68mm

145mm

# VELOFT

**[Levofloxacin]**
**250mg, 500mg**
**Tablets, DS Tablets**

# ویلوفٹ

۲۵۰ ملی گرام، ۵۰۰ ملی گرام گولیاں

**QUALITATIVE AND QUANTITATIVE COMPOSITION:**
**VELOFT** (Levofloxacin) is available for oral administration as:
**1, VELOFT Tablet 250mg**
Each film coated tablet contains:
Levofloxacin Hemihydrate USP eq. to Levofloxacin.....250mg
(Product Specs.: USP)
**2, VELOFT DS Tablet 500mg**
Each film coated tablet contains:
Levofloxacin Hemihydrate USP eq. to Levofloxacin.....500mg
(Product Specs.: USP)

**CLINICAL PHARMACOLOGY:**
**Mechanism of Action:**
Levofloxacin is the L-isomer of the racemate, ofloxacin, a quinolone antimicrobial agent. The main mechanism of action of levofloxacin involves the inhibition of bacterial topoisomerase IV and DNA gyrase (both of which are type II topoisomerases.) Enzymes required for DNA replication, transcription, repair and recombination. It is often bactericidal at concentrations equal to or slightly greater than inhibitory concentration. It is generally considered to be about twice as active as its isomer, ofloxacin.
**Microbiology:**
Levofloxacin has been shown to be active against the following micro-organism.
***Commonly susceptible species:***
**Aerobic Gram-positive bacteria:**
Staphylococcus aureus methicillin-susceptible, Staphylococcus saprophyticus, Streptococci group C and G, Streptococcus agalactiae, Streptococcus pneumoniae, Streptococcus pyogenes.
**Aerobic Gram-negative bacteria:**
Eikenella corrodens , Haemophilus influenzae, Haemophilus para-influenzae, Klebsiella oxytoca, , Morexella catarhalis, Pasteurella multocida, Proteus vulgaris,
Providencia rettgeri.
**Anaerobic bacteria:**
Peptostreptococcus
**Other:**
Chlamydophila pneumoniae, Chlamydophila psittaci, chlamydia trachomatis, Legionella pneumophila, Mycoplasma pneumoniae, Mycoplasma hominis, Ureaplasma urealyticum.
***Species for which acquired resistance may be a problem:***
**Aerobic Gram-positive bacteria:**
Enterococcus faecalis, Staphylococcus aureus, methicillin-resistant, Coagulase negative Staphylococcus spp.
**Aerobic Gram-negative bacteria:**
Acinetobacter baumanni, Citrobacter freundii, Enterobacter aerogenes, Enterobacter cloacae, Escherichia coli, Klebsiella pneumonia, Morganella morganni, Proteus mirabilis, Providencia stuartii, pseudomonas aeruginosa, Serratia marcescens.
**Anaerobic bacteria:**
Bacteroides fragilis, Clostridium difficile.
Levofloxacin has been shown to be active against Bacillus anthracis in vitro.
**Pharmacokinetics**
Levofloxacin is rapidly and almost completely absorbed with absolute bioavailability of 99% following oral use with peak plasma concentrations achieved within 1-2 hours of a dose. The mean volume of distribution of Levofloxacin ranges from 74 to 112 L after single or multiple 500mg doses indicating distribution into body tissues including the bronchial mucosa and lungs, but penetration into CSF is relatively poor. Levofloxacin is approximately 24% to 38% bound to plasma proteins. It is only metabolize to a small degree to in-active metabolites. The elimination half-life of Levofloxacin is 6 to 8 hours although this may be prolonged in patients with renal impairment. Approximately 87% of an administered dose was recovered as unchanged drug in urine within 48 hours, whereas less than 4% of the dose was recovered in feces in 72 hours, and less than 5% of an administered dose is recovered in the urine as desmethyl and N-oxide metabolites. It is not removed by hemodialysis or peritoneal dialysis. Levofloxacin is excreted largely as unchanged drug in the urine.
**Special Population:**
**Renal Insufficiency:**
Clearance of levofloxacin is substantially reduced and plasma elimination half-life is substantially prolonged in patients with impaired renal function (creatinine) clearance <50mL/min), requiring dosage adjustment in such patients to avoid accumulation, Neither hemodialysis nor continuous ambulatory peritoneal dialysis (CAPD) is effective in removal of levofloxacin from the body, indicating that supplemental doses of levofloxacin are not required following hemodialysis or CAPD.

**INDICATIONS:**
**VELOFT** (Levofloxacin) is indicated for the treatment of adults (> 18 years of age) with mild, moderate, and severe infections caused by susceptible strains of the designated micro-organisms in the conditions listed below:
- Acute bacterial sinusitis.
- Acute bacterial exacerbation of chronic bronchitis.
- Community-acquired pneumonia and nosocomial pneumonia.
- Complicated skin and skin structure infections.
- Uncomplicated skin and skin structure infections (mild to moderate) including abscesses, cellulitis, furuncles, impetigo, pyoderma, wound infections.
- Chronic bacterial prostatitis.
- Complicated urinary tract infections (mild to moderate).
- Uncomplicated urinary tract infections (mild to moderate).
- Acute pyelonephritis (mild to moderate).
- Inhalational anthrax, post exposure.

