
Package leaflet: Information for user

Levofloxacin AIWA 500 mg film-coated tablets active substance: 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 AIWA 500 mg is and what it is used for
2. What you need to know before you take Levofloxacin AIWA 500 mg
3. How to take Levofloxacin AIWA 500 mg
4. Possible side effects
5. How to store Levofloxacin AIWA 500 mg
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1. What Levofloxacin AIWA 500 mg is and what it is used for

The name of your medicine is Levofloxacin AIWA 500 mg film-coated tablets. Levofloxacin AIWA 500 mg film-coated tablets contain an active substance 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 AIWA 500 mg film-coated tablets can be used to treat infections of the:

- sinuses
In severe sinusitis, Levofloxacin AIWA should only be used if other antibiotics commonly recommended to treat these infections are considered unsuitable.
- bronchia/lungs, in people with long-term respiratory diseases or pneumonia
- In acute exacerbation of a chronic obstructive respiratory disease, including chronic bronchitis, Levofloxacin AIWA should only be used if other antibiotics commonly recommended to treat these infections are considered unsuitable.
- urinary tract, including the kidneys or bladder
In uncomplicated inflammations of the bladder, Levofloxacin AIWA should only be used if other antibiotics commonly recommended to treat these infections are considered unsuitable. prostate gland, for a long-lasting infection,
- skin and subcutaneous tissue, including muscles. This is sometimes called 'soft tissue'.

In some special situations, Levofloxacin AIWA 500 mg film-coated 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 AIWA 500 mg

Do not take Levofloxacin AIWA 500 mg 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: rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- you have ever had or suffer from 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 AIWA 500 mg.

Warnings and precautions

Before taking this medicine

You should not take fluoroquinolone/quinolone antibiotics, including Levofloxacin AIWA, 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 AIWA 500 mg if:

- you are 60 years of age or older,
- you are using corticosteroids; sometimes they are called steroids (see section "Other medicines and Levofloxacin AIWA 500 mg"),
- 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 or have heart problems. Caution should be taken when using this 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 "Taking other medicines").
- if you have been diagnosed with leaky heart valves (heart valve insufficiency).
- if there have been cases of aortic aneurysm or aortic dissection or congenital heart valve defects in your family or if there are other risk factors or predisposing (promoting) conditions (e.g. connective tissue diseases such as Marfan syndrome, vascular Ehlers-Danlos syndrome, Turner syndrome, Sjörger syndrome [an inflammatory autoimmune disease], or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behçet's disease, high blood pressure or known atherosclerosis, rheumatoid arthritis [disease of the joints] or endocarditis [inflammation of the endocardium]).

- you are diabetic,
- you have ever had or have liver problems,
- you have myasthenia gravis (muscle weakness).
- **you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Levofloxacin.**

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Levofloxacin AIWA 500 mg.

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 Levofloxacin AIWA 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 AIWA, contact your doctor and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture. Due to possible undesirable effects on joints and/or tissue close to joints, levofloxacin should only be used after a careful risk-benefit analysis.

If you suddenly notice intense pain in the stomach, in the chest region or in the back which could be the symptoms of an aortal aneurysm (bulge of the aortic wall) and of an aortic dissection (splitting of the layers of the aortic wall), go to an emergency department immediately. Your risk may be increased in case of concomitant treatment with systemic corticosteroids.

If you suddenly suffer from shortness of breath, particularly if you are lying flat in your bed, or if you notice swollen ankles, feet or stomach or if you experience a sudden palpitation (a feeling of rapid or irregular heartbeat), you should contact a doctor immediately.

You may rarely experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness especially in the feet and legs or hands and arms. If this happens, stop taking Levofloxacin AIWA and inform your doctor immediately in order to prevent the development of a potentially irreversible condition.

Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone/quinolone antibiotics, including Levofloxacin AIWA, have been associated with very rare but serious side effects, some of them being long lasting (continuing for 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, smell, and hearing, depression, memory impairment, severe fatigue, and severe sleep disorders.

If you experience any of these side effects when taking Levofloxacin AIWA, 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.

- **Stevens-Johnson syndrome/toxic epidermal necrolysis 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.

Taking Levofloxacin AIWA 500 mg film-coated tablets with other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Levofloxacin AIWA 500 mg can affect the way some other medicines work. Also some medicines can affect the way Levofloxacin AIWA 500 mg 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 AIWA 500 mg:

- 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 airway diseases. You are more likely to have a fit (seizure) if taken with Levofloxacin AIWA 500 mg.
- Non-steroidal anti-inflammatory drugs (NSAIDs) - used for pain and inflammation such as acetylsalicylic acid, ibuprofen, fenbufen, ketoprofen and indomethacin, which are used in pain and inflammation. You are more likely to have a fit (seizure) if taken with Levofloxacin AIWA 500 mg.
- Ciclosporin – used after organ transplants. You may be more likely to get 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, amiodarone, sotalol, dofetilide, ibutilide), for depression (tricyclic antidepressants such as amitriptyline and imipramine), for bacterial infections (‘macrolide’ antibiotics such as erythromycin, azithromycin and clarithromycin), for psychiatric disorders (antipsychotics).
- Probenecid – used for gout. If you have kidney problems, your doctor may want to give you a lower dose.
- Cimetidine– used for ulcers and heartburn. If you have kidney problems, your doctor may want to give you a lower dose.

