



LEVO-X 500 mg film-coated tablet

Levofloxacin

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed only for you.
- Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

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1. What is LEVO-X and what it is used for

LEVO-X is broad - spectrum quinolone antibiotic. It has antibacterial effect by stopping bacterial growth of different bacteria species causing infections in your body. Your doctor has prescribed you levofloxacin for treatment of some of the following bacterial infections:

- Acute sinusitis;
- Acute chronic bronchitis;
- Community acquired pneumonia;
- Urinary infections with complications, including kidney infections (pyelonephritis)
- Chronic bacterial prostatitis;
- Skin and soft-tissue infections;

2. Before you take LEVO-X

Do not take LEVO-X and tell your doctor

if you:

- are allergic (hypersensitive) to Levofloxacin or any of the ingredients of this medicine (listed in section 6), or if you allergic to any other quinolone antibiotic (ofloxacin, ciprofloxacin);
- suffer epilepsy;
- have had tendon problems and were treated with quinolone antibiotic;
- are pregnant or breast –feeding, this medicine could harm your baby; this medicine is prescribed only to adults, it should not be given to children and youths in the growing period (under 18 years), since there is a risk of joint harming;

Always strictly follow the instructions given to you by your doctor. Take special care with LEVO-X

Check with your doctor if any of the following applies to you:

If you:

- have had brain damage (stroke or hard brain trauma), the risk of seizures could be increased.
- the risk of seizures could also be increased if you take this medicine with other medicines like fenbupren or similar drugs for treatment of joint inflammations or teophylline used for treatment of respiratory diseases. (See also treatment with other medicines). Make sure that your doctor is well aware of your anamnesis, so could give you an appropriate advice.
- tell your doctor or nurse if you are diabetic or are taking insulin or other hypoglycemia medications, since during treatment with this medicine it's possible to suffer significant lowering of blood sugar levels. Symptoms could be increased appetite, nervousity, sweating or tremor. Your doctor will test your blood sugar levels.
- have had kidney problems, it's possible your doctor to change your dose.
- suffer glucose-6-phosphate dehydrogenase deficiency tell your doctor because during treatment with this medicine there's a risk of erythrocytes demolition (hemolysis) and anemia.
- get serious allergic reaction (skin rash, breathing difficulty, tongue swelling), even at the time of administration or after administration of the first dose, immediately tell your doctor or contact the nearest hospital and stop taking the medicine.
- during treatment with LEVO-X appear symptoms of tendon inflammations (pain, edema, flushing in joint areas), immediately tell your doctor and leave the affected limb to rest so you'd avoid tendon damage. The risk is higher if you are elderly patient or are taking corticosteroids. It may be necessary to stop the administration of the medicine.
- immediately tell your doctor if during or after the treatment you get hard, obstinate and/or bloody diarrhea. That may be a sign of a serious disease (pseudomembranous colitis), it may be necessary to stop the treatment with LEVO-X and start treatment of the intestinal disease.
- have had mental health problems, since during the treatment the risk of self - harming behavior is increased. If that happens the treatment will be discontinued.
- are taking blood thinning medicines like warfarin, since combined intake of both medicines may increase the risk of bleeding (See also other medicines). Bleeding examinations should be strictly followed.
- have liver problems. It is possible in rare cases during treatment with this medicine the liver problem to progress to liver insufficiency, commonly in patients with basic diseases. If you get symptoms of appetite loss, your skin or the white of your eyes become yellow, your urine darken, itching, painful stomach, immediately tell your doctor.
- have had heart problems and risk of heart failure (prolonged QT inter-

val). The risk is increased if you are elderly patient or you have electrolyte imbalance or have definite heart disease (heart insufficiency, myocardial infarction, etc.). The risk is also increased at concomitant use of LEVO-X with medicines known to prolong QT interval – ex. medicines used in cardiac rhythm disorders (class IA and III antiarrhythmic drugs), medicines for treatment of mental disorders (tricyclic antidepressants), for inflammations (macrolides). Tell your doctor if you have cardiac rhythm changes or you feel faint.

- have nervous damage symptoms: weakness, arms, foot or face formication, immediately tell your doctor or nurse, since it may be necessary to discontinue the treatment.
- avoid direct sunlight exposure during treatment with this medicine do not use quartz lamps or solarium because in very rare cases is possible to develop hypersensitivity to light with symptoms similar to sunburn.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking LEVO-X film - coated tablets.

Taking other medicines

*Some medicines can affect the way other medicines work. **Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or herbal medicines.***

This is necessary because LEVO-X could prolong the action of some medicines and other medicines could affect the action of levofloxacin. Following drugs should be considered when they are used in combination with LEVO-X:

Corticosteroids, sometimes called steroids – used for inflammation. You may be more likely to have inflammation and/or breakage of your tendons;

Theophylline - used for breathing problems;

Vitamin K antagonists (e.g. warfarin which is a medication to prevent blood clots). Levofloxacin leads to increased bleeding in patients taking vitamin K antagonists. Coagulation tests should be monitored in patients treated with vitamin K antagonists;

Non-steroidal anti-inflammatory drugs (NSAIDs) - used for pain and inflammation such as aspirin, ibuprofen, fenbupren, ketoprofen and indomethacin. You are more likely to have a fit (seizure) if taken with LEVO-X; *Cyclosporin* - used after organ transplants. You may be more likely to get the side effects of Cyclosporin.

