PACKAGE LEAFLET: INFORMATION FOR THE USER

[Moxifloxacin Teva 400 mg Film-coated Tablets and associated names]
Moxifloxacin hydrochloride

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 any further 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.

IN THIS LEAFLET:

1. WHAT [MOXIFLOXACIN TEVA] IS AND WHAT IT IS USED FOR

[Moxifloxacin Teva] contains moxifloxacin as the active ingredient which belongs to a group of antibiotics called fluoroquinolones. [Moxifloxacin Teva] works by killing bacteria that cause infections.
[Moxifloxacin Teva] 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 Teva] should only be used to treat these infections when usual antibiotics cannot be used or have not worked:

o Infection of the sinuses, sudden worsening of long-term inflammation of the airways or infection of the lungs (pneumonia) acquired outside the hospital (except in 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 Teva] tablets are not sufficient on their own for treating this kind of infection. Therefore, another antibiotic in addition to [Moxifloxacin Teva] should be prescribed by your doctor for the treatment of infections of the female upper genital tract (see section Before you take [Moxifloxacin Teva]).

If the following bacterial infections have shown improvement during initial treatment with moxifloxacin solution for infusion, [Moxifloxacin Teva] 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 Teva] 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 TEVA]

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

Do not take [Moxifloxacin Teva] if:

- You are allergic (hypersensitive) to the active ingredient moxifloxacin, any other quinolone antibiotics or any of the other ingredients. The ingredients are listed in section 6. Further

information.
- You are pregnant or breast-feeding.
- You are under 18 years of age.
- You have previously had problems with your tendons related to treatment with quinolone antibiotics (see section Take special care with… and section 4 Possible side effects).
- You were born with or have
  - had any condition with abnormal heart rhythm (seen on ECG, electrical recording of the heart)
  - a salt imbalance in the blood (especially low concentrations 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 certain abnormal ECG changes (see section Taking other medicines). This is because [Moxifloxacin Teva] can cause change 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 limit of normal.

Warnings and precautions

Before taking [Moxifloxacin Teva]:
- [Moxifloxacin Teva] can **change your heart's ECG**, especially if you are female or elderly. If you are taking any medicine that decreases your blood potassium levels talk to your doctor before taking [Moxifloxacin Teva].
- If you suffer from **epilepsy** or a condition which makes you likely to have **convulsions** talk to your doctor before taking [Moxifloxacin Teva].
- If you have or have ever had any **mental health problems**, consult your doctor before taking [Moxifloxacin Teva]
- If you suffer from **myasthenia gravis** (abnormal muscle fatigue leading to weakness and in serious cases paralysis), taking [Moxifloxacin Teva] 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 Teva] 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 Teva] 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 Teva]. If there is no improvement in symptoms after 3 days of treatment, please consult your doctor.

When taking [Moxifloxacin Teva]:
- If you experience **palpitations or irregular heartbeat** 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 Teva] and seek medical advice immediately.**
- [Moxifloxacin Teva] may cause a **rapid and severe inflammation of the live**r 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 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 and/or peeling of the skin and/or mucosal reactions** (see section 4. Possible side effects) contact your doctor immediately before you continue treatment.
- Quinolone antibiotics may cause **convulsions** (fits). If this happens, stop taking [Moxifloxacin Teva] 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 Teva].
- You may experience **mental health problems** even when taking quinolone antibiotics, including [Moxifloxacin Teva], 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, stop taking Avelox and inform your doctor immediately.
- You may develop **diarrhoea** whilst or after taking antibiotics including [Moxifloxacin Teva]. If this becomes severe or persistent or you notice that your stool contains blood or mucus you should **stop taking [Moxifloxacin Teva] immediately and consult your doctor**. You should not take medicines that stop or slow down bowel movement.
- [Moxifloxacin Teva] may occasionally cause **pain and inflammation of your tendons** (especially Achilles tendon at the back of your ancle), sometimes on both legs, even within 48 hours of starting treatment and up to several months after discontinuing [Moxifloxacin Teva] therapy. The risk of pain and inflammation of your tendons and tendon rupture 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 should stop taking [Moxifloxacin Teva], 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 Teva]... and 4. Possible side effects).
- If you are elderly and have **kidney problems** make sure that you drink plenty whilst taking [Moxifloxacin Teva]. If you get dehydrated this may increase the risk of kidney failure.
- If your eyesight becomes impaired or if your **eyes seem to be affected** whilst taking [Moxifloxacin Teva], **consult an eye specialist immediately** (see Sections Driving and using mach8ines and 4. Possible side effects)**.**
- Quinolone antibiotics may make your **skin** become more **sensitive to sunlight or UV light**. You should avoid prolonged exposure to sunlight or strong sunlight and should not use a sunbed or any other UV lamp while taking [Moxifloxacin Teva].
- The efficacy of [Moxifloxacin Teva] 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

Moxifloxacin is contraindicated in children and adolescents (<18 years). Efficacy and safety of moxifloxacin in children and adolescents have not been investigated.

