

LEVOQUIN FILM COATED CAPLET

Levofloxacin hemihydrate (250mg, 500mg)

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This leaflet refers to Levoquin. Please read it carefully before you start to take it. Because this leaflet does not tell you everything about your medicine, if you have any questions or are not sure about everything, ask your doctor or pharmacist.

What Levoquin is used for

Levoquin can be used to treat infections of the:

- Sinuses
- Lungs, in people with long-term breathing problems or pneumonia (inflammation of the lungs which causes breathlessness, cough and raised temperature)
- Urinary tract, including your kidneys or bladder
- Prostate gland, complication from urinary tract infection, UTI (mild and moderate bacteria infections)
- Skin and underneath the skin, including muscles. This is sometimes called 'soft tissue'

How Levoquin works

Levoquin contains a medicine 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.

Before you use Levoquin

- *When you must not use it*

Do not take Levoquin if you are allergic to levofloxacin, or other quinolone antibiotics or any of the product components.

- *Pregnancy and lactation*

Do not take this medicine if:

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

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

- *Before you start to use it*

Tell your healthcare provider about all your medical conditions, including if you:

- Have tendon problem
- Have central nervous system problems (such as epilepsy).
- Have or anyone in your family has an irregular heartbeat; especially a condition called "QT prolongation".
- Have liver problems.
- Have *Clostridium difficile* associated diarrhea.
- Have peripheral neuropathy (damage to nerves of peripheral nervous system (consists of the nerves outside of the brain and spinal cord)).
- Have blood glucose disturbances.
- Have been diagnosed with an enlargement or "bulge" of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- Have experienced a previous episode of aortic dissection (a tear in the aorta wall)
- 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 syndrome, or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet's disease, high blood pressure, or known atherosclerosis).

You should not take fluoroquinolone antibacterial medicines, including Levoquin, if you have experienced any serious adverse reaction in the past when taking a fluoroquinolone (see section Things to be careful of and Side effects). In this situation, you should inform your healthcare providers as soon as possible

- *Taking other medicines*

Please tell your healthcare provider if you are taking or have recently taken any other medicines. Because levofloxacin can affect the way some other medicines work. Also some other medicines can affect the way levofloxacin works. Especially tell your healthcare provider if you take:

- Iron tablets, magnesium or aluminum- containing antacids or sucralfate. These agents should be taken at least two hours before or two hours after levofloxacin administration.
- Theophylline - has resulted in prolonged elimination half-life, elevated serum theophylline levels.
- Warfarin – associated with episodes of bleeding.
- Cyclosporin – no dosage adjustment required.
- Medicines known to affect the way your heart beats such as digoxin.
- Probenecid - used for gout, and cimetidine - used for stomach ulcers and heartburn.
- Non-steroidal anti-inflammatory drugs (NSAIDs) - may increase the risk of CNS stimulation and convulsive seizures.
- Antidiabetic - disturbances of blood glucose, including hyperglycemia and hypoglycemia

How to take Levoquin

- *How much to use*

Your doctor will decide the most suitable dose for you base on your type and severity of infection. Take Levoquin exactly as prescribed by your healthcare provider. The label on it will usually tell you how many to take and how often. If you are not sure, please ask your doctor or pharmacist.

- *When to take it*

- Take Levoquin at about the same time each day.
- Drink plenty of fluids while taking Levoquin.
- Levoquin can be taken with or

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without food.

- How long to use it

Do not skip any doses, or stop taking Levoquin even if you begin to feel better, until you finish your prescribed treatment, unless:

- You have tendon problems.
- You have a serious allergic reaction or your healthcare provider tells you to stop.

- If you forget to use it

If you miss a dose of Levoquin, take it as soon as you remember. Do not take more than one dose in one day.

- If you use too much (overdose)

If you take too much, call your healthcare provider or get medical help immediately.

While you are using it

- Things you must do

Take Levoquin exactly as prescribed by your doctor or pharmacist until you completed your prescribed course.

Levoquin can make your skin sensitive to the sun (photosensitivity) and the light from sunlamps and tanning beds. You should use a sunscreen and wear a hat and clothes that cover your skin if you have to be in sunlight.

Tell your doctor or pharmacist if your condition is not getting better or side effects happen while you are taking Levoquin.

- Things you must not do

Levoquin can make you feel dizzy and lightheaded. Do not drive, operate machinery, or do other activities that require mental alertness or coordination until you know how Levoquin affects you. The expiry date of this medicinal product is printed on the box and blister foil. Do not use this medicinal product after the expiry date.

