

## Package leaflet: Information for the user

### Levoact 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 Levoact tablets is and what it is used for
2. What you need to know before you take Levoact tablets
3. How to take Levoact tablets
4. Possible side effects
5. How to store Levoact tablets
6. Contents of the pack and other information

#### **1. What Levoact tablets is and what it is used for**

The name of this medicine is Levoact film-coated tablets. Levoact tablets contain an active ingredient called levofloxacin, which belongs to the group of medicines called antibiotics. Levofloxacin is a quinolone antibiotic and it works by killing bacteria that cause infections in your body.

**Antibiotics are used to treat bacterial infections. They are not effective in the treatment of viral infections, such as flu or colds.**

**Please follow your doctor's instructions carefully with regard to dose, administration interval and duration of treatment.**

**Do not keep or reuse this medicine. If you have any antibiotics remaining at the end of your course of treatment, please return them to your pharmacist for proper disposal. Do not dispose of any medicines via wastewater or household waste.**

#### **Levoact tablets can be used to treat infections in:**

- the paranasal sinuses
- the lungs, in people with long-term breathing problems or pneumonia
- the urinary tract, including the kidneys or bladder
- the prostate, when the infection is persistent
- the skin and under the skin, including the muscles. This is sometimes referred to as "soft tissues".

In some special situations, Levoact tablets can be used to reduce the possibility of acquiring a lung infection called anthrax or a worsening of the disease after you have been exposed to the bacterium that causes anthrax.

## **2. What you need to know before you start taking Levoact tablets**

### **Do not take this medicine and consult your doctor**

- if you are allergic to levofloxacin, other quinolone antibiotics such as moxifloxacin, ciprofloxacin or ofloxacin or to any of the other ingredients of this medicine (see section 6).
- if the signs of an allergic reaction include: skin rash, difficulty breathing or swallowing, swollen lips, face, throat or tongue
- if you suffer or have suffered from epilepsy
- if you have ever suffered tendon problems, such as tendinitis, which were related to treatment with quinolone antibiotics. The tendon is the tissue that attaches your muscle to your skeleton
- if you are a growing child or adolescent
- if you are pregnant, might fall pregnant or think you might be pregnant
- if you are breastfeeding.

Do not take this medicine if you are affected by any of the cases described above. Before taking Levoact, check with your doctor or pharmacist if you are not sure.

### **Warnings and precautions**

#### **Talk to your doctor or pharmacist before using this medicine if:**

- You are 60 years old or older
- You are using corticosteroids, sometimes called steroids (see section “Other medicines and Levoact”)
- You have received a transplant
- You have ever had an epileptic fit (seizures)
- You have suffered brain damage due to a stroke or other brain injury
- You have kidney problems
- You have what is known as “glucose-6-phosphate dehydrogenase deficiency”, as you may be prone to having serious blood problems when taking this medicine
- You have ever had mental health problems
- You have ever had heart problems: caution should be exercised when using this type of medicine, if you were born with, or have a family history of prolongation of the QT interval (seen in an electrocardiogram (ECG), graphical representation of the electrical activity of the heart), you have an imbalance in your blood salt levels (especially a low level of potassium or magnesium in your blood), you have a slow heart rate (also known as “bradycardia”), you have a weak heart (heart failure), you have a history of heart attack (myocardial infarction), if you are a woman or an elderly person or are taking other medications that may cause abnormal changes in the ECG (see section “Other medicines and Levoact”)
- You are diabetic
- You have ever had liver problems
- You suffer from myasthenia gravis
- You suffer peripheral nerve disorders (peripheral neuropathy)
- If you have been diagnosed with an enlargement or “bulge” in a large blood vessel (aortic aneurysm or aneurysm of a large peripheral vessel)
- If you have had a previous episode of aortic dissection (tear in the wall of the aorta)
- If you have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing disorders (e.g. connective tissue disorders like Marfan syndrome or Ehlers-Danlos syndrome, or vascular disorders like Takayasu’s arteritis, giant cell arteritis, Behçet’s disease, arterial hypertension or known atherosclerosis).
- You have ever developed a severe skin rash or flaking skin, blisters and/or sores in the mouth after taking levofloxacin.

