

OLFOVEL 500[®] TABLET

Levofloxacin hemihydrate (512.5mg)

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What Olfovel is used for

Olfovel is used to treat:

- Pneumonia (inflammation of the lung)
- Acute exacerbation of chronic bronchitis (breathing difficulty due to airway narrowing)
- Acute sinusitis (inflammation of sinus)
- Skin and skin structure infections
- Chronic bacterial prostatitis (recurring infections in the prostate)
- Acute pyelonephritis (sudden and severe kidney infection)
- Urinary tract infections

How Olfovel works

Levofloxacin is an antimicrobial agent. It inhibits the enzymes that required for growth of microorganisms (bacteria)

It is active against many microorganisms.

Before you use Olfovel

- When you must not use it

Do not take Olfovel, if you:

- Are allergic to levofloxacin, any other quinolone antibiotic or any of the other ingredients of this medicine
- Have ever had epilepsy
- Have ever had a problem with your tendons such as tendonitis that was related to treatment with a 'quinolone antibiotic'.
- Are a child or a growing teenager
- Are pregnant, might become pregnant or think you may be pregnant
- Are breast-feeding

- Before you start to use it

Talk to your doctor or pharmacist if you

- Are 60 years old or older
- Are using corticosteroids
- Have ever had a fit (seizure)
- Have kidney problems

- Have something known as 'glucose-6-phosphate dehydrogenase deficiency'
- Have ever had mental health problems
- Are diabetic
- Have ever had liver problems
- Have myasthenia gravis
- Are born with or have family history of abnormal heart rate
- Have salt imbalance in the blood (low level of potassium or magnesium in the blood)
- Have a history of heart attack
- Are taking vitamin K antagonist

- Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription. You may need to use different amounts of these medicines, or you may need to take different medicines. Your doctor will advise you. In particular, tell your doctor if you take any of the following:

- Antacids containing magnesium or aluminium (for acid or heartburn)
- Sucralfate (for stomach ulcers)
- Metal cations
- Multivitamins
- Theophylline (used for breathing problems)
- Non-Steroidal Anti-Inflammatory drugs (used for pain and inflammation)
- Antidiabetic agents
- Probenecid (used for gout)
- Cimetidine (used for ulcers and heartburn)
- Cyclosporin (used after organ transplants)
- Drugs known to cause abnormal heart rate
- Warfarin (anticoagulant)
- Thyroid medication
- Caffeine

Levofloxacin may also interfere with the results of the following laboratory or diagnostic testing:

- Urine tests for opiates

Pregnancy and lactation

Do not take this medicine if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

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

The doctor will prescribe a suitable dose according to your condition. The dose may vary from 250mg-500mg taken once daily depending on your condition.

There will be dosing adjustment if you have kidney impairment which will be advised by your doctor.

No dosing adjustment required for elderly or individuals with liver impairment.

- When to use it

The medications should be taken during meals or between meals.

- How long to use it

The administration of Olfovel should be continued for a minimum of 48 to 72 hours. Thus, continue taking Olfovel for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it almost time for your next dose, wait until then to take the medicine and skip the missed dose. 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 think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause confusion, dizziness, impairment of consciousness, convulsive seizures, abnormal heart rate, nausea and mucosal erosions (ulcer).

While you are using it

- Things you must do

- Always take Olfovel exactly according to the instructions given by your doctor or pharmacist. Check with your doctor or pharmacist if you are unsure.
- Tell your doctor or pharmacist immediately if you notice any side effects, or if the side

effects gets serious or anything else that make you feel unwell.

- If you become pregnant, or plan on becoming pregnant while taking Olfovel tell your doctor immediately.
- If you are about to be started on new medicine, remind your doctor and pharmacist that you are taking Olfovel.

- Things you must not do

- Do not stop taking your medicines without consulting your doctor.
- Do not use Olfovel after the expiry date which is stated on the carton and bottle.
- Do not give this medication to anyone else, even if they have the same condition as you.

- Things to be careful of

• Driving and using machines:
Some side effects such as dizziness, drowsiness and visual disturbances may impair your ability to concentrate and react. Make sure you are not affected before you drive or operate machinery.

Side effects

Like many medicines, Olfovel tablets can cause side effects, although not everybody gets them.

