

PACKAGE LEAFLET: INFORMATION FOR THE USER

Levofloxacin 250 mg Film-coated Tablets

Levofloxacin 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.

In this leaflet:

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

1. What Levofloxacin Tablets are and what they are used for

Levofloxacin tablet contains a drug called levofloxacin. Levofloxacin is an antibiotic which is used to treat bacterial 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 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 Tablets

Do not take Levofloxacin Tablets and tell your doctor if:

- You are allergic to levofloxacin, any other quinolone antibiotic such as moxifloxacin, ciprofloxacin or ofloxacin or to 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.
- If your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately.
- 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, trying to become pregnant or 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 Tablets.

Warnings and precautions

Before taking this medicine

You should not take fluoroquinolone/quinolone antibacterial medicines, including [product name], 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 or pharmacist before taking Levofloxacin Tablets if:

- You are 60 years of age or older.
- You are using corticosteroids, sometimes called steroids (see section “Other medicines and Levofloxacin Tablets”).
- 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 Tablets*).
- 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]).
- 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.

While taking Levofloxacin Tablets:

- 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.

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.

Other warnings

When taking this medicine

- 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 Tablets 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 Tablets, 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 Tablets and inform your doctor immediately in order to prevent the development of potentially irreversible condition.
- If you start having severe, persistent and/or bloody diarrhoea during or after treatment with levofloxacin, tell your doctor immediately. This could mean you have serious inflammation of your bowel (pseudomembranous colitis), which can sometimes occur after antibiotic treatment. You may need to stop taking levofloxacin and for your doctor to give you another medicine.
- Whilst taking Levofloxacin Tablets you are advised to stay out of strong sunlight and not to use a sun lamp. This is because some patients may become more sensitive to light whilst taking the tablets and get a sun-burn like reaction.
- Levofloxacin is not a optimal therapy for most severe cases of Pneumococcal pneumonia.
- Infections got from a hospital during treatment due to *P.aeruginosa* may require combination therapy.
- Levofloxacin is not effective against infections caused by MRSA. In infections suspicious for MRSA levofloxacin should be combined with an agent approved to treat MRSA infections.

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

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone/quinolone antibacterial medicines, including [product name], 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 tablets, 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.

Other medicines and Levofloxacin Tablets

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

- 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 Tablets
- 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 Tablets
- 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 Tablets. If you have kidney problems, your doctor may want to give you a lower dose.

Do not take Levofloxacin Tablets at the same time as the following medicines. This is because it can affect the way Levofloxacin 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 tablets. If your doctor is due to take a urine test, tell them you are taking Levofloxacin tablets.

Tuberculosis tests

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

Taking Levofloxacin Tablets with food and drink

Take without regard to meals. Take with water, drink with plenty of water. Taking this product with orange juice can result in reduced quinolone plasma levels.

Pregnancy and breast-feeding

You must not take Levofloxacin Tablets if you are pregnant, trying to become pregnant or are breast-feeding.

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.

3. How to take Levofloxacin Tablets

Always take **Levofloxacin Tablets** exactly as your doctor has told you. You should 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

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 Tablets. Take your dose of these medicines at least 2 hours before or after Levofloxacin Tablets.

How much to take

- Your doctor will decide on how many Levofloxacin 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 Tablets 250 mg, once each day
- Or, one tablet of Levofloxacin Tablets 500 mg, once each day

Lungs infection, in people with long-term breathing problems

- Two tablets of Levofloxacin Tablets 250 mg, once each day
- Or, one tablet of Levofloxacin Tablets 500 mg, once each day

Pneumonia

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

Infection of urinary tract, including your kidneys or bladder

- One or two tablets of Levofloxacin Tablets 250 mg, each day
- Or, 1/2 or one tablet of Levofloxacin Tablets 500 mg, each day

Prostate gland infection

- Two tablets of Levofloxacin Tablets 250 mg, once each day

- Or, one tablet of Levofloxacin Tablets 500 mg, once each day

Infection of skin and underneath the skin, including muscles

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

Adults and the elderly with kidney problems

Your doctor may need to give you a lower dose.

Children and adolescents

This medicine must not be given to children or teenagers.

If you take more Levofloxacin Tablets 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 a dose of Levofloxacin Tablets

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not double-up the next dose to make up for the missed dose.

If you stop taking Levofloxacin Tablets

Do not stop taking Levofloxacin Tablets 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 product, 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 Tablets 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 Tablets 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)
- 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)

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

- Burning, tingling, pain or numbness. These may be signs of something called ‘neuropathy’

Other:

- 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

Not known (frequency 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.

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

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)
- Lowering of your blood sugar levels (hypoglycaemia). This is important for people that have diabetes.
- Seeing or hearing things that are not there (hallucinations, paranoia), change in your opinion

and thoughts (psychotic reactions) with a risk of having suicidal thoughts or actions

- Feeling depressed, mental problems, feeling restless (agitation), abnormal dreams or nightmares
- 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).
- 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

Other side effects include:

- 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)
- 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)
- Problems moving and walking (dyskinesia, extrapyramidal disorders)
- Temporary loss of consciousness or posture (syncope)
- Temporary loss of vision
- 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)
- 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
- Attacks of porphyria in people who already have porphyria (a very rare metabolic disease)
- Persistent headache with or without blurred vision (benign intracranial hypertension)

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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Levofloxacin Tablets

- This medicinal product does not require any special storage conditions
- 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 strip after EXP. The expiry date refers to the last day of that month.
- 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 Tablets contains

Each tablet contains either 250 mg or 500 mg of Levofloxacin as active substance corresponding to 256.23 mg or 512.46 mg of levofloxacin hemihydrate.

The other ingredients are

Core tablet: povidone, crospovidone (Type-B), cellulose microcrystalline, magnesium stearate, silica colloidal anhydrous, tablet coating: hypromellose E5, talc, titanium dioxide (E171), macrogol 400, red iron oxide (E172) and yellow iron oxide (E172).

What Levofloxacin Tablets looks like and contents of the pack

For 250 mg tablets: Pink coloured, capsule shaped, biconvex, film coated tablet with break line on both sides. Debossed 'L' and 'F' either side of the break line on one face.

The tablets can be divided into equal halves.

For 500 mg tablets: Pink coloured, capsule shaped, biconvex, film coated tablet with break line on both sides. Debossed 'L' and 'V' either side of the break line on one face.

The tablets can be divided into equal halves.

Tablets are packed in PVC/aluminium blisters.

For 250 mg, the tablets are provided in pack sizes of 1, 2, 3, 5, 7, 10, 30, 50 and 200 tablets.

For 500 mg, the tablets are provided in pack sizes of 1, 2, 5, 7, 10, 30, 50, 200 and 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

Accord Healthcare Limited
Sage House, 319, Pinner Road,
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Manufacturer

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