

OLFOVEL 500MG TABLET

Levofloxacin hemihydrate 512.2mg equivalent to Levofloxacin 500mg

What is in this leaflet

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

What OLFOVEL is used for

OLFOVEL is an oral antibacterial agent used to treat adults with certain kinds of infection.

How OLFOVEL works

OLFOVEL interferes with bacterial enzymes to prevent bacterial growth, thereby killing the susceptible bacteria.

Before you use OLFOVEL

- When you must not use it

Do not take **OLFOVEL** if you are under 18 years of age.

Do not take **OLFOVEL** if you are allergic to levofloxacin, any of the group of antibiotics known as quinolones or any other ingredients of this medicine (listed in Product Description).

You should not take **OLFOVEL** if you have had tendinitis or tendon rupture while taking quinolone antibiotics.

- Before you start to use it

It is important to let your doctor know if you have decreased kidney function, epilepsy or have a history of seizures, problems with heart rhythm, heart rate, or taking antidiabetic drugs.

Tell your healthcare providers if you:

- 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 **OLFOVEL**, 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.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breastfeeding before using any medicine.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Inform your doctor or pharmacist if you are taking:

- theophylline (used for breathing problems)
- Non-Steroidal Anti-Inflammatory drugs (used for pain and inflammation)
- probenecid (used for gout)
- cimetidine (used for ulcers and heartburn)
- ciclosporin (used after organ transplants)
- drugs known to prolong QT interval
- warfarin (anticoagulant)

OLFOVEL should be taken at least two hours before or after taking antacids, sucralfate, or multivitamins.

How to use OLFOVEL

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- How much to use

A tablet of 250 mg or 500 mg once a day as prescribed by your doctor. **OLFOVEL** tablets are available in the strength of 500 mg only and may not be suitable for all dosage recommendations as stated. Therefore, other suitable available strengths and/or dosage forms of levofloxacin should be used in such cases.

- When to use it

Each tablet should be swallowed whole and may be taken with or without food.

- How long to use it

As prescribed by your doctor.

- If you forget to use it

Take the missed dose as soon as you remember. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using OLFOVEL

- Things you must do

You should complete the full course of medication. You should drink fluids liberally to maintain a hydrated condition.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give **OLFOVEL** to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Since symptoms (e.g. disturbance of consciousness) may occur during **OLFOVEL** treatment, you should be careful while operating dangerous machine, such as driving a motor vehicle.

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

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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 after 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 **OLFOVEL** therapy. At the first sign of pain or inflammation of a tendon (for example in your ankle, wrist, elbow, shoulder, or knee), stop taking **OLFOVEL**, 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 **OLFOVEL** 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 **OLFOVEL** 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 **OLFOVEL** 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).

Like all medicines, **OLFOVEL** can cause side effects, although not everybody gets them.

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

Very rare: Psychotic behaviour.

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

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of OLFOVEL

- Storage

Keep in tight container. Protect from light. Do not store below 30°C. Keep out of the reach and sight 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

It is a pale orange, long round biconvex film coated tablets with bisec-line and letter B, L on one side and figure 500 on the other side.

- Ingredients

- Active ingredient
 - Levofloxacin hemihydrate 512.5 mg equivalent to levofloxacin 500.0 mg.
- Inactive ingredients
 - Microcrystalline cellulose, sodium lauryl sulphate, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, hydroxypropyl methylcellulose 2910, titanium dioxide, talc, polyethylene glycol 6000, red iron oxide, yellow iron oxide.

- MAL number:

MAL11010021AZ

Manufacturer

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Product Registration Holder

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