Tell your doctor if you have any of these symptoms:

Blood and lymphatic system disorder

- Change in number of white blood cell, platelets, red blood cells and clotting factors
- Lymph nodes disease
- Inflammation & damage to blood vessels
- Swelling of clotted blood within tissue
- Nose bleed
- Blockage of an artery in the lungs
- Purpura (blood spot)

Infection and infestation

- Fungal and bacterial overgrowth
- Painful pus
- Viral/Fungal infection
- Inflammation of the middle ear

Immune system disorder

- Loss of circulation (anaphylactic-like shock)

Metabolism and nutrition disorder

- Change in glucose level
- Thirst
- Dehydration
- Electrolyte abnormality
- Loss of appetite
- Gout

- Increase of urea, biuret and ammonia
- Weight decrease

Psychotic disorder

- Nervousness
- Depression
- Confusional state
- Agitation
- Anxiety
- Hallucination
- Movement disorder
- Paranoia (delusion)
- Restlessness
- Impotence (erectile dysfunction)
- Nightmares
- Sleep disorder

Other special senses disorder

- Abnormality in the sense of smell
- Taste perversion

Reproductive disorder

- Menstrual cramps
- Thick, whitish/yellowish vaginal discharge

Central and peripheral nervous system disorder

- Dizziness
- Drowsiness
- Headache
- Seizure
- Tremor
- Tingling sensation
- Numbness
- Excessive physical sensitivity
- Hyperactivity
- Damaged motor neuron
- Involuntary muscle contractions
- Paralysis
- Speech disorder
- Unresponsive
- Brain dysfunction syndrome
- Abnormal walking pattern
- Leg cramps
- Build-up pressure around the brain
- Loss control of bodily movement
- Nerve cell damaged

Vision disorder

- Visual disturbances

Ear disorder

- Hearing impaired or disturbance

Cardiovascular disorder

- Change in blood pressure
- Shock
- Swelling
- Heart failure
- Chest pain / heart attack
- Flushing

- Blockage in the blood vessel of the brain
- Cell death
- Vein inflammation
- Abnormal heart rate or rhythm
- Heart block

Respiratory disorders

- Difficulty breathing
- Lung inflammation
- Coughing / coughing of blood
- Inflammation of the voice box
- Excess fluid around the lungs
- Respiratory depression
- Respiratory tract infection

Gastrointestinal system disorder

- Nausea
- Diarrhoea
- Vomiting
- Abdominal pain
- Indigestion
- Flatulence
- Constipation
- Dry mouth
- Difficulty in swallowing
- Inflammation of esophagus
- Inflammation of the lining of the stomach
- Digestive disorder
- Bleeding of digestive tract
- Intestinal obstruction
- Bloody diarrhea

Liver

- Abnormal liver function test results.
- Gall bladder inflammation
- Presence of gallstone
- Hepatitis
- Jaundice
- Acute liver failure

Urinary system disorder

- Abnormal kidney function
- Blood in urine
- Abnormally small amount of urine
- Involuntary leakage of urine
- Bladder failure
- Urinary tract infection

Skin and subcutaneous tissue disorders

- Itchiness
- Rash
- Photosensitivity reaction
- Swelling
- Skin cancer
- Alopecia (hair loss)
- Dry skin
- Eczema
- Increased sweating
- Skin exfoliation
- Blister

Musculoskeletal and connective tissue disorder

- Joint pain
- Muscle pain
- Tendon disorder
- Joint inflammation
- Degenerative joint disease
- Bone infection
- Skeletal pain
- Inflammation of the synovial membrane
- Muscle weakness

General disorder

- Lack of energy
- Fever
- Pain
- Fluid retention
- Allergic reaction
- Hot flashes
- Influenza-like symptoms
- Discomfort
- Chilliness
- Faint
- Multiple organ failure
- Changed temperature sensation
- Withdrawal syndrome
- Muscle weakness

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 Olfovel

Storage

Store in a cool, dry place below 30°C.
Protect from light.

Keep 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

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
Each tablet contains Levofloxacin Hemihydrate 512.5mg equivalent to Levofloxacin 500.0mg.

- Inactive ingredients
Red iron oxide, purified water, polyethylene glycol 6000, alcohol, talc, colloidal silicon dioxide, magnesium stearate, hydroxypropyl methylcellulose 2910 (E15), sodium starch glycolate, sodium lauryl sulfate, titanium dioxide, microcrystalline cellulose, yellow iron oxide.

- Packing

Aluminium-PVDC blister strip of 10 tablets per strip.
Box of 3x10, 5x10, 10x10 and 50x10 tablets.

- MAL Number

MAL11010021AZ

Manufacturer

T.O CHEMICALS (1979) CO. LTD.
280 Soi Sabaijai, Suthisarnwinijai Rd.,
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Product Registration Holder

IMEKS Pharma Sdn. Bhd.
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Date of revision

20/02/2018

Serial number

NPRA(R4/1)061217/00346