## Severe cutaneous reactions

Severe cutaneous reactions including Stevens–Johnson syndrome, toxic epidermal necrolysis (NET) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported with the use of levofloxacin.

- SJS/NET can initially appear on the trunk as red target-like spots or circular patches often with blisters in the middle. Ulcers can also appear in the mouth, throat, nose, genitals and eyes (red, puffy eyes). These severe skin rashes are often preceded by fever and/or flu-like symptoms. The rash can progress to generalised flaking of the skin and life-threatening or fatal complications.
- DRESS initially presents with flu-like symptoms and a rash on the face, followed by a more extensive rash with a high temperature, elevated levels of liver enzymes in blood tests and an increase in a certain type of white blood cells (eosinophilia) and enlarged lymph nodes.

If you develop a severe rash or any of these skin symptoms, stop taking levofloxacin and contact your doctor or seek medical attention immediately.

You should not take antibacterial medicines containing fluoroquinolones or quinolones, including Levoact, if you have previously experienced any serious adverse reaction when taking a quinolone or fluoroquinolone. If you have, you must inform your doctor as soon as possible.

### **Consult your doctor, nurse or pharmacist during treatment with fluoroquinolones if:**

- You feel a sudden sharp pain in your abdomen, chest or back; seek emergency medical attention immediately.

On rare occasions, pain and swelling in the joints and inflammation or rupture of the tendons may occur. The risk is greater if you are older (over 60 years of age), have received an organ transplant, have kidney problems or are being treated with corticosteroids. Inflammation and tendon rupture may occur in the first 48 hours of treatment and even up to several months after stopping treatment with Levoact. At the first sign of pain or inflammation of a tendon (for example, in the ankle, wrist, elbow, shoulder or knee), stop taking Levoact, contact your doctor and rest the painful area. Avoid any unnecessary exercise, as this could increase the risk of tendon rupture.

On rare occasions, you may experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness, especially in the feet and legs or the hands and arms. If this happens, stop taking Levoact and tell your doctor immediately to prevent the development of a potentially irreversible condition.

### **Serious, disabling, long-lasting, and potentially irreversible adverse reactions**

Antibacterial medicines containing fluoroquinolones or quinolones, including Levoact, have been associated with very rare but severe adverse effects, some of which were long-lasting (persisting for months or years), disabling or potentially irreversible. This includes pain in the tendons, muscles and joints of the upper and lower limbs, difficulty in walking, abnormal sensations such as sharp pains, tingling, tickling, numbness or a burning sensation (paraesthesia), disorders of the senses such as impaired vision, taste, smell and hearing, depression, memory impairment, intense fatigue and severe sleep disorders.

If you experience any of these adverse effects after taking Levoact, contact your doctor immediately, before continuing with the treatment. You and your doctor will decide whether to continue the treatment or not, also considering the use of a different class of antibiotic.

Tell your doctor or pharmacist before taking Levoact, if you are not sure if any of the cases described above are applicable to you.

### **Other medicines and Levoact**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Levoact can affect the functioning of other medicines. In addition, some medications may affect the functioning of Levoact.

### **In particular, tell your doctor if you are taking any of the following medicines, as it increases the possibility of suffering adverse effects when taken together with Levoact:**

- Corticosteroids, sometimes called steroids - used for inflammation. You may be more likely to suffer inflammation and/or rupture of your tendons.
- Warfarin - used to thin the blood. You may be more likely to suffer bleeding. Your doctor may need to perform regular blood tests to check if your blood clots correctly.
- Theophylline - used for respiratory problems. You are more likely to have an epileptic fit (seizures) if you take it with Levoact.
- Non-steroidal anti-inflammatory drugs (NSAIDs) - used for pain and inflammation, such as aspirin, ibuprofen, ketoprofen, fenbufen and indomethacin. You are more likely to have an epileptic fit (seizures) if you take them with Levoact.
- Cyclosporin - used after organ transplants. You may be more likely to suffer the adverse effects of cyclosporin.
- Drugs with a known action on your heartbeat. This includes drugs used for abnormal heart rhythm (anti-arrhythmics 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 (antibiotics “macrolides” such as erythromycin, azithromycin and clarithromycin).
- Probenecid - used for gout. Your doctor may need to give you a lower dose, if you have kidney problems.
- Cimetidine - used for ulcers and heartburn. Your doctor may need to give you a lower dose, if you have kidney problems.