**DOSAGE AND ADMINISTRATION:**
**VELOFT** (Levofloxacin) Tablets 250mg and 500mg administered orally every 24 hours. **VELOFT** (Levofloxacin) Tablets should be administered at least two hours before or two hours after antacids containing magnesium, aluminium, as well as sucralfate, metal cations such as iron and multivitamin preparations with zinc or didanosine chewable/buffered tablets that may interfere with the gastrointestinal absorption of levofloxacin resulting in systemic levels considerably lower than desired
The dosage guidelines as per the infection are given as under:

**Dosage in adult patients with normal renal function (creatinine clearance >50mL/min)**

| Indication | Daily Dosage (mg) | Duration (Days) |
|---|---|---|
| Acute bacterial sinusitis | 500mg OD | 10 - 14 |
| Acute bacterial exacerbations of chronic bronchitis | 500mg OD | 7 - 10 |
| Community-acquired pneumonia | 500mg OD or b.i.d | 7 - 14 |
| Acute Pyelonephritis | 250mg OD | 10 |
| Complicated urinary tract infections | 250mg OD | 10 |
| Uncomplicated urinary tract infections | 250mg OD | 3 |
| Chronic bacterial prostatitis | 500mg OD | 28 |
| Uncomplicated skin and soft tissue infections | 500mg OD | 7-10 |
| Inhalation Anthrax (Post Exposure) | 500mg OD | 60 |

**Special populations:**
Dosage in adult patients with impaired renal function:
(creatinine clearance >50ml/min)

| Dosage in normal renal functions every 24 hours | Creatinine Clearance 20 to 49mL/min | Creatinine Clearance 10 to 19mL/min | Hemodialysis or Chronic Ambulatory Peritoneal Dialysis |
|---|---|---|---|
| 500mg | 500mg initial dose, then 250mg every 24 hours | 500mg initial dose, then 250mg every 48 hours | 500mg initial dose, then 250mg every 48 hours |
| 250mg | No dosage Adjustment | 250mg every 48 hours. If treating uncomplicated UTI, then no dosage adjustment is required | No information on dosing adjustment is available |

**CONTRAINDICATIONS:**
Levofloxacin is contraindicated in
- Patients with a history of hypersensitivity to this drug and/or other quinolone antibacterial.
- Children or growing adolescents.

**PRECAUTIONS:**

**WARNING:** Fluoroquinolones, including **VELOFT** are associated with an increased risk of tendinitis and tendon rupture in all ages. This risk is further increased in older patients usually over 60 years of age, in patients taking corticosteroid drugs, and in patients with kidney, heart or lung transplants. **VELOFT** should be discontinued if the patient experiences pain, swelling, inflammation or rupture of a tendon. Patients should be advised to rest at the first sign of tendinitis or tendon rupture, and to contact their healthcare provider regarding changing to a non-quinolone antimicrobial drug. symptoms of tendinitis.

**Discontinued VELOFT if;**
Pseudomembranous colitis is suspected, patient experiences symptoms of neuropathy, signs and symptoms of hepatic disease develop such as anorexia, jaundice, dark urine, pruritus or tender abdomen.
**Use VELOFT with caution in;**
Patients predisposed to seizures; such as patients with pre-existing central nervous system lesions, concomitant treatment with fenbufen, NSAIDs and theophylline, patients with G-6-phosphate dehydrogenase deficiency, psychotic patients, patients with known risk factors for prolongation of the QT interval.
Monitoring level with **VELOFT**,
Careful monitoring of blood glucose is recommended when use with hypoglycemic agent or with insulin, coagulation tests should be monitored when use with warfarin as concomitant used has been associated with increases of the International Normalized Ratio (INR) or prothrombin time and clinical episodes of bleeding.
- Adequate hydration of patients should be maintained to prevent the formation of highly concentrated urine.

**Pregnancy:**
**VELOFT** should be used during pregnancy only if the potential benefits justifies the potential risk to the fetus.
**Nursing Mothers:**
Because of the potential for serious adverse reactions from levofloxacin in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**DRUG INTERACTIONS:**
**Probenecid and cimetidine:** Caution should be exercised when levofloxacin is co-administered with drugs that affect the tubular renal secretion such as probenecid and cimetidine, especially in renally impaired patients.
**Cyclosporine:** The half-life of cyclosporine was increased by 33% when co-administered with levofloxacin.

**ADVERSE REACTIONS:**

Levofloxacin is usually well tolerated, However, following are the adverse effects reported during its therapy.
**Common:** Moniliasis, insomnia, headache, dizziness, dyspnea, nausea, diarrhea, constipation, abdominal pain, vomiting, dyspepsia, rash, pruritus, vaginitis, edema and chest pain.
**Less common:** anemia, thrombocytopenia, granulocytopenia, allergic reaction, hyperglycemia, hypoglycemia, depression, sleep disorder, anorexia, tremor, convulsions, abnormal gait, somnolence, cardiac disorders, gastritis, abdominal disorders ,pseudomembranous/C, defficile colitis, increased hepatic enzymes, tendonitis, myalgia, skeletal pain, abnormal renal function and acute renal failure.

**OVERDOSAGE:**
In the event of overdose, symptomatic treatment should be implemented ECG monitoring should be undertaken because of the possibility of QT interval prolongation. Antacids may be used for protection of gastric mucosa. Hemodialysis, including peritoneal dialysis and CPAD are not effective in removing levofloxacin from the body.

**INSTRUCTIONS:**
- Store below 30°C
- Protect from light & moisture
- Keep out of reach of children

***To be sold on prescription of a registered medial practitioner.***

**HOW SUPPLIED**
**VELOFT** (Levofloxacin) Tablets 250mg are available in pack of 10's.
**VELOFT** DS (Levofloxacin) Tablets 500mg are available in pack of 10's.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایت: دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔


SIGMA PHARMA

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SIGMA PHARMA International (Pvt.) Ltd.
E-50 North Western Industrial Zone,
Port Qasim Authority, Karachi-Pakistan.
www.sigmapharma.com.pk