Package leaflet: Information for the patient

Levofloxacin Krka 250 mg film-coated tablets
Levofloxacin Krka 500 mg film-coated tablets

levofloxacin

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. See section 4.

What is in this leaflet

1. What Levofloxacin Krka is and what it is used for

The name of your medicine is Levofloxacin Krka tablets. Levofloxacin Krka tablets contain a medicine called levofloxacin. This belongs to a group of medicines called antibiotics. Levofloxacin is a ‘quinolone’ antibiotic. It works by killing the bacteria that cause infections in your body.

Levofloxacin Krka tablets can be used to treat infections of the:

- Sinuses
- Lungs, in people with long-term breathing problems or pneumonia
- Urinary tract, including your kidneys or bladder
- Prostate gland, where you have a long-lasting infection
- Skin and underneath the skin, including muscles. This is sometimes called ‘soft tissue’

In some special situations, Levofloxacin Krka tablets may be used to lessen the chances of getting a pulmonary disease named anthrax or worsening of the disease after you are exposed to the bacteria causing anthrax.

2. What you need to know before you take Levofloxacin Krka

Do not take Levofloxacin Krka and tell your doctor:
- if you are allergic to levofloxacin, any other quinolone antibiotic such as moxifloxacin, ciprofloxacin or ofloxacin or any of the other ingredients of this medicine (listed in section 6)
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have ever had epilepsy
- You have ever had a problem with your tendons such as tendonitis that was related to treatment with a ‘quinolone antibiotic'. A tendon is the cord that joins your muscle to your skeleton
- You are a child or a growing teenager
- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Levofloxacin Krka.

Warnings and precautions
Talk to your doctor or pharmacist before taking Levofloxacin Krka if:
- You are 60 years of age or older
- You are using corticosteroids, sometimes called steroids (see section "Other medicines and Levofloxacin Krka")
- You have received a transplantation
- You have ever had a fit (seizure)
- You have had damage to your brain due to a stroke or other brain injury
- You have kidney problems
- You have something known as 'glucose – 6 – phosphate dehydrogenase deficiency'. You are more likely to have serious problems with your blood when taking this medicine
- You have ever had mental health problems
- You have ever had heart problems: caution should be taken when using this kind of medicine, if you were born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart), have salt imbalance in the blood (especially low level of potassium or magnesium in the blood), have a very slow heart rhythm (called 'bradycardia'), have a weak heart (heart failure), have a history of heart attack (myocardial infarction), you are female or elderly or you are taking other medicines that result in abnormal ECG changes (see section "Other medicines and Levofloxacin Krka")
- You have nerve problems (peripheral neuropathy)
- You have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm)
- You have experienced a previous episode of aortic dissection (a tear in the aorta wall)
- You have been diagnosed with leaking heart valves (heart valve regurgitation)
- 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))
- You are diabetic
- You have ever had liver problems
- You have myasthenia gravis
- You have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking levofloxacin.

<u>Before taking this medicine</u>
You should not take fluoroquinolone/quinolone antibacterial medicines, including Levofloxacin Krka, 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.

<u>When taking this medicine</u>
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 you start experiencing sudden involuntary jerks, twitches of the muscles or muscle contractions - see a doctor straight away as this could be signs of myoclonus. Your doctor may need to stop treatment with levofloxacin and to start an appropriate treatment.

If you are having nausea, feeling generally unwell, have severe discomfort or on-going pain or worsening pain in the stomach area or vomiting – see a doctor straight away as this could be a sign of an inflamed pancreas (acute pancreatitis).

If you are experiencing fatigue, skin pale, bruising, uncontrolled bleeding, fever, sore throat and serious deterioration of your general condition, or a feeling that your resistance to infection may be decreased - see a doctor straight away as this could be signs of blood disorders. Your doctor should monitor your blood with blood counts. In case of abnormal blood counts, your doctor may need to stop treatment.

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 Levofloxacin Krka therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder or knee), stop taking Levofloxacin Krka, contact your doctor and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.

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 Levofloxacin Krka and inform your doctor immediately in order to prevent the development of potentially irreversible condition.

Prolonged, disabling and potentially irreversible serious side effects
Fluoroquinolone/quinolone antibacterial medicines, including Levofloxacin Krka, 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 Levofloxacin Krka, 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.

Serious skin reactions
Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported with the use of levofloxacin.

- 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.
- 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 levofloxacin and contact your doctor or seek medical attention immediately.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Levofloxacin Krka.

Children and adolescents
This medicine must not be given to children or teenagers.

