rhythm abnormalities, angina pectoris (chest pain)
- Widening of blood vessels
- 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)

- 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 (gammaglutamyl-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

Rare side effects (may affect up to 1 in 1,000 people)
- Increased blood uric acid
- Emotional instability, hallucination Impairment of skin sensation, changes in smell (including loss of smell), abnormal dreams, balance disorder and poor coordination (due to dizziness), convulsions, disturbed concentration, impaired 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)
- Fainting
- High blood pressure, low blood pressure
- Difficulty in swallowing, inflammation of the mouth, 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)
- Discomfort or pain to the eyes, especially due to light exposure (contact an eye specialist immediately)

Very rare side effects (may affect up to 1 in 10,000 people)
- Increased blood clotting, significant decrease of special white blood cells (agranulocytosis)
- Increase of skin sensitivity
- Transient loss of vision (contact an eye specialist immediately)
- Abnormal heart rhythms
- A drop in the number of red and white blood cells and platelets (pancytopenia)

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.

Not known (frequency cannot be estimated from the available data)

- Increased sensitivity of the skin to sunlight or UV light (see also section 2, Warnings and precautions)
- Sharply demarcated, erythematous patches with/without blistering that develop within hours of administration of moxifloxacin and heals with post inflammatory residual hyperpigmentation; it usually recurs at the same site of the skin or mucous membrane upon subsequent exposure to moxifloxacin

The following symptoms have been observed more frequently in patients treated intravenously:

Common (may affect up to 1 in 10 users)
- Increase of a special liver enzyme in the blood (gamma-glutamyl-transferase)

Uncommon (may affect up to 1 in 100 users)
- 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

The following side effects have been reported following treatment with other quinolone antibiotics, which might possibly also occur during treatment with Moxifloxacin:

Very rare (may affect up to 1 in 10,000 people)
- Increased blood sodium levels, increased blood calcium levels
- A special type of reduced red blood cell count (haemolytic anaemia)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist immediately to get advice **before receiving the next dose**. This includes any side effects not listed in this leaflet.
You can also report side effects directly via:

For UK – The Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

For Ireland – The HPRA Pharmacovigilance. Website: www.hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Moxifloxacin

Since this product will be administered by medical professionals they will be responsible for the correct storage of the product both before and during its use, as well as for the correct disposal.

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 refrigerate or freeze.
Keep the bottle in the outer carton in order to protect from light.

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.

Your doctor or the hospital staff will normally store Moxifloxacin and they are responsible for the quality of the product when it has been opened and if it is not used immediately. They are also responsible for disposing of any unused Moxifloxacin correctly.

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 250 ml bottle contains 400 mg moxifloxacin (as hydrochloride). Each ml contains 1.6 mg moxifloxacin (as hydrochloride).
- The other ingredients are sodium acetate-trihydrate, sulfuric acid (for pH-adjustment), sodium sulfate, anhydrous and water for injections (see section *Moxifloxacin contains sodium*).

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 low-density polyethylene bottles (KabiPac) as primary packaging closed with a cap containing a rubber disc to allow insertion of the needle. Packs contain 1, 10, 20, 25 or 40 bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

For UK
Fresenius Kabi Ltd
Cestrian Court

Eastgate Way, Manor Park
Runcorn, Cheshire, WA7 1NT
United Kingdom

For Ireland
Fresenius Kabi Deutschland GmbH
Else-Kröner-Straße 1,
61352 Bad Homburg v.d.Höhe
Germany

Manufacturer

HP Halden Pharma AS
Svinesundsveien 80
1788 Halden, Norway

Fresenius Kabi Polska Sp. z.o.o.
Sienkiewica 25,
99-300 Kutno
Poland

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

Country	**Trade Name**
Austria	Moxifloxacin Kabi 400 mg Infusionslösung
Belgium	Moxifloxacine Fresenius Kabi 400mg/250ml oplossing voor infusie
Bulgaria	Моксифлоксацин Каби 400 mg/250 ml инфузионен разтвор
Croatia	Moxifloxacin Kabi 400 mg/250 ml otopina za infuziju
Czech Republic	Moxifloxacin Kabi 400 mg/250 ml infuzní roztok
Denmark	Moxifloxacin Fresenius Kabi
Germany	Moxifloxacin Kabi 400 mg Infusionslösung
Finland	Moxifloxacin Fresenius Kabi 400 mg/250 ml infuusioneste, liuos
Hungary	Moxifloxacin Kabi 400 mg/250 ml oldatos infúzió
Ireland	Moxifloxacin 400 mg/250 ml solution for infusion
Luxembourg	Moxifloxacin Kabi 400 mg/250 ml solution pour perfusion
Netherlands	Moxifloxacine Fresenius Kabi 400mg/250ml oplossing voor infusie
Poland	Moxifloxacin Kabi
Romania	Moxifloxacina Kabi 400 mg/250 ml soluţie perfuzabilă
Slovakia	Moxifloxacin Kabi 400 mg/250 ml infúzny roztok
Slovenia	Moksifloksacin Kabi 400 mg/250 ml raztopina za infundiranje
Spain	Moxifloxacino Kabi 400 mg/250 ml solución para perfusión
Sweden	Moxifloxacin Fresenius Kabi 400 mg/250 ml, infusionsvätska, lösning
United Kingdom	Moxifloxacin 400 mg/250 ml solution for infusion

This leaflet was last revised April 2024.
To be completed nationally

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%, glucose 5% / 10%, 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 are incompatible with Moxifloxacin.
Sodium chloride 10% and 20% solutions,
Sodium bicarbonate 4.2% and 8.4% solutions