Other medicines and [Moxifloxacin Teva]

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

For [Moxifloxacin Teva], be aware of the following:

- If you are taking [Moxifloxacin Teva] and other <u>medicines that affect your heart</u> there is an increased risk for altering your heart rhythm. Therefore, do not take [Moxifloxacin Teva] 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 or cause a slow heart rate because these can also increase the risk of serious heart rhythm disturbances while taking [Moxifloxacin Teva]
- 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 Teva]. Take your [Moxifloxacin Teva] tablet 6 hours before or after taking the other medicine.
- Taking any medicine containing **charcoal** at the same time as [Moxifloxacin Teva] reduces the action of [Moxifloxacin Teva]. It is recommended that these medicines are not used together.
- If you are currently taking **medicines to thin your blood** (oral anticoagulants such as warfarin), it may be necessary for your doctor to monitor your blood clotting time.

[Moxifloxacin Teva] with food and drink

[Moxifloxacin Teva] can be taken with or without food (including dairy products).

Pregnancy and breast-feeding

Do not take [Moxifloxacin Teva] if you are pregnant or breast-feeding.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

[Moxifloxacin Teva] may make you feel dizzy or light-headed or you may lose you eyesight suddenly for a short time or you may faint for a short period. If you are affected in this way, do not drive or operate machinery.

3. HOW TO TAKE [MOXIFLOXACIN TEVA]

Always take [Moxifloxacin Teva] exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure how to take [Moxifloxacin Teva].

The usual dose for adults is one 400 mg film-coated tablet once daily.

[Moxifloxacin Teva] is for oral use. Swallow the tablet whole (to mask the bitter taste) and with plenty of liquid. You can take [Moxifloxacin Teva] 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 Teva] 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
- for 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

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 Teva] 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 Teva].

The recommended dose and duration of treatment should not be exceeded (see section **Take special care**).

If you take more of [Moxifloxacin Teva] 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 Teva]

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 tablet. If you are unsure about what to do ask your doctor or pharmacist.

If you stop taking [Moxifloxacin Teva]

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 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. The following side effects have been observed during treatment with [Moxifloxacin Teva]. The frequency of possible side effects listed below is defined using the following convention:

Very common: may affect more than 1 in 10 people
Common: may affect up to 1 in 10 people
Uncommon: may affect up to 1 in 100 people
Rare: may affect up to 1in 1,000 people
Very rare: may affect up to 1 in 10,000 people
Not known: frequency cannot be estimated from the available data

Common side effects:

- Infections caused by resistant bacteria or fungi, e.g. oral and vaginal infections caused by Candida (thrush)
- Change of the heart rhythm (ECG) in patients with low blood potassium level
- Headache:
- Dizziness
- Feeling sick (nausea)
- Being sick (vomiting)
- Stomach and abdominal ache
- Diarrhoea
- Increase of a special liver enzyme in the blood (transaminases)

Uncommon side effects:

- Allergic reaction

- Low red blood cell count (anaemia)
- Low white blood cells count
- Low numbers of special white blood cells (neutrophils)
- Decrease or increase of special blood cells necessary for blood clotting
- Increased specialised white blood cells (eosinophils)
- Decreased blood clotting
- Increased blood lipids (fats)
- Change of the heart rhythm (ECG), palpitations, irregular and fast heartbeat, severe heart rhythm abnormalities, chest pain (angina pectoris)
- Feeling anxious, restless, or agitated
- Tingling sensation (pins and needles) and/or numbness
- Changes in taste (in very rare cases loss of taste)
- Feeling confused and disorientated
- Sleep problems (e.g. sleeplessness or sleepiness)
- Shaking
- Sensation of dizziness (spinning or falling over)
- Problems with vision (including double or blurred vision)
- Widening of the blood vessels (flushing)
- Difficulty in breathing (including asthmatic conditions)
- Loss of appetite
- Wind and constipation
- Stomach upset (indigestion or heartburn)
- Inflammation of the stomach
- Increase of a special digestive enzyme in the blood (amylase)
- Problems with liver function (including increase of a special liver enzyme in the blood (LDH)), increase of bilirubin in the blood, increase of a special liver enzyme in the blood (gamma-glutamyltransferase and/or alkaline phosphatase)
- Itching, rash, skin hives, dry skin
- Joint pain, muscle pain
- Dehydration
- Feeling unwell (usually weakness or tiredness), aches and pains such as back, chest, pelvic pains and pains in the extremities
- Sweating.

