

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Levomac (Levofloxacin Tablets 250mg, 500mg and 750mg) is and what it is used for
2. Before you take Levomac (Levofloxacin Tablets 250mg, 500mg and 750mg)
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1. WHAT LEVOMAC (LEVOFLOXACIN TABLETS 250MG, 500MG and 750MG) IS AND WHAT IT IS USED FOR

Levofloxacin tablets are fluoroquinolone antibiotic medicine used in adults age 18 years or older to treat certain infections caused by certain germs called bacteria. These bacterial infections include:

- nosocomial pneumonia
- plague
- community acquired pneumonia
- urinary tract infections, complicated and uncomplicated
- skin infections, complicated and uncomplicated
- acute kidney infection (pyelonephritis)
- chronic prostate infection
- acute sinus infection
- inhalation anthrax germs
- acute worsening or chronic bronchitis

Studies of levofloxacin tablets for use in the treatment of plague and anthrax were done in animals only, because plague and anthrax could not be studied in people.

Levofloxacin tablets should not be used in patients with uncomplicated urinary tract infections, acute bacterial exacerbation of chronic bronchitis, or acute bacterial sinusitis if there are other treatment options available.

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Levofloxacin tablets are also used to treat children who weigh at least 66 pounds (or at least 30 kilograms) and may have breathed in anthrax germs, have plague, or been exposed to plague germs.

It is not known if levofloxacin tablets are safe and effective in children under 6 months of age.

The safety and effectiveness in children treated with levofloxacin tablets for more than 14 days is not known.

2. BEFORE YOU TAKE LEVOMAC (LEVOFLOXACIN TABLETS 250MG, 500MG and 750MG)

Do not take this medicine and tell your doctor if: if you have ever had a severe allergic reaction to an antibiotic known as a fluoroquinolone, or if you are allergic to levofloxacin or any of the ingredients in levofloxacin tablets. See the end of this leaflet for a complete list of ingredients in levofloxacin tablets.

Take special care with Levofloxacin Tablets if :

Talk to your doctor or pharmacist before taking your medicine if you:

- have tendon problems; levofloxacin tablets should not be used in people who have a history of tendon problems
- have a problem that causes muscle weakness (myasthenia gravis); levofloxacin tablets should not be used in people who have a known history of myasthenia gravis
- have central nervous system problems such as seizures (epilepsy)
- have nerve problems; levofloxacin tablets should not be used in patients who have a history of a nerve problem called peripheral neuropathy
- have or anyone in your family has an irregular heartbeat, especially a condition called “QT prolongation”
- have low blood potassium (hypokalemia)
- have bone problems
- have joint problems including rheumatoid arthritis (RA)
- have kidney problems. You may need a lower dose of levofloxacin tablets if your kidneys do not work well
- have liver problems
- have diabetes or problems with low blood sugar (hypoglycemia)
- are pregnant or plan to become pregnant. It is not known if levofloxacin tablets will harm your unborn child
- are breastfeeding or plan to breastfeed. It is not known if levofloxacin passes into your breast milk. You and your healthcare provider should decide if you will take levofloxacin tablets or breastfeed.

Levomac (Levofloxacin Tablets 250mg, 500 mg & 750mg)

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You should not do both

Other medicines and Levomac (Levofloxacin Tablets 250mg, 500mg and 750mg)

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Levofloxacin tablets and other medicines can affect each other causing side effects.

Especially tell your healthcare provider if you take:

- a steroid medicine.
- an anti-psychotic medicine
- a tricyclic antidepressant
- a water pill (diuretic)
- certain medicines may keep levofloxacin tablets from working correctly. Take levofloxacin tablets either 2 hours before or 2 hours after taking these medicines or supplements:
 - an antacid, multivitamin, or other medicines or supplements that have magnesium, aluminum, iron, or zinc
 - sucralfate
 - didanosine
- a blood thinner (warfarin, Coumadin, Jantoven)
- an oral anti-diabetes medicine or insulin
- an NSAID (Non-Steroidal Anti-Inflammatory Drug). Many common medicines for pain relief are NSAIDs. Taking an NSAID while you take levofloxacin tablets or other fluoroquinolones may increase your risk of central nervous system effects and seizures.
- theophylline (Theo-24 , Elixophyllin , Theochron , Uniphyl , Theolair)
- a medicine to control your heart rate or rhythm (antiarrhythmics)

Ask your healthcare provider if you are not sure if any of your medicines are listed above.