Other medicines and Levofloxacin Krka
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Levofloxacin Krka can affect the way some other medicines work. Also some medicines can affect the way Levofloxacin Krka work.

In particular, tell your doctor if you are taking any of the following medicines. This is because it can increase the chance of you getting side effects, when taken with Levofloxacin Krka:
- Corticosteroids, sometimes called steroids – used for inflammation. You may be more likely to have inflammation and/or rupture of your tendons
- Warfarin - used to thin the blood. You may be more likely to have a bleed. Your doctor may need to take regular blood tests to check how well your blood can clot
- Theophylline - used for breathing problems. You are more likely to have a fit (seizure) if taken with Levofloxacin Krka
- Non-steroidal anti-inflammatory drugs (NSAIDS) - used for pain and inflammation such as aspirin, ibuprofen, fenbufen, ketoprofen and indomethacin. You are more likely to have a fit (seizure) if taken with Levofloxacin Krka
- Ciclosporin - used after organ transplants. You may be more likely to get the side effects of ciclosporin
- Medicines known to affect the way your heart beats. This includes medicines used for abnormal heart rhythm (antiarrhythmics such as quinidine, hydroquinidine, disopyramide, sotalol, dofetilide, ibutilide and amiodarone), for depression (tricyclic antidepressants such as amitriptyline and imipramine,), for psychiatric disorders (antipsychotics), and for bacterial infections (‘macrolide’ antibiotics such as erythromycin, azithromycin and clarithromycin)
- Probenecid – used for gout and cimetidine – used for ulcers and heartburn. Special care should be taken when taking either of these medicines with Levofloxacin Krka. If you have kidney problems, your doctor may want to give you a lower dose.

Do not take Levofloxacin Krka tablets at the same time as the following medicines. This is because it can affect the way Levofloxacin Krka tablets work:
- Iron tablets (for anemia), zinc supplements, magnesium or aluminum-containing antacids (for acid or heartburn), didanosine or sucralfate (for stomach ulcers). See section 3 “If you are already taking iron tablets, zinc supplements, antacids, didanosine or sucralfate” below.

Urine tests for opiates
Urine tests may show ‘false-positive’ results for strong painkillers called ‘opiates’ in people taking Levofloxacin Krka. If your doctor has prescribed a urine test, tell your doctor you are taking Levofloxacin Krka.

Tuberculosis tests
This medicine may cause “false negative” results for some tests used in laboratory to search for the bacteria causing tuberculosis.

Pregnancy and breast-feeding
Do not take this medicine if:
- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding or planning to breast-feed

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.

Driving and using machines
You may get side effects after taking this medicine, including feeling dizzy, sleepy, a spinning feeling (vertigo) or changes to your eyesight. Some of these side effects can affect you being able to concentrate and your reaction speed. If this happens, do not drive or carry out any work that requires a high level of attention.

Levofloxacin Krka contains sunset yellow FCF
May cause allergic reactions.

3. How to take Levofloxacin Krka

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine
- Take this medicine by mouth
- Swallow the tablets whole with a drink of water
- The tablets may be taken during meals or at any time between meals
- The tablets can be divided into equal doses

Protect your skin from sunlight
Keep out of direct sunlight while taking this medicine and for 2 days after you stop taking it. This is because your skin will become much more sensitive to the sun and may burn, tingle or severely blister if you do not take the following precautions:
- Make sure you use high factor sun cream
- Always wear a hat and clothes which cover your arms and legs
- Avoid sun beds

If you are already taking iron tablets, zinc supplements, antacids, didanosine or sucralfate
- Do not take these medicines at the same time as Levofloxacin Krka. Take your dose of these medicines at least 2 hours before or after Levofloxacin Krka tablets.

How much to take
- Your doctor will decide on how many Levofloxacin Krka tablets you should take.
- The dose will depend on the type of infection you have and where the infection is in your body.
- The length of your treatment will depend on how serious your infection is.
- If you feel the effect of your medicine is too weak or strong, do not change the dose yourself, but ask your doctor.

