



# LEVOREC®

## Levofloxacin 750 mg Film-coated tablets

### 1 WHAT IS LEVOREC 750 mg, film-coated tablets AND WHEN IS IT USED?

**Pharmaco-therapeutic class:** Antibiotic, which belongs to the group of quinolones

**ATC Code:** J01MA12  
The name of your medicine is LEVOREC 750 mg film-coated tablet. LEVOREC 750 mg film-coated tablet contains an active substance called levofloxacin. It belongs to a group of medicines called antimicrobials. Levofloxacin is a quinolone antibiotic. It works by killing the bacteria that cause infection in your body.  
**LEVOREC 750 mg film-coated tablets is indicated to treat infections of the:**

- Sinuses.
- Lungs, in people with long-term breathing problems or pneumonia
- Urinary tract, including the kidneys
- 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, LEVOREC 750 mg film-coated tablets may be used to lessen the chance of getting a pneumonia disease named anthrax or worsening of the disease after you are exposed to the bacteria causing anthrax.

### 2 WHAT INFORMATION TO KNOW BEFORE USING LEVOREC 750 MG, film-coated tablets ?

**Do not take LEVOREC 750 MG, film-coated tablets if you:**

- You are allergic to levofloxacin, any other quinolone antibiotic such as moxifloxacin, ciprofloxacin or gatifloxacin or any of the other ingredients of this medicine (listed in section 1)
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You have ever had epilepsy.
- If you have ever had a seizure (fit) or tremor 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 LEVOREC 750 mg film-coated tablets.

**Warnings and precautions**

Before taking this medicine:

- You should not take antibiotics from the family of fluoroquinolones/quinolones, including levofloxacin or ciprofloxacin, for a severe allergic reaction in the past when taking quinolone or fluoroquinolone. If so, you should inform your doctor as soon as possible.

**Talk to your doctor or pharmacist before taking LEVOREC 750 mg film-coated tablets if:**

- You are 60 years of age or older.
- You are using corticosteroids, sometimes called steroids (see section 'Taking other medicines').
- You've ever had a transplant.
- You have already had an epilepsy (convulsions) crisis.
- You had a seizure or a stroke 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.
- If you have had heart problems, 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').
- You are on diabetes.
- You have ever had liver problems.
- You have myasthenia gravis
- If you have been diagnosed with an enlargement or «bulge» of a large blood vessel (called aneurysm) or a large vessel peripheral aneurysm)
- If you have experienced a previous episode of aortic dissection (a tear in the aorta wall).
- If you have a family history of aortic aneurysm or aortic dissection or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, or vascular Ehlers-Danlos connective tissue disorders such as Takayasu arteritis, giant cell arteritis (Horton disease), Behcet's disease, high blood pressure, or known atherosclerosis).
- You have already developed a severe skin rash, severe skin peeling, blisters and/or mouth sores after taking levofloxacin.

**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 this medicine.

• SJS/TEN can appear initially as reddish large-flake 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 other symptoms such as malaise, 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 white blood cells (leucocytosis), and enlarged lymph nodes.

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

If you are not sure that any of the above conditions applies to your case, please contact your doctor or pharmacist before taking LEVOREC 750 mg film-coated tablets.

**When taking this medicine**

Contact your doctor, pharmacist or nurse when taking a fluoroquinolone if:

- You feel a sudden and intense pain in the abdomen, chest or back, go immediately to a hospital or urgent care department.
- 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.

• If you have a history of tendonitis, you are at an increased risk of tendon rupture 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 further physical activity until you are better.

• 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 a permanent or potentially irreversible condition.

**Prolonged, disabling and potentially irreversible serious side effects**

Fluoroquinolone/quinolone antibacterial medicines, including Levofloxacin tablets, 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 deficit (including innumeration, touch 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-free alternative.

**Other medicines and Levorec 750 mg film-coated 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 in your body and some other medicines can affect the way Levofloxacin tablets work in your body.

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 Levorec 750 mg film-coated 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.

• Probenecid - used for kidney problems. You are more likely to have a fit (seizure) if taken with Levorec 750 mg film-coated tablets.

• Non-steroidal anti-inflammatory drugs (NSAIDs) - used for pain and inflammation such as aspirin, ibuprofen, tenifen, ketoprofen and indomethacin. You are more likely to have a fit (seizure) if taken with Levorec 750 mg film-coated tablets.