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Levofloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the baby

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Driving and using machines

Levofloxacin tablets 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 levofloxacin tablets affects you.

3. HOW TO TAKE LEVOMAC (LEVOFLOXACIN TABLET 250 MG, 500MG and 750MG)

- Take levofloxacin tablets exactly as your healthcare provider tells you to take it
- Take levofloxacin tablets at about the same time each day
- Drink plenty of fluids while you take levofloxacin tablets
- Levofloxacin tablets can be taken with or without food
- If you miss a dose of levofloxacin tablets, take it as soon as you remember. Do not take more than 1 dose in 1 day.
- Do not skip any doses of levofloxacin tablets or stop taking it, even if you begin to feel better.

Taking all of your levofloxacin tablets doses will help make sure that all of the bacteria are killed. Taking all of your levofloxacin tablets doses will help you lower the chance that the bacteria will become resistant to levofloxacin tablets. If your infection does not get better while you take levofloxacin tablets, it may mean that the bacteria causing your infection may be resistant to levofloxacin tablets. If your infection does not get better, call your healthcare provider. If your infection does not get better, levofloxacin tablets and other similar antibiotic medicines may not work for you in the future. If you take too much levofloxacin tablets, call your healthcare provider or get medical help right away.

What should I avoid while taking levofloxacin tablets ?

Avoid sunlamps, tanning beds, and try to limit your time in the sun. Levofloxacin tablets can make your skin sensitive to the sun (photosensitivity) and the light from sunlamps and tanning beds. You could get severe sunburn, blisters or swelling of your skin. If you get any of these symptoms while you take levofloxacin tablets, call your healthcare provider right away. You should use a sunscreen and wear a hat and clothes that cover your skin if you have to be in sunlight.

4. POSSIBLE SIDE EFFECTS

Allergic reactions can happen in people taking fluoroquinolones, including levofloxacin tablets, even after only 1 dose. Stop taking levofloxacin tablets and get emergency medical help right away if you have any of the following symptoms of a severe allergic reaction:

- hives
- trouble breathing or swallowing

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- swelling of the lips, tongue, face
- throat tightness, hoarseness
- rapid heartbeat
- faint
- skin rash

Skin rash may happen in people taking levofloxacin tablets, even after only 1 dose. Stop taking levofloxacin tablets at the first sign of a skin rash and immediately call your healthcare provider. Skin rash may be a sign of a more serious reaction to levofloxacin tablets.

- **Liver damage (hepatotoxicity):** Hepatotoxicity can happen in people who take levofloxacin tablets.

Call your healthcare provider right away if you have unexplained symptoms such as:

- nausea or vomiting
- stomach pain
- fever
- weakness
- abdominal pain or tenderness
- itching
- unusual tiredness
- loss of appetite
- light colored bowel movements
- dark colored urine
- yellowing of your skin or the whites of your eyes

Stop taking levofloxacin tablets and tell your healthcare provider right away if you have yellowing of your skin or white part of your eyes, or if you have dark urine. These can be signs of a serious reaction to levofloxacin tablets (a liver problem).

Aortic aneurysm and dissection

Tell your healthcare provider if you have ever been told that you have an aortic aneurysm, a swelling of the large artery that carries blood from the heart to the body. Get emergency medical help right away if you have sudden chest, stomach, or back pain.

Intestine infection (Pseudomembranous colitis)

Pseudomembranous colitis can happen with many antibiotics, including levofloxacin tablets. Call your healthcare provider right away if you get watery diarrhea, diarrhea that does not go away, or bloody

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stools. You may have stomach cramps and a fever. Pseudomembranous colitis can happen 2 or more months after you have finished your antibiotic.