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

### **Do not take Levoact tablets at the same time as the following medications because they can affect the mode of action of Levoact tablets:**

- Iron tablets (for anaemia), zinc supplements, antacids that contain aluminium or magnesium (for acidity 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.

### **Measurement of opiates in urine**

Urine tests may show “false positive” results from the presence of strong pain medications called “opiates” in patients taking Levoact. Tell your doctor if you are taking Levoact if you have been asked to take a urine test.

### **Tuberculosis test**

This medicine may cause a “false negative” result in some laboratory tests that look for the bacteria that causes tuberculosis.

### **Pregnancy and breast-feeding**

Do not take this medicine if:

- you are pregnant, might fall pregnant or think you might be pregnant
- you are breast-feeding or plan to do so

### **Driving and using machines**

Some adverse effects may occur such as dizziness, drowsiness, altered balance (vertigo) or visual disturbances. Some of these adverse effects can affect your ability to concentrate or decrease your reaction speed. If this occurs, do not drive or perform any job that requires a high level of attention.

### **3. How to take Levoact tablets**

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

#### **How to take this medicine**

- Take this medicine by mouth
- Swallow the tablets whole with a little water
- The tablets can be taken with or between meals

#### **If you are already taking iron tablets, zinc supplements, antacids, didanosine or sucralfate**

- Do not take these medicines at the same time as Levoact. You must take these medicines for at least two hours before or two hours after taking Levoact tablets.

#### **What dose should you take**

- Your doctor will decide what amount of Levoact tablets you should take.
- The dose will depend on the type of infection you have and where the infection is located in your body.
- The duration of treatment depends on the severity of your infection.
- If you think that the effect of the medicine is too weak or strong, do not change the dose yourself, ask your doctor.

#### **Adults and elderly patients**

##### **Infection in the paranasal sinuses**

- one 500 mg Levoact tablet once a day

##### **Lung infection in people with long-term respiratory problems**

- one 500 mg Levoact tablet once a day

##### **Pneumonia**

- one 500 mg Levoact tablet, once or twice a day

##### **Urinary tract infection, including kidneys or bladder**

- half or one 500 mg Levoact tablet once a day

##### **Prostate infection**

- one 500 mg Levoact tablet once a day

##### **Infection in the skin and under the skin, including muscles**

- one 500 mg Levoact tablet, once or twice a day

##### **Adults and elderly patients with kidney problems**

Your doctor may give you a lower dose.

##### **Use in children and adolescents**

This medicine should not be administered to children or adolescents.

### **Protect your skin from sunlight**

Do not expose your skin to direct sunlight (even when cloudy) while taking this medicine and for two days after you stop taking it, because your skin will become much more sensitive to the sun and may burn, sting or even be covered with blisters if you do not take the following precautions:

- Make sure you use sunscreens with a high protection factor
- Always wear a hat and clothing that covers your arms and legs
- Avoid ultraviolet (UVA) lamps

### **If you take more Levoact tablets than you should**

If you accidentally take more tablets than you should, tell your doctor or get medical help immediately. Bring the medicine with you so your doctor knows what you have taken. The effects that may occur are: epileptic fits (seizures), confusion, dizziness, loss of consciousness, tremors, heart disorders that can cause irregular heart beats as well as sickness (nausea) or heartburn.

### **If you forget to take Levoact tablets**

If you forget to take a dose, take it right away, unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Levoact tablets**

Do not stop taking Levoact, even if you feel better. It is important that you finish the treatment your doctor has prescribed for you. If you stop taking the tablets too soon, the infection may come back, your condition may worsen 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. Effects are normally mild to moderate and usually disappear in a short time.