- Things to be careful of

If you feel sudden, severe pain in your abdomen, chest or back, go immediately to the emergency department.

- Prolonged, disabling and potentially irreversible serious side effects

Fluoroquinolone antibacterial

medicines, including Levoquin, have been associated with very rare but serious side effects, some of them being long lasting (continuing months or years), disabling or potentially irreversible.

Stop taking your fluoroquinolone antibiotic and contact your healthcare providers immediately if you have the following signs of a side effect:

- Tendon pain or swelling, often beginning in the ankle or calf. If this happens, rest the painful area until you can see your healthcare providers.
- Pain in your joints or swelling in your shoulder, arms, or legs.
- Abnormal pain or sensations (such as persistent pins and needles, tingling, tickling, numbness, or burning), weakness in your body, especially in the legs or arms, or difficulty walking.
- Severe tiredness, depressed mood, anxiety, problems with your memory, or severe problems sleeping.
- Changes in your vision, taste, smell, or hearing.

Tell your healthcare providers if you have had one of the above effects during or shortly taking a fluoroquinolone-this means you should avoid them in the future. You and your healthcare providers will decide on continuing the treatment considering also an antibiotic from another class.

- Tendinitis and tendon rupture

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 Levoquin therapy. At the first sign of pain or inflammation of a tendon (for example

in your ankle, wrist, elbow, shoulder or knee), stop taking Levoquin, contact your healthcare providers and rest the painful area. Avoid any unnecessary exercise as this might increase the risk of a tendon rupture.

- Peripheral neuropathy

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 Levoquin and inform your healthcare providers immediately in order to prevent the development of potentially irreversible condition.

You may experience mental health problems even when taking/ using fluoroquinolone antibiotics, including Levoquin for the first time. In very rare cases depression or mental health problems have led to suicidal thoughts and self-injurious behaviour such

as suicide attempts. If you develop such reactions, stop taking/ using Levoquin and inform your doctor immediately.

Side effects

Fluoroquinolones have been reported to cause serious side effects involving tendons, muscles, joints, and the nerves- in a small proportion of patients, these side effects caused long-lasting or permanent disability (see section Before you start to use it and Things to be careful of).

Some of the reported side effects are feeling sick (nausea) and diarrhea Increase in the level of some liver enzymes in your blood.

Rare: Change in your opinion and thoughts (psychotic reactions) with a risk of having suicidal thoughts or actions, hallucination, depression.

Very rare: Psychotic behaviour.

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Not known (frequency cannot be estimated from the available data):
Psychotic reactions with a risk of having suicidal thoughts or actions.

Please tell your doctor or pharmacist if you experience any other unwanted side effects.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by visiting the website np.ra.moh.gov.my (Consumers - > Reporting -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Levoquin

- Storage

In a dry, cool place (<30°C).

Protect from light.

Keep Levoquin 250 and all medicines out of the reach of children.

- Disposal

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.

Product Description

- What it looks like

Levoquin 250mg film – coated caplet appears as plain, oblong, yellow film-coated tablets.

Levoquin 500 film – coated caplet appears as yellow film – coated caplet, engraved “P” on one side.

- Ingredients

- Active ingredient:

Each Levoquin 250mg film coated caplet contains levofloxacin hemihydrate equivalent to levofloxacin 250 mg.

Each Levoquin 500mg film coated caplet contains levofloxacin hemihydrate equivalent to levofloxacin 500 mg.

- Inactive ingredients: Maize starch, lactose, croscarmellose sodium, povidone magnesium stearate, HPMC, colloidal silicon dioxide, PEG 6000,

titanium dioxide and quinoline yellow, sodium starch glycolate, purified water

-MAL number:

Levoquin 250mg film coated caplet

MAL12095077AZ

Levoquin 500mg film coated caplet:

MAL12095080AZ

Manufacturer

PYMEPHARCO JOINT STOCK COMPANY

(Pymepharco is a subsidiary of STADA Arzneimittel AG)

166-170 Nguyen Hue Str, Tuy Hoa City, Phu Yen Province, VietNam

Product Registration Holder

DKSH Malaysia Sdn Bhd.

B-11-01, The Ascent, Paradigm, No.1, Jalan SS7/26A, Kelana Jaya, 47301, Petaling Jaya, Selangor, Malaysia

Date of revision

19/04/2024

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