

LEVOQUIN FILM COATED CAPLET

Levofloxacin hemihydrates (250mg, 500mg)

What is in this leaflet

1. What Levoquin is used for
2. How Levoquin works
3. Before you use Levoquin
4. How to use Levoquin
5. While you are using it
6. Side effects
7. Storage and disposal of Levoquin
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

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.

- 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 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.

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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 your symptoms do not improve within a few days, or if they become worse, check with your doctor.

Side effects

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

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 calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Levoquin

- Storage

Protect from light (below 30°C).

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 yellow film – coated caplet, engraved “P” on one side. Dimension of caplet is 15.8 x 8.0 (mm) (L x W).

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

(Pymepharco is a subsidiary of STADA Arzneimittel AG)

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

Product Registration Holder

STADPHARM SDN BHD

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Selangor Darul Ehsan

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