**Stop treatment with Levoact and contact a doctor or go to a hospital quickly if you notice the following adverse effects:**

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

- If you have an allergic reaction. The signs may include: skin rash, difficulty breathing or swallowing, swollen lips, face, throat or tongue

**Stop treatment with Levoact and contact a doctor immediately if you notice the following serious adverse effects, as you might need urgent medical treatment:**

**Rare** (may affect up to 1 in 1,000 people)

- Watery diarrhoea that may contain blood, possibly with stomach cramps and fever. These could be signs of a serious intestinal problem
- Pain and inflammation in your tendons or ligaments, which could lead to a rupture. The Achilles tendon is most commonly affected
- Epileptic fits (seizures)
- Seeing or hearing things that are not real (hallucinations, paranoia),
- Depression, mental disorders, feeling restless (agitation), abnormal dreams or nightmares
- Generalised rash, high temperature, elevated liver enzymes, abnormal blood count (eosinophilia), enlarged lymph nodes and involvement of other organs in the body (drug

reaction with eosinophilia and systemic symptoms known as DRESS or drug hypersensitivity syndrome). See section 2.

- Syndrome associated with water retention and low levels of sodium (SIADH).
- Decreased blood sugar levels (hypoglycaemia) or decreased blood sugar levels which can lead to coma (hypoglycaemic coma). This is important for diabetic patients

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

- Burning, tingling, pain or numbness. These may be signs of what is called “neuropathy”

**Frequency not known** (cannot be estimated from the available data).

- Severe skin rashes, including Stevens-Johnson syndrome and toxic epidermal necrolysis. These can appear on the trunk as red target-like or circular patches with blisters in the middle, flaking skin and ulcers in the mouth, throat, nose, genitals and eyes, and they may be preceded by fever and flu-like symptoms. See section 2.
- Loss of appetite, yellowing of the skin and eyes, dark urine, stinging or stomach painful on palpation (abdomen). These may be signs of liver problems which may include fulminant liver failure.
  - Changes of opinion and thoughts (psychotic reactions) with risk of suicidal thoughts or actions

Immediately consult an eye specialist if your vision deteriorates or you have any other problems in your eyes while taking Levoact.

The administration of antibiotics containing quinolones and fluoroquinolones has been linked to very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as inflammation of tendons, tendon rupture, joint pain, pain in the limbs, difficulty 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, in some cases regardless of the presence of pre-existing risk factors.

Aortic wall enlargement and weakening or tearing (aneurysms and dissections), which could lead to rupture and become fatal, and heart valve failure have been reported in patients who have received fluoroquinolones. See also section 2.

**Tell your doctor if any of the following adverse effects worsen or last for more than a few days.**

**Common** (may affect up to 1 in 10 people).

- Sleep problems
- Headache, dizziness
- Malaise (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 a fungus called Candida, which may need treatment
- Changes in the number of white blood cells in your blood test results (leukopenia, eosinophilia)
- Stress (anxiety), confusion, nervousness, drowsiness, tremors, dizziness (vertigo)
- Breathing difficulties (dyspnoea)
- Changes in the taste of things, loss of appetite, stomach disorders or indigestion (dyspepsia), pain in the stomach area, feeling of bloating (flatulence) or constipation

- Itching and skin rash, intense itching or hives (urticaria), excessive sweating (hyperhidrosis)
- Joint or muscle pain
- Abnormal levels in your blood tests due to liver problems (increased bilirubin) or kidney (increased creatinine)
- Generalised weakness

