Package leaflet: Information for the patient

FLOXSAFE 400

(Moxifloxacin Tablets 400 mg)

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. 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 Tablets is and what it is used for
2. What you need to know before you take Moxifloxacin Tablets
3. How to take Moxifloxacin Tablets
4. Possible side effects
5. How to store Moxifloxacin Tablets
6. Contents of the pack and other information

1. What Moxifloxacin Tablets is and what it is used for

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

Moxifloxacin Tablets is used in patients aged 18 years and above for treating the following bacterial infections when caused by bacteria against which moxifloxacin is active. Moxifloxacin Tablets 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.

Moxifloxacin tablets are not sufficient on their own for treating this kind of infection. Therefore, another antibiotic in addition to Moxifloxacin 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 Moxifloxacin Tablets, Warnings and precautions, Talk to your doctor before taking Moxifloxacin Tablets).

If the following bacterial infections have shown improvement during initial treatment with Moxifloxacin Tablets solution for infusion, Moxifloxacin 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.

Moxifloxacin 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. What you need to know before you take Moxifloxacin Tablets

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

Do not take Moxifloxacin Tablets

- 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 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 Moxifloxacin Tablets**). This is because Moxifloxacin Tablets 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.

Warnings and precautions

Talk to your doctor before taking Moxifloxacin Tablets

- Moxifloxacin Tablets 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 Moxifloxacin Tablets (see also sections **Do not take** and **Other medicines and Moxifloxacin Tablets**).

- If you suffer from **epilepsy** or a condition which makes you likely to have **convulsions** talk to your doctor before taking Moxifloxacin Tablets.
- If you have or have ever had any **mental health problems**, consult your doctor before taking Moxifloxacin Tablets.
- If you suffer from **myasthenia gravis** (abnormal muscle fatigue leading to weakness and in serious cases paralysis), taking Moxifloxacin Tablets 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 Moxifloxacin Tablets 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 Moxifloxacin Tablets 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 Moxifloxacin Tablets. If there is no improvement in symptoms after 3 days of treatment, please consult your doctor.

When taking Moxifloxacin Tablets

- 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 Moxifloxacin Tablets and seek medical advice immediately.**
- Moxifloxacin Tablets 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 Moxifloxacin Tablets, may cause **convulsions**. If this happens, stop taking Moxifloxacin Tablets 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 Moxifloxacin Tablets.
- You may experience **mental health problems** even when taking quinolone antibiotics, including Moxifloxacin Tablets, 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 Moxifloxacin Tablets and inform your doctor immediately.
- You may develop **diarrhoea** whilst or after taking antibiotics including Moxifloxacin Tablets. If this becomes severe or persistent or you notice that your stool contains blood or mucus you should **stop taking Moxifloxacin Tablets immediately and consult your doctor**. You should not take medicines that stop or slow down bowel movement.
- Moxifloxacin Tablets may cause **pain and inflammation of your tendons**, even within 48 hours of starting treatment and up to several months after discontinuing Moxifloxacin Tablets 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 Moxifloxacin Tablets, 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 Moxifloxacin Tablets**... and **4. Possible side effects**). .
- If you are elderly and have **kidney problems** make sure that you drink plenty whilst taking Moxifloxacin Tablets. If you get dehydrated this 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 **Driving and using machines** and **4. Possible side effects).**
- Fluoroquinolone antibiotics may cause **disturbances in blood sugar**, including both a decrease in blood sugar below normal levels (hypoglycemia) and an increase in blood sugar above normal levels (hyperglycemia). In patients treated with Moxifloxacin Tablets, disturbances in blood sugar occurred predominantly in elderly patients receiving concomitant treatment with oral antidiabetic medicines that lower blood sugar (e. g. sulfonylurea) or with insulin. If you suffer from diabetes, your blood sugar should be carefully monitored (see section **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 Moxifloxacin Tablets.
- The efficacy of Moxifloxacin Tablets 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 Moxifloxacin Tablets**).

Other medicines and Moxifloxacin Tablets

Tell your doctor or pharmacist about any other medicines that you are taking, took recently or might take.

For Moxifloxacin Tablets, be aware of the following:

- If you are taking Moxifloxacin Tablets and other **medicines that affect your heart** there is an increased risk for altering your heart rhythm. Therefore, do not take Moxifloxacin Tablets 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 Moxifloxacin Tablets.
- 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 Moxifloxacin tablets. Take your Moxifloxacin Tablets tablet 6 hours before or after taking the other medicine.
- Taking any medicine containing **charcoal** at the same time as Moxifloxacin Tablets reduces the action of Moxifloxacin Tablets. 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.

Moxifloxacin Tablets with food and drink

Moxifloxacin Tablets can be taken with or without food (including dairy products).

Pregnancy, breast-feeding and fertility

Do not take Moxifloxacin Tablets 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

Moxifloxacin Tablets 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.

Moxifloxacin Tablets contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, speak to your doctor before taking Moxifloxacin Tablets.

3. How to take Moxifloxacin Tablets

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 400mg film-coated tablet once daily.

Moxifloxacin Tablets are for oral use. Swallow the tablet whole (to mask the bitter taste) and with plenty of liquid. You can take Moxifloxacin Tablets 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 Moxifloxacin Tablets 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 Moxifloxacin film-coated tablets are used to complete a course of therapy started with Moxifloxacin 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 Moxifloxacin Tablets 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 Moxifloxacin Tablets 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 Moxifloxacin Tablets 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 Moxifloxacin Tablets.

The recommended dose and duration of treatment should not be exceeded (see section **2**. **What you need to know before you take Moxifloxacin Tablets, Warnings and precautions**).

If you take more Moxifloxacin Tablets 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 Moxifloxacin Tablets

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 Moxifloxacin Tablets

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 **most serious side effects** observed during treatment with Moxifloxacin Tablets 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))

- alterations of the skin and mucous membranes like painful blisters in the mouth/nose or at the penis/vagina (Stevens-Johnson syndrome or toxic epidermal necrolysis) (very rare side effects, potentially life threatening)
- 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)

stop taking Moxifloxacin Tablets 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 spcialist immediately.

If you have experienced life-threatening irregular heart beat (Torsade de Pointes) or stopping of heart beat while taking Moxifloxacin Tablets (very rare side effects), **tell your treating doctor immediately that you have taken Moxifloxacin Tablets 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 Tablets 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
- 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 the stomach
- dehydration
- severe heart rhythm abnormalities
- dry skin
- angina pectoris

Rare (may affect up to 1 in 1,000 people)

- 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)

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 Moxifloxacin Tablets:

- 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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist.

5. How to store Moxifloxacin Tablets

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

Do not use this medicine after the expiry date stated on the blister and on the carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

Protect from the light and moisture.

Store in the original package in order to protect from moisture.

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 Tablets contains

Lactose monohydrate, Povidone, Lactose anhydrous, Croscarmellose sodium, Colloidal silicon Dioxide, Magnesium Stearate,

Coating: Hypromellose, Polyethylene Glycol, Titanium Dioxide & Iron oxide Red.

What Moxifloxacin Tablets looks like and contents of the pack

Caplet shaped brick red colored smooth film coated tablets plain on both sides.

Carton pack (15 tablets) of 3 blisters each of 5 tablets: Primary packaging is a blister of aluminium foil and PVC/PVDC foil.

Marketing Authorisation Holder

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This leaflet was last revised in 29th April 2016.