Adults and the elderly
Sinuses infection
- Two tablets of Levofloxacin Krka 250 mg, once each day
- Or, one tablet of Levofloxacin Krka 500 mg, once each day

Lungs infection, in people with long-term breathing problems
- Two tablets of Levofloxacin Krka 250 mg, once each day
- Or, one tablet of Levofloxacin Krka 500 mg, once each day

Pneumonia
- Two tablets of Levofloxacin Krka 250 mg, once or twice each day
- Or, one tablet of Levofloxacin Krka 500 mg, once or twice each day

Infection of urinary tract, including your kidneys or bladder
- One or two tablets of Levofloxacin Krka 250 mg, each day
- Or, 1/2 or one tablet of Levofloxacin Krka 500 mg, each day

Prostate gland infection
- Two tablets of Levofloxacin Krka 250 mg, once each day
- Or, one tablet of Levofloxacin Krka 500 mg, once each day

Infection of skin and underneath the skin, including muscles

- Two tablets of Levofloxacin Krka 250 mg, once or twice each day
- Or, one tablet of Levofloxacin Krka 500 mg, once or twice each day

Adults and the elderly with kidney problems
Your doctor may need to give you a lower dose.

Use in children and adolescents
This medicine must not be given to children or teenagers.

If you take more Levofloxacin Krka than you should
If you accidentally take more tablets than you should, tell a doctor or get other medical advice straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. The following effects may happen: convulsive fits (seizures), feeling confused, dizzy, less conscious, having tremor and heart problems - leading to uneven heart beats as well as feeling sick (nausea) or having stomach burning.

If you forget to take Levofloxacin Krka
If you forgot to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Levofloxacin Krka
Do not stop taking Levofloxacin Krka just because you feel better. It is important that you complete the course of tablets that your doctor has prescribed for you. If you stop taking the tablets too soon, the infection may return, your condition may get worse or the bacteria may become resistant to the medicine.

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. These effects are normally mild or moderate and often disappear after a short time.

Stop taking Levofloxacin Krka and see a doctor or go to a hospital straight away if you notice the following side effect:

Very rare: may affect up to 1 in 10 000 people
- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

Stop taking Levofloxacin Krka and see a doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

Rare: may affect up to 1 in 1 000 people
- Watery diarrhoea which may have blood in it, possibly with stomach cramps and a high temperature. These could be signs of a severe bowel problem
- Pain and inflammation in your tendons or ligaments, which could lead to rupture. The Achilles tendon is affected most often
- Fits (convulsions)
- Seeing or hearing things that are not there (hallucinations, paranoia)
- Feeling depressed, mental problems, feeling restless (agitation), abnormal dreams or nightmares
- 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). See also section 2

- Syndrome associated with impaired water excretion and low levels of sodium (SIADH)
- Lowering of your blood sugar levels (hypoglycaemia) or lowering of your blood sugar levels leading to coma (hypoglycaemic coma). This is important for people that have diabetes

Very rare: may affect up to 1 in 10 000 people
- Burning, tingling, pain or numbness. These may be signs of something called 'neuropathy'

Not known: cannot be estimated from the available data
- 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. See also section 2.
- Loss of appetite, skin and eyes becoming yellow in colour, dark-coloured urine, itching, or tender stomach (abdomen). These may be signs of liver problems which may include a fatal failure of the liver.
- Change in your opinion and thoughts (psychotic reactions) with a risk of having suicidal thoughts or actions.
- Nausea, feeling generally unwell, discomfort or pain in the stomach area or vomiting. These could be signs of an inflamed pancreas (acute pancreatitis). See section 2.

If your eyesight becomes impaired or if you have any other eye disturbances whilst taking Levofloxacin Krka, consult an eye specialist immediately.

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), fatigue, memory and concentration impairment, mental health effects (which may include sleep disorders, anxiety, panic attacks, depression and suicidal ideation), 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.

Tell your doctor if any of the following side effects gets serious or lasts longer than a few days:

Common: may affect up to 1 in 10 people
- Sleeping problems
- Headache, feeling dizzy
- Feeling sick (nausea, vomiting) and diarrhoea
- Increase in the level of some liver enzymes in your blood

Uncommon: may affect up to 1 in 100 people
- Changes in the number of other bacteria or fungi, infection by fungi named Candida, which may need to be treated
- Changes in the number of white blood cells shown up in the results of some blood tests (leukopenia, eosinophilia)
- Feeling stressed (anxiety), feeling confused, feeling nervous, feeling sleepy, trembling, a spinning feeling (vertigo)
- Shortness of breath (dyspnoea)
- Changes in the way things taste, loss of appetite, stomach upset or indigestion (dyspepsia), pain in your stomach area, feeling bloated (flatulence) or constipation
- Itching and skin rash, severe itching or hives (urticaria), sweating too much (hyperhidrosis)
- Joint pain or muscle pain

- Blood tests may show unusual results due to liver (bilirubin increased) or kidney (creatinine increased) problems
- General weakness