**Rare** (may affect up to 1 in 1,000 people)

- Bruising and bleeding easily due to the decrease in the number of blood platelets (thrombocytopenia)
- Decrease in the number of white blood cells in your blood (neutropenia)
- Exaggerated immune response (hypersensitivity)
- Tingling in your hands and feet (paraesthesia)
- Ear (tinnitus) or vision (blurred vision) disorders
- Abnormally fast heart beat (tachycardia) or decreased blood pressure (hypotension)
- Muscle weakness. This is important in people with myasthenia gravis (rare nervous system disease)
- Kidney function changes and occasionally kidney failure, which can be the result of an allergic reaction in the kidneys called interstitial nephritis
- Fever
- Clearly defined erythematous patches with or without blisters that develop several hours after administration of levofloxacin and heal with residual post-inflammatory hyperpigmentation; it generally recurs in the same area of skin or mucous membrane after subsequent exposure to levofloxacin.
- Memory impairment

**Frequency not known** (cannot be estimated from the available data).

- Decrease in red blood cells in the blood (anaemia): this can make your skin pale or yellowish due to red blood cell damage; decrease in the number of all types of blood cells (pancytopenia)
- Fever, sore throat and persistent general malaise. This may be due to a decrease in the number of white blood cells (agranulocytosis)
- Circulatory collapse (anaphylactic-type shock)
- Increased sugar levels in blood (hyperglycaemia). This is important in people with diabetes
- Changes to your sense of smell, loss of smell or taste (parosmia, anosmia, ageusia)
- Movement and gait disorders (dyskinesia, extrapyramidal disorders)
- Temporary loss of consciousness or posture (syncope)
- Temporary loss of vision, inflammation of the eyes
- Hearing problems or loss
- Abnormally fast heartbeat, life-threatening irregular heartbeat, including the heart stopping, altered heart rhythm (so-called “prolongation of the QT interval”, observed in an ECG, graphical representation of the electrical activity of the heart)
- Shortness of breath or wheezing (bronchospasm)
- Lung allergic reactions
- Inflammation of the pancreas (pancreatitis)
- Inflammation of the liver (hepatitis)
- Increased sensitivity of the skin to sunlight and ultraviolet light (photosensitivity)
- Inflammation of the vessels that carry blood throughout the body due to an allergic reaction (vasculitis)
- Inflammation of the tissue found inside the mouth (stomatitis)
- Muscle rupture and destruction of the muscle (rhabdomyolysis)
- Red and swollen joints (arthritis)



- Pain, including back pain, chest pain, and in the extremities
- Porphyria attack in patients with porphyria (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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Levoact tablets**

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is shown on the packaging. The expiry date refers to the last day of the month.

Do not store at a temperature above 30°C.

Keep the blister in the outer carton in order to protect from light.

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. Contents of the pack and other information**

### **What Levoact contains**

The active ingredient is levofloxacin.

Each tablet of Levoact 500 mg tablets contains 512.5 mg of levofloxacin hemihydrate equivalent to 500 mg of levofloxacin.

The other ingredients are:

Tablet core: hydroxypropyl methylcellulose, crospovidone, microcrystalline cellulose, colloidal anhydrous silica, pregelatinized corn starch and sodium stearyl fumarate.

- Film coating: Opadry Y-1-7000 and red iron oxide (E-172).

### **What Levoact looks like and contents of the pack**

Levoact 500 mg film-coated tablets are biconvex pink color film coated oblong tablets, scored and with “L” engraved on one side. The tablet can be divided into equal halves.

Each pack contains 5 tablets (5's blister x 1), 7 tablets (7's blister x 1) or 10 tablets (10's blister x 1).

### **Marketing Authorisation Holder and Manufacturer**

Laboratorios Cinfa, S.A.

Olaz-Chipi, 10 - Polígono Industrial Areta.

31620-Huarte (Navarra) – Spain

### **This leaflet was last revised in: February 2021**

To report any side effect(s):

The National Pharmacovigilance and Drug Safety Centre (NPC)

- Fax: +966-11-205-7662

- Call NPC at +966-11-2038222, Exts: 2317-2356-2340.
- SFDA Call Center: 19999
- E-mail: [npc.drug@sfda.gov.sa](mailto:npc.drug@sfda.gov.sa)
- Website: <https://ade.sfda.gov.sa/>

**This is a Medicament**

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

**Council of Arab Health Ministers  
Union of Arab Pharmacists**