• Clozapine - used after organ transplants. You may be more likely to get the side effects of clozapine

• Medicines known to affect the way your heart beats. This includes medicines used for abnormal heart rhythm (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, clarithromycin and claritromycin)

• Other medicines - used for ulcers and heartburn. Special care should be taken when taking either of these medicines with Levorec 750 mg film-coated tablets. 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 Levorec 750 mg film-coated tablets at the same time as the following medicines. This is because it can affect the way Levorec 750 mg film-coated tablets work:**

• Iron tablets (for anemia), zinc supplements, magnesium or aluminum-containing antacids (for acid or heartburn), didanosine, or sucralofate (for stomach ulcers). See section 3 if you are taking iron tablets, zinc supplements, antacids, didanosine or sucralofate.

**Urine tests for opiates**

Urine tests may show «false-positive» results for strong painkillers called «opiates» in people taking Levorec 750 mg film-coated tablets. If your doctor is due to take a urine test, tell them you are taking Levorec 750 mg film-coated tablets.

**Tuberculosis tests**

This medicine may cause «false negative» results for some tests used in laboratory to search for tuberculosis. Tell your doctor if you are taking this medicine.

**Taking LEVOREC 750 mg with food and drink**

Not applicable.

**Pregnancy and breast-feeding**

You must not take Levorec 750 mg film-coated tablets if you are pregnant, trying to become pregnant or are breastfeeding.

**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. So, until these side effects can affect you, you should not be 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.

Levorec 750 mg film-coated tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially sodium-free.

**3 How to take LEVOREC 750 mg film-coated tablets ?**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if in doubt.

**Taking this medicine**

• Take this medicine by mouth

• Swallow the tablets without crushing with a drink of water

• The tablets may be taken during meals or at any time between meals

If you are already taking iron tablets, zinc supplements, antacids, didanosine or sucralofate. Do not take these medicines at the same time as LEVOREC 750 mg film-coated tablet.

• Take these medicines at least 2 hours before or after LEVOREC 750 mg film-coated tablet.

**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 by taking your doctor.

**Adults and the elderly**

Sinuses infection

• One tablet of Levorec 750 mg, once each day

Lung infection, in people with long-term breathing problems

• One tablet of Levorec 750 mg, once each day

Pneumonia

• One tablet of Levorec 750 mg, once or twice each day

Infection of urinary tract, including your kidneys or bladder

• One tablet of Levorec 750 mg, each day

Prostate gland infection

• One tablet of Levorec 750 mg, once each day

Infection of skin and underneath the skin, including muscles

• One tablet of Levorec 750 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 teenagers**

This medicine must not be given to children or teenagers

**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 take more LEVOREC 750 mg film-coated 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 LEVOREC 750 mg film-coated**

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 LEVOREC 750 mg film-coated**

Do not stop taking LEVOREC 750 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 product, ask your doctor or pharmacist.

### 4 POSSIBLE EFFECTS?

**Likely 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 Levorec 750 mg film-coated tablets and see a doctor or go to a hospital straight away if you notice any of the following side effects - you may need urgent medical treatment:

**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

• If you notice high boiling temperatures, 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)**

• Convulsions

• Pain and inflammation in your tendons or ligaments, which could lead to rupture. The Achilles tendon is affected most often.

• Changes in your opinions and thoughts (psychotic reactions), with a risk of suicidal thoughts and actions.

• Feeling of depression, mental problems (restlessness), abnormal dreams or nightmares.

• Widespread allergic reactions, 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)

• Lower blood sugar level (hypoglycaemia) or lower blood sugar level leading to coma (hypoglycaemic coma). This is important for people with diabetes.

• Burning, tingling, pain or numbness. These may be signs of something called «neuropathy».

**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 large-flake macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms. See also section 2.

• Loss of appetite, skin and eyes becoming yellow in colour, dark-coloured urine, itching or tender stomach (abdomen). These may be signs of liver problems which may include a fatal failure of the liver.

• Changes in your opinions and thoughts (psychotic reactions), with a risk of suicidal thoughts and actions.

• Nausea, general malaise, discomfort or pain in the stomach area, or vomiting. These could be signs of inflammation of the pancreas (acute pancreatitis). See section 2.

If your eyesight becomes impaired or if you have any other eye disturbances whilst taking Levorec 750 mg film-coated tablets, consult an eye specialist immediately.

• Very rare cases of long lasting (up to months or years) or permanent adverse drug reactions, such as tendon inflammations, tendon rupture, joint pain, pain in the limbs, difficulty in walking, abnormal sensations such as pins and needles, tingling, tickling, burning, numbness or pain (neuropathy), 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 respectively pre-existing risk factors.

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

• Headaches/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 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

• 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 respectively pre-existing risk factors.

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