Tell your doctor if any of the above applies to you.

Do not take Levofloxacin AIWA 500 mg film-coated tablets at the same time as the following medicines. This is because it can affect the way Levofloxacin AIWA 500 mg film-coated tablets work:

- Iron tablets (for anemia), zinc supplements, magnesium or aluminum-containing antacids (for 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 AIWA 500 mg. If your doctor has prescribed a urine test, tell your doctor you are taking Levofloxacin AIWA 500 mg.

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 Levofloxacin AIWA 500 mg if:

- you are pregnant, might become pregnant or think you may be pregnant,
- you are breast-feeding or planning to breast-feed.

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 AIWA 500 mg contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Levofloxacin AIWA 500 mg film-coated tablets

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

Taking Levofloxacin AIWA 500 mg film-coated tablets

- Take these film-coated tablets by mouth.
- Swallow the film-coated 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 artificial UV radiation (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 AIWA 500 mg. Take your dose of these medicines at least 2 hours before or after Levofloxacin AIWA 500 mg film-coated tablets.

How much to take

- Your doctor will decide on how many Levofloxacin AIWA 500 mg film-coated 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

- One tablet of Levofloxacin AIWA 500 mg, once each day

Lungs infection, in people with long-term respiratory diseases

- One tablet of Levofloxacin AIWA 500 mg, once each day

Pneumonia

- One tablet of Levofloxacin AIWA 500 mg, once or twice each day

Infection of urinary tract, including your kidneys or bladder

- ½ or one tablet of Levofloxacin AIWA 500 mg, each day

Prostate gland infection

- One tablet of Levofloxacin AIWA 500 mg, once each day

Infection of skin and subcutaneous tissue, including muscles

- One tablet of Levofloxacin AIWA 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 AIWA 500 mg film-coated 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, 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 trouble.

If you forget to take Levofloxacin AIWA 500 mg film-coated tablets

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 double-up the next dose to make up for the missed dose.

If you stop taking Levofloxacin AIWA 500 mg film-coated tablets

Do not stop taking Levofloxacin AIWA 500 mg 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 AIWA 500 mg 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)

- Allergic reactions. The signs may include: rash, swallowing or breathing problems, swelling of your lips, face, throat, or tongue.

Stop taking Levofloxacin AIWA 500 mg 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 or involvement of other body organs (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 (SIDAH).**

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

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

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

- **Severe skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis. These can appear as reddish target-like spots 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.

If your eyesight becomes impaired or if you have any other eye disturbances whilst taking Levofloxacin AIWA 500 mg, 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 diarrhea,
- 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,
- tingling 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 heal with post-inflammatory residual hyperpigmentation; on repeated use of levofloxacin this usually recurs at the same site on the skin or mucous membrane.**

Not known (Frequency 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),
- 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 blood sugar levels (hyperglycaemia) or lowering of 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, eye inflammation
- 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,
- inflammation of the pancreas (pancreatitis),
- inflammation of the liver (hepatitis),
- increased sensitivity of the 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).
- a syndrome associated with impaired water excretion and low sodium levels (SIADH).

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, taste and smell have been associated with administration of quinolone and fluoroquinolone antibiotics, in some cases irrespective of pre-existing risk factors.

Cases of enlargement and weakening of the aortic wall or ruptures in the aortic wall (aneurysms and aortic dissections) which may tear up and can be lethal as well as cases of leaky heart valves have been reported with patients taking fluoroquinolones. See also section 2.

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 the Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Alle 3, 53175 Bonn, Germany, website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of his medicine.

5. How to store Levofloxacin AIWA 500 mg

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 foil after “EXP”. The expiry date refers to the last day of the month.

This medicine does not require any special storage conditions but it is best to keep Levofloxacin AIWA 500 mg film-coated tablets in the original box (strips in packet) in a dry place.

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 AIWA 500 mg contains

The active ingredient is levofloxacin. Each tablet of Levofloxacin AIWA 500 mg film-coated tablets contains 500 mg of levofloxacin.

The other ingredients are:

- For the tablet core: microcrystalline cellulose, cellulose powdered, pregelatinised starch (maize), maize starch, crospovidone, povidone K 25, sodium stearyl fumarate hypromellose
- For the tablet coating: lactose monohydrate, hypromellose, titanium dioxide, macrogol 4000, ferric oxide (E172) and ferric hydroxide (E172)

What Levofloxacin AIWA 500 mg film-coated tablets look like and contents of the pack

Levo AIWA 500 mg film-coated tablets are for oral use. The tablets are pink, oblong, arched on both sides with one break mark on each face. The tablet can be divided into equal doses.

Levofloxacin AIWA 500 mg film-coated tablets are provided in pack sizes of 5, 7, 10 and 200 film-coated tablets.

Not all pack sizes may be marketed.

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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