Probenecid - used for gout, and cimetidine -used for ulcers and heartburn. Special care should be taken when taking either of these medicines with LEVO-X. If you have kidney problems, your doctor may want to give you a lower dose.

Medicines known to alter your heart rhythm. This includes medicines used for abnormal heart rhythm (antiarrhythmics such as quinidine and amiodarone), for depression (tricyclic antidepressants such as amitriptyline and imipramine) and for bacterial infections ('macrolide' antibiotics such as erythromycin, azithromycin and Clarithromycin). *Antidepressants* (tricyclic antidepressants – amitriptyline and imipramine).

Antibacterial infections – macrolide antibiotics (erythromycin, azithromycin, clarithromycin). See section: take special care using LEVO-X.

Do not take LEVO-X at the same time as the following medicines:

- medicines containing iron (against anemia).
- *antacid medicines* (medicines against stomach pain and acids), containing magnesium or aluminium or sucralfate (gastro protection medicine).

Take LEVO-X at least 2 hours before and two hours after administration of the above medicines to avoid the possibility of decreasing levofloxacin action.

Urine tests for opiates

Urine tests may show "false-positive" results for strong painkillers called "opiates" in people taking LEVO-X. If your doctor is due to take a urine test, tell him you are taking LEVO-X.

Administration of LEVO-X with food and drinks

LEVO-X could be administered during or between meals. Do not use alcohol during LEVO-X treatment.

Pregnancy and breast - feeding

Ask your doctor or pharmacist before taking any medicine.

Do not take LEVO-X if you are pregnant or trying to become pregnant, or think you might be pregnant. Do not take LEVO-X while you are breast –feeding.

Driving and using machines

LEVO-X has minor or moderate influence on the ability to drive and use machines. Some side-effects like dizziness, drowsiness, visual disturbance may impair your ability to concentrate and react. Do not drive or operate machinery if you feel that your ability to concentrate and react is impaired.

3. How to take LEVO-X

Always take LEVO-X exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Film – coated tablets LEVO-X should be swallowed whole with sufficiency of liquid. Prescribed dose should be taken in regular intervals of 12 or 24 hours. Tablets could be taken during or between meals.

Dosage

If you are not sure why you are treated with LEVO-X or you have any questions about the dosage you are taking, please ask your doctor or pharmacist.

- The doctor will determine your exact dose of LEVO-X;

- The dose is defined by the place and type of the infection;
- Treatment duration depends on the infection complexity

Dosage in patient with normal renal function:

Therapeutic area	Dosage and treatment duration
Acute sinus infection	500 mg once daily
Acute chronic bronchitis	250 – 500 mg once daily
Community acquired pneumonia	500 mg once or twice daily
Complicated urinary tract infections	250 mg* once daily
Chronic, bacterial prostate infection	500 mg once daily for 28 days
Skin and soft tissue infections	250 mg* or 500 mg once or twice daily

* administered dose might be increased in case of complicated infections.

Patients with impaired kidney functions

LEVO-X is excreted mainly by the kidneys, administered dose should be adjusted in patients with impaired renal functions.

Follow your doctor instructions.

Elderly patients:

Follow your doctor instructions.

Children and youths

Levofloxacin is contraindicated in children and growing adolescents (less than 18 years of age).

If you take more than you should

You should not take more tablets than your doctor tells you to. If you take too many tablets contact your doctor, pharmacist or hospital as soon as possible, and take your medicine with you.

Symptoms of an overdose can be dizziness, confusion, impairment of consciousness, convulsive seizures, heart problems and nausea.

If you forget to take LEVO-X

If you have forgotten to take one dose of LEVO-X take it as soon as you remember it unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose of LEVO-X.

If you stop taking LEVO-X

It is important to finish your course of tablets as prescribed by your doctor. Do not stop, even if you begin to feel better before you have finished them all. If you stop taking the tablets too soon your infection may return, your condition may get worse or the bacteria may become resistant to the medicine. If you feel you have to stop because of a side-effect, tell a doctor immediately to get advice before taking the next dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, LEVO-X can cause side effects, although not everybody gets them.

If you are worried about side effects, ask your doctor. It is important that you know what can happen, so that you can take action if LEVO-X does have a side effect. LEVO-X sometimes causes side effects but these usually go away during treatment as your body gets used to the medicine.

Frequency of side effects:

Very common (more than 1/10 patients); Common (1 to 10/100 patients); Uncommon (1 to 10/1 000 patients); Rare (1 to 10/10 000 patients); Very rare (less than 1/10 000); Unknown frequency (there is not enough data available).

If any of the following happen, stop taking LEVO-X and tell your doctor immediately, or go to the nearest hospital and bring the medicine with you:

Very rare side effects:

- Face or lips oedema, throat swelling, breathing and swallowing difficulties.
- Serious, itching skin rash, it could affect the mouth mucosa, nose, eyes or genitals.
- Strong dizziness or consciousness loss.
- Burning, tingling, pain or numbness. These may be signs of something called "neuropathy".