Serious heart rhythm changes (QT prolongation and t or s ades de pointes)

Tell your healthcare provider right away if you have a change in your heart beat (a fast or irregular heartbeat), or if you faint. Levofloxacin tablets may cause a rare heart problem known as prolongation of the QT interval. This condition can cause an abnormal heartbeat and can be very dangerous. The chances of this happening are higher in people:

- who are elderly
- with a family history of prolonged QT interval
- with low blood potassium (hypokalemia)
- who take certain medicines to control heart rhythm (antiarrhythmics)

Joint Problems

Increased chance of problems with joints and tissues around joints in children can happen. Tell your child's healthcare provider if your child has any joint problems during or after treatment with levofloxacin tablets.

Changes in blood sugar

People who take levofloxacin tablets and other fluoroquinolone medicines with oral anti-diabetes medicines or with insulin can get low blood sugar (hypoglycemia) and high blood sugar (hyperglycemia). Follow your healthcare provider's instructions for how often to check your blood sugar. If you have diabetes and you get low blood sugar while taking levofloxacin, stop taking levofloxacin tablets and call your healthcare provider right away. Your antibiotic medicine may need to be changed.

Sensitivity to sunlight (photosensitivity)

The most common side effects of levofloxacin tablets include:

- nausea
- headache
- diarrhea
- insomnia
- constipation
- dizziness

In children 6 months and older who take levofloxacin tablets to treat anthrax disease or plague, vomiting is also common.

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5. HOW TO STORE LEVOMAC (LEVOFLOXACIN TABLETS 250 MG, 500MG and 750MG)

Do not store above 30°C. Keep away from light and moisture.

Do not use Levomac (Levofloxacin Tablets 250mg, 500 mg & 750mg) after the expiry date which is stated on the label, carton, bottle after expiry date. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What Levomac (Levofloxacin Tablets) contains

The active ingredient is Levofloxacin Hemihydrate USP equivalent to Levofloxacin.

The other ingredients are:

Levomac (Levofloxacin Tablets 250mg, 500 mg & 750mg): Microcrystalline cellulose, Crospovidone, Hypromellose, Magnesium Stearate, Titanium Dioxide, Macrogol 400, Polysorbate 80, Iron Oxide Red, Iron Oxide Yellow.

What Levomac (Levofloxacin Tablets) looks like and contents of the pack

Levomac 250 (Levofloxacin Tablets 250mg) : Brownish red colored, circular shaped, biconvex, film coated tablets, debossed 'T' and '62' on either side of deep score line on one side of the tablet and deep core line on other side.

Levomac 500 (Levofloxacin Tablets 500mg) : Brownish red colored, capsule shaped, biconvex, film coated tablets, debossed 'T' and '63' on either side of deep score line on one side of the tablet and deep core line on other side.

Levomac 750 (Levofloxacin Tablets 750mg) : Brownish red colored, oval shaped, biconvex, film coated tablets, debossed 'T' and '64' on either side of deep score line on one side of the tablet and deep core line on other side.

Levofloxacin Tablets will be packed in,

Levomac 250 (Levofloxacin Tablets 250mg): Alu./ PVC (Peach) colour Blister pack of 5 Tablets. Such 20 blisters packed in a carton along with pack insert.

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Levomac 500 (Levofloxacin Tablets 500mg): Alu./ PVC (Orange) colour Blister pack of 5 Tablets. Such 20 blisters packed in a carton along with pack insert.

Levomac 750 (Levofloxacin Tablets 750mg): Alu./ PVC (Blue) colour Blister pack of 10 Tablets. Such 10 blisters packed in a carton along with pack insert.

Supplier

Macleods Pharmaceuticals Ltd.

304, Atlanta Arcade,

Marol Church Road,

Andheri (East)

Mumbai- 400 059,

India

Phone: +91-22-66762800

Fax: +91-22-2821 6599

E-mail: exports@macleodspharma.com

Manufacturer

Macleods Pharmaceuticals Ltd

Plot No. 25 - 27,

Sr. No. 366,

Premier Ind. Estate,

Kachigam, Daman (U,T),

India

Tel: +91-0260 2244337

Fax: +91-0260 2241565