

LEVOFLOX[®] 500 MG

Levofloxacin

1- What is LEVOFLOX[®] 500 mg?

Form and presentations :

LEVOFLOX[®] 500 mg : scored orange film-coated tablets – Boxes of 05 tablets and of 10 tablets.

Pharmacotherapeutic class :

Levofloxacin is an antibacterial antibiotic belonging to the quinolones' family.

Composition :

Each tablet contains:

Levofloxacin hemihydrate (500 mg as levofloxacin base).. 512.46 mg
Excipients: microcrystalline cellulose, lactose monohydrated, sodium croscarmellose, magnesium stearate and opadry .. s.q.f one tablet

2- In which case can LEVOFLOX[®] 500 mg be used?

LEVOFLOX[®] is indicated in adults for the treatment of the following infections:

- acute bacterial sinusitis.
- Acute exacerbations of chronic bronchitis.
- Community-acquired pneumonia (second line).

For infections mentioned above, LEVOFLOX[®] should be used only when the antibiotics recommended in the initial treatment of these infections, are deemed inappropriate.

- Bacterial Chronic Prostatitis.
 - Inhalation anthrax post-exposure prophylaxis and curative treatment.
- LEVOFLOX[®] can also be used to relay an initial intravenous treatment of levofloxacin in patients who showed improvement in their condition.

It should be given to official recommendations on the appropriate use of antibacterial agents.

3- What is necessary to know before using LEVOFLOX[®] 500 mg?

Contraindications

- Hypersensitivity to this drug, to any other quinolone or to one of the excipients.
- Epilepsy
- Glucose-6-phosphate dehydrogenase (rare congenital disease).
- History of tendinopathy with a fluoroquinolone.
- Children until the end of the growth period and adolescents, because of the articular toxicity showed in animals.

Warnings and precautions of use

- Infections due to clostridium difficile: rare cases of pseudo-membranous colitis during or after treatment with levofloxacin: stop treatment if already started.
- Tendinitis: tendonitis touches particularly Achilles tendons and can lead to their rupture. They can occur since the first 48 hours of treatment and become bilateral. They occur preferably in risky patients: 65 years and more and subjects under corticoids (including inhaled corticotherapy). These two factors clearly increase the risk of tendonitis. The occurrence of tendonitis signs requires the immediate treatment discontinuation and the immobilization of the two Achilles tendons with an appropriate contention or with heel pads and a specialized advising.
- Levofloxacin should be used with caution in patients having myasthenia.
- Levofloxacin should be used with caution in subjects with a history of convulsions or with factors predisposing to convulsions.
- Levofloxacin has essentially eliminated by renal excretion. A dosage adjustment is required in patients with renal impairment.
- Avoid sun UV (tanning lamps, solarium...) exposition during the treatment and during the 48 hours following its discontinuation, because of the risk of photosensitization.
- Levofloxacin can inhibit the mycobacterium tuberculosis growth and can by the way, induce negative bacteriological diagnosis of tuberculosis.

Use during pregnancy and breastfeeding

Pregnancy:

It is preferable, as a precaution, not to use levofloxacin during pregnancy.

Breastfeeding:

Fluoroquinolones pass in the mother's milk. The risk of articular lesions in the infant contraindicates breastfeeding when the mother is treated by a fluoroquinolone.

Effects on the aptitude to drive or to operate on machines:

Some undesirable effects can reduce the concentration and the reaction capacities, necessary to execute some works. Drivers and machines operators should be informed about this potential risk.

Drug interactions :

Levofloxacin does not modify the pharmacokinetics of theophyllin and digoxin.

To be taken into the account:

Probenecide, cimetidin: reduction of the levofloxacin renal tubular secretion. This interaction does not have consequences except in patients with renal insufficiency.

Special problems with INR imbalance:

Fluoroquinolones, like several other antibiotics, can damage the colic flora and by the way, the physiological production of vitamin K. This can lead to a reduction in the prothrombin level (or an increase in the INR). It is recommended to monitor this, especially in patients under anti-vitamin K agents.

4. How can LEVOFLOX[®] 500 mg be used?

Dosage:

The dosage depends on the indication, the infection severity and site, the germ's sensitiveness and the body weight.

The usual dose is: 500mg once a day. Your doctor can double the dose of LEVOFLOX[®] 500 mg to 500mg, 2 times per day. In case of renal insufficiency, the dosage should be adjusted to creatinin clearance.

Mode of administration:

Tablets should be administered by oral route. Tablets can be taken during or between meals.

5. What are the eventual undesirable effects?

- Digestive disorders (nausea, vomiting, diarrhea, abdominal pains) are the most common undesirable effects. The administration of LEVOFLOX[®] 500 mg during meals can reduce these effects incidence.
- Like all other fluoroquinolones, levofloxacin can cause neurological effects (headaches, confusion, tremor, convulsions).
- Cutaneous manifestations (erythematous and maculo-papulous eruptions, very rarely, photosensitization).
- Haematological manifestations (leucopenia, thrombocytopenia, hyper-eosinophilia).
- Hepatic manifestations (increase in transaminases, alkaline phosphatases and bilirubinemia).
- Other effects: loco-motor tract effects (muscular and/or articular pains, rare cases of tendonitis which can be observed during the first days of treatment, Achilles tendons rupture).

6. How can LEVOFLOX[®] 500 mg be stored?

To be stored in its original packaging away from light and humidity.

7. What are the delivery conditions?

Table A. Only under medical prescription.

8. Presentation and M.A. number :

Speciality	M.A. number	Presentations
LEVOFLOX [®] 500 mg	923 343 1	Box of 5 tablets
LEVOFLOX [®] 500 mg	923 343 2	Box of 10 tablets

Date of the last review: October 2016

This is a drug

- A drug is a specific product agent.
- A drug is a product acting on your health and its use, contrary to prescriptions may be dangerous for you.
- Strictly respect the doctor's prescription and the instructions of use he has prescribed.
- Follow your pharmacist's know this drug ; its indications and contra-indications.
- Do not discontinue the drug intake by yourself during the prescription period.
- Do not repeat the prescription or increase the dosage without consulting your doctor.

Keep any drug out of the reach of children.

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