Rare side effects:

- Obstinate water diarrhea with blood, it could be caused by intestine infection (see also "take special care using LEVO-X").
- Pain, oedema and/or tendon redness.
- Seizures, cramps.

Other side effects:

- Loss of appetite, yellowing of the skin or whites of the eyes (jaundice), urine darkening, itching, painful stomach (symptoms of liver problems).

Tell your doctor if some of the following side effects appear and continue more than several days or gets serious:

Common side effects:

- Nausea, vomiting, diarrhea.
- High blood levels of some liver enzymes.

Uncommon side effects:

- Itching, skin rash (urticaria).
- Headache, dizziness, vertigo, nervousness, sleepiness and difficulty in sleeping.
- Weakness or loss of strength.
- Loss of appetite, vomiting, stomach pain, flatulence, constipation and indigestion.
- Alteration in blood tests relating to increase or reduction of white blood cells.
- Alteration in blood tests relating to abnormalities in liver function (increase in bilirubin which is a waste product). Alteration in blood tests relating to abnormalities in kidney function.
- Fungus growing (fungus infection) and/or other resistant bacteria.

Rare side effects:

- Muscle and joint pain, chest pain, limbs pain.
- Hand and feet tremor (parasthesia).

- Breathing difficulties, wheezing, constriction.
- Depression, mental health disorders, Generalised fear (anxiety), feeling extreme sadness (depression), seeing or hearing things that are not there.
- Problems with your hearing or eyesight or changes in the way things taste and smell..
- Alteration of the heart rhythm, abnormal blood pressure lowering.
- Decrease in blood cells (thrombocytes) – aptitude to bruises and bleeding.
- Decrease in white blood cells (neutropenia).

Very rare side effects:

- Hypersensitivity to sunlight or ultra violet radiation (see also „Take special care with “LEVO-X” use)
- Big decrease of white blood cells number (agranulocytosis), which leads to constant fever recurrence: temperature, painful swallowing, feeling faint, sore throat.
- Decrease in blood sugar to a too low level (hypoglycaemia) which may be of special importance in patients treated for diabetes (see also „Take special care with “LEVO-X” use).
- Disturbance or loss of taste and/or sense of smell.
- Hearing damages.
- Vision damages.
- Pulmonary allergic reactions – inflammation, temperature, asthma, cough.
- Acute kidney failure due to allergic kidney reaction (interstitial nephritis).
- Liver inflammation (hepatitis).
- Tendon breakage (see also: Take special care with LEVO-X use).
- Nerve damages (reduced touch sense, paralytic syndrome).
- Abnormal high temperature.
- Change in opinion and thoughts (psychotic reactions) with a chance of having suicidal thoughts or actions. (see also: Take special care with LEVO-X use).
- Circulatory collapse (anaphylactic like shock) (see also: Take special care with LEVO-X use).

Not known (frequency cannot be estimated from the available data):

- Sweating too much (hyperhidrosis).
- Heart problems: Abnormal fast heart rhythm, life-threatening irregular heart rhythm, alteration of the heart rhythm (called "prolongation of QT interval", seen on ECG, electrical activity of the heart)
- Ringing or buzzing in the ears (tinnitus).
- Decrease in red blood cells (anaemia) due to blood cell damage..
- Decrease in the number of all types of blood cells (pancytopenia).
- Muscle reactions with muscle cell damage (rhabdomyolysis).
- Muscle weakness. Important to patients with myasthenia gravis (rare nerve system disease).
- Severe bullous (blister-type) eruptions such as Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyll's syndrome which is a blistering and peeling of the skin) and erythema multiforme (blisters or lesions). Muco-cutaneous (e.g. hives or flushing) may sometimes occur even after the first dose.
- Yellowing of the skin or whites of the eyes (jaundice). (see also: Take special care with LEVO-X use).

Other undesirable effects which have been associated with fluoroquinolone administration include:

- Hypersensitivity vasculitis (inflammation of small blood vessels).
- Extrapyramidal (neurological) symptoms and other disorders of muscular coordination.
- Attacks of porphyria (disease affecting the metabolism) in patients with porphyria.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store LEVO-X

Keep out of the reach and sight of children.

Do not store above 30°C. Keep blister in the outer carton in order to protect from moisture.

Do not use LEVO-X after the expiry date stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

6. Further information

Each tablet contains:

Active substance – Each 500 mg film-coated tablet contains 500 mg of levofloxacin equivalent to 512.46 mg of levofloxacin hemihydrate.

Excipients: microcrystalline cellulose, hypromellose, crospovidone, siliconified microcrystalline cellulose, sodium stearyl fumarate, silica colloidal anhydrous.

What LEVO-X looks like and content of the pack:

LEVO-X are film – coated tablets for oral use.

Round biconvex film – coated tablet with yellow color.

7 film-coated tablets are packed in a PVDC/Al foil blister.

1 or two blisters are packed together in a carton box with patient information leaflet.

Marketing authorization holder and manufacturer:

ADIPHARM EAD

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