Rare: may affect up to 1 in 1 000 people
- Bruising and bleeding easily due to a lowering in the number of blood platelets (thrombocytopenia)
- Low number of white blood cells (neutropenia)
- Exaggerated immune response (hypersensitivity)
- Tingly feeling in your hands and feet (paraesthesia)
- Problems with your hearing (tinnitus) or eyesight (blurred vision)
- Unusual fast beating of your heart (tachycardia) or low blood pressure (hypotension)
- Muscle weakness. This is important in people with myasthenia gravis (a rare disease of the nervous system)
- Memory impairment
- Changes in the way your kidney works and occasional kidney failure which may be due to an allergic kidney reaction called interstitial nephritis
- Fever
- Sharply demarcated, erythematous patches with/without blistering that develop within hours of administration of levofloxacin and heals with postinflammatory residual hyperpigmentation; it usually recurs at the same site of the skin or mucous membrane upon subsequent exposure to levofloxacin

Not known: cannot be estimated from the available data
- Lowering in red blood cells (anemia): this can make the skin pale or yellow due to damage of the red blood cells; lowering in the number of all types of blood cells (pancytopenia)
- Bone marrow stops producing new blood cells, this may cause tiredness, lower ability to fight infection and uncontrolled bleeding (bone marrow failure)
- Fever, sore throat and a general feeling of being unwell that does not go away. This may be due to a lowering in the number of white blood cells (agranulocytosis)
- Loss of circulation (anaphylactic like shock)
- Increase of your blood sugar levels (hyperglycaemia) or lowering of your blood sugar levels leading to coma (hypoglycaemic coma). This is important for people that have diabetes
- Changes in the way things smell, loss of smell or taste (parosmia, anosmia, ageusia)
- Feeling very excited, elated, agitated or enthusiastic (mania)
- Problems moving and walking (dyskinesia, extrapyramidal disorders)
- Temporary loss of consciousness or posture (syncope)
- Temporary loss of vision, inflammation of the eye
- Impairment or loss of hearing
- Abnormal fast heart rhythm, life-threatening irregular heart rhythm including cardiac arrest, alteration of the heart rhythm (called ‘prolongation of QT interval’, seen on ECG, electrical activity of the heart)
- Difficulty breathing or wheezing (bronchospasm)
- Allergic lung reactions
- Pancreatitis
- Inflammation of the liver (hepatitis)
- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity), darker areas of skin (hyperpigmentation)
- Inflammation of the vessels that carry blood around your body due to an allergic reaction (vasculitis)
- Inflammation of the tissue inside the mouth (stomatitis)
- Muscle rupture and muscle destruction (rhabdomyolysis)
- Joint redness and swelling (arthritis)
- Pain, including pain in the back, chest and extremities
- Sudden involuntary jerks, twitches of the muscles or muscle contractions (myoclonus)
- Attacks of porphyria in people who already have porphyria (a very rare metabolic disease)

- Persistent headache with or without blurred vision (benign intracranial hypertension)

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 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 Levofloxacin Krka

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 carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Levofloxacin Krka contains
- The active substance is levofloxacin. Each film-coated tablet contains 250 mg or 500 mg levofloxacin as levofloxacin hemihydrate.
- The other ingredients (excipients) are microcrystalline cellulose, hydroxypropylcellulose, crospovidone (type A) and magnesium stearate in the tablet core and hypromellose, indigo carmine (E132), sunset yellow FCF (E110), macrogol 4000, titanium dioxide (E171), iron red oxide (E172) and iron yellow oxide (E172) *(only for 500 mg)* in the film coating.

What Levofloxacin Krka looks like and contents of the pack
The 250 mg film-coated tablets are pink, oblong, biconvex tablets with a score line and dimension 13.7 mm x 6.7 mm and thickness 3.8 mm. The tablet can be divided into equal doses.

The 500 mg film-coated tablets are orange, oblong, biconvex, tablets with a score line and dimensions 19.3 mm x 7.8 mm and thickness 5.0 mm. The tablet can be divided into equal doses.

The 250 mg and 500 mg film-coated tablets are available in boxes of 1, 5, 7, 10 and 14 tablets in blister packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

This medicine is authorised in the Member States of the European Economic Area under the following names:

Name of the member state	**Name of the medicine**
Austria, Finland, Ireland, Sweden	Levofloxacin Krka
Bulgaria, Croatia, Lithuania, Latvia, Poland, Romania, Slovak Republic	Levalox
Slovenia	Leviaben

Hungary, Estonia	Levnibiot
France	Levofloxacine Krka
Italy	Levofloxacina Krka
Spain	Levofloxacino Krka

This leaflet was last revised in