Rare side effects:

- Severe, sudden allergic reaction including very rarely life-threatening shock (e.g. difficulty in breathing, drop of blood pressure, fast pulse), swelling (including potentially life-threatening swelling of the airway)
- Severe diarrhoea containing blood and/or mucus (antibiotic associated colitis including pseudomembranous colitis), which very rarely, may develop into complications that are lifethreatening
- Abnormal fast heart rhythm, fainting
- Jaundice (yellowing of the whites of the eyes or skin), inflammation of the liver
- Pain and swelling of the tendons (tendonitis)
- Increased blood sugar
- Increased blood uric acid
- Feeling particularly emotional
- Depression (which in very rare cases may lead to self-harm, such as suicidal ideations/thoughts, or suicide attempts)
- Hallucination
- Problems with skin sensations
- Changes in smell (including loss of smell)
- Unusual dreams
- Problems with balance and co-ordination (due to dizziness)

- Convulsions
- Disturbed concentration
- Problems with speech
- Partial or total loss of memory
- Ringing or noise in the ears, hearing impairment including deafness (usually reversible)
- High or low blood pressure
- Difficulty in swallowing
- Inflammation of the mouth
- Muscle cramps or twitching
- Muscle weakness
- Kidney problems (including an increase in special kidney laboratory test results like urea and creatinine), kidney failure
- Swelling (of the hands, feet, ankles, lips, mouth or throat).

Very rare side effects:

- Severe inflammation of the liver potentially leading to life-threatening liver failure (including fatal cases)
- Changes to the skin and mucous membranes (painful blisters in the mouth/nose or at the penis/vagina), potentially life-threatening (Stevens-Johnson-Syndrome, toxic epidermal necrolysis)
- Rupture of tendons
- Increased blood clotting, significant decrease of special white blood cells (agranulocytosis)
- Abnormal heart rhythms, life-threatening irregular heartbeat, stopping of heartbeat
- A feeling of self-detachment (not being yourself)
- Feeling mentally unwell (potentially leading to self-harm, such as suicidal ideations/thoughts, or suicide attempts)
- Transient loss of vision
- Skin feeling more sensitive
- Inflammation of joints
- Muscles feeling stiff
- Worsening of the symptoms of myasthenia gravis (abnormal muscle fatigue leading to weakness and in serious cases paralysis)

Also, there have been very rare cases of the following side effects reported following treatment with other quinolone antibiotics, which might possibly also occur during treatment with [Moxifloxacin Teva]:

- 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 the extremities.

If you feel you are suffering from a side effect, especially if any of the side effects gets serious, or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist immediately to get advice before taking the next dose.

5. HOW TO STORE [MOXIFLOXACIN TEVA]

Keep [Moxifloxacin Teva] out of the sight and reach of children.
Do not use [Moxifloxacin Teva] after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Store below 25ºC 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 Teva] contains

- The active substance is moxifloxacin hydrochloride anhydrous. Each tablet contains 436.34 mg moxifloxacin hydrochloride anhydrous equivalent to 400 mg moxifloxacin.
- The other ingredients are cellulose, microcrystalline; silica, colloidal anhydrous; croscarmellose sodium; magnesium stearate; talc. The tablets are film-coated with a mixture of hypromellose, macrogol 4000, iron oxide (red) (E172) and titanium dioxide (E171).

What [Moxifloxacin Teva] looks like and contents of the pack

Film-coated tablet.
Oval shaped tablet, debossed with "93" on one side of the tablet and "7387"on the other side of the tablet available in aluminium/aluminium blister packs of 1, 5, 7, 10, 25 (5x5), 50 (5x10), 70 (7x10), 80 (5x16) and 100 (10x10) film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<To be completed nationally>

This medicinal product is authorised in the Member States of the EEA under the following names:
<To be completed nationally>

This leaflet was last revised in **MM-YYYY**.

Advice/medical education
Antibiotics are used to treat infections caused by bacteria. They have no effect against infections caused by viruses.
Sometimes an infection caused by bacteria does not respond to a course of an antibiotic. One of the commonest reasons for this to occur is because the bacteria causing the infection are resistant to the antibiotic that is being taken. This means that they can survive and even multiply despite the antibiotic.
Bacteria can become resistant to antibiotics for many reasons. Using antibiotics carefully can help to reduce the chance of bacteria becoming resistant to them.
When your doctor prescribes a course of an antibiotic it is intended to treat only your current illness. Paying attention to the following advice will help prevent the emergence of resistant bacteria that could stop the antibiotic working.
1. It is very important that you take the antibiotic at the right dose, at the right times and for the right number of days. Read the instructions on the label and if you do not understand anything ask your doctor or pharmacist to explain.
2. You should not take an antibiotic unless it has been prescribed specifically for you and you should use it only to treat the infection for which it was prescribed.
3. You should not take antibiotics that have been prescribed for other people even if they had an infection that was similar to yours.
4. You should not give antibiotics that were prescribed for you to other people.
5. If you have any antibiotic left over when you have taken the course as directed by your doctor you should take the remainder to a pharmacy for appropriate disposal.