

LEVOPYX

Levofloxacin Tablets USP 500mg

DESCRIPTION

Levopyx [Levofloxacin] is a synthetic broad-spectrum antibacterial agent for oral intravenous administration. Chemically, Levopyx [levofloxacin], a chiral fluorinated caboxyquinolone, is the pure (-)-(S)-enantiomer of the racemic drug substance ofloxacin. The chemical name is (-)-(S)-9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido(1,2,3-de)-1,4-benzoxazine-6-carboxylic acid hemihydrate.

COMPOSITION

Each film coated tablet contains:

Levofloxacin Hemihydrate USP

Eq. to Levofloxacin 500 mg

Excipients QS

Colour : Titanium Dioxide BP

PHARMACOLOGY

Pharmacological classification:

Broad and Medium Spectrum Antibiotics.

PHARMACOLOGICAL ACTION

Levopyx [Levofloxacin] bactericidal action results from interference with the enzymes topoisomerase IV and DNA gyrase, which are needed for the DNA replication, transcription, repair and recombination. Levopyx [Levofloxacin] is bactericidal in-vitro. Cross-resistance exists between Levopyx [Levofloxacin] and other fluoroquinolones in-vitro. Generally there is no cross-resistance between levofloxacin and other classes of antibacterial agents, due to the mechanism of action of levofloxacin. The antibacterial spectrum of levofloxacin cover many Gram-positive and Gram-negative bacteria. In vitro sensitivity does not affect vivo efficacy.

Gram-negative organisms : *Acinetobacter calcoaceticus*, *Enterobacter cloacae*, *Escherichia coli*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Moraxella catarrhalis*, *Proteus mirabilis* and *Pseudomonas aeruginosa*.

Gram-positive organisms: *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Streptococcus pyogenes* and *Streptococcus faecalis*.

Other organisms: *Chlamydia pneumoniae*, *Legionella pneumophila* and *Mycoplasma pneumoniae*.

PHARMACOKINETICS

Absorption:

After oral administration Levopyx [Levofloxacin] is rapidly and almost completely absorbed with peak plasma concentrations being obtained within one hour. Food has little effect on the absorption of Levopyx [levofloxacin] and the tablets may be taken during or between meals. The absolute bio availability is approximately 100%.

Distribution, Metabolism and Excretion:

Levopyx [Levofloxacin] is approximately 30-40% bound to serum protein. Steady-state is achieved within three days. Levopyx [Levofloxacin] is metabolised to a small degree to inactive metabolites being desmethyl levofloxacin and levofloxacin-N-oxide. The elimination half-life of Levopyx [Levofloxacin] is excreted largely unchanged, primarily via the kidney.

Distribution in tissues and fluids:

Levopyx [Levofloxacin] penetrates well into lung tissue, bone tissue, bronchial mucosa, epithelial lining fluid and blister fluid.

INDICATION

Levopyx [Levofloxacin] can be used in adults, in the treatment of the following bacterial infections: Acute exacerbations of chronic bronchitis: caused by H. Influenzae, K. pneumoniae, S. aureus, M. catarrhalis, E. coli, H. parainfluenzae or S. pneumoniae.

Pneumonia (community acquired): caused by H. influenzae, S. pneumoniae, S. aureus, M. catarrhalis, H. parainfluenzae, E. coli, Mycoplasma pneumoniae, Chlamydia pneumoniae or Legionella pneumophila.

Sinusitis: Caused by H. influenzae, S. pneumoniae, S. aureus, M. catarrhalis, or H. Parainfluenzae.

Urinary tract infections (complicated) and acute pyelonephritis: caused by E. coli, K. pneumoniae, S. faecalis, P. mirabilis, Enterobacter cloacae and P. aeruginosa.

Uncomplicated urinary tract infections in women: caused by E. coli, K. pneumoniae.

Skin and soft tissue infections (uncomplicated): caused by S. aureus, S. pyogenes, Acinetobacter calcoaceticus, E. cloacae, P. mirabilis, P. aeruginosa, E. coli, K. pneumoniae or S. faecalis.

Skin and soft tissue infection (complicated): caused by S. aureus, S. pyogenes, P. mirabilis, E. coli, K. pneumoniae, S. faecalis, E. cloacae, K. oxytoca. Intra-abdominal infections: caused by E. coli and anaerobic micro-organisms.

CONTRA-INDICATIONS

The use of Levopyx [Levofloxacin] is contra-indicated in hypersensitivity reactions to levofloxacin, other quinolones, or any other ingredient, Epilepsy, Patients with a history of tendon disorders associated with fluoroquinolone administration, children or adolescents (under 18 years of age), During pregnancy and lactation.

PRECAUTIONS

Caution should be exercised when using Levopyx [Levofloxacin] in patients prone to seizures, such as patients with pre-existing central nervous system lesion, being treated with fenbufen or nonsteroidal anti-inflammatory medicines or using medicines which lower the cerebral seizure threshold, such as theophylline, driving or operating machinery as the use of Levopyx [Levofloxacin] may alter the ability to drive or operate machinery, being tested for tuberculosis as Levopyx [Levofloxacin] inhibits the growth of Mycobacterium tuberculosis and therefore may give false-negative results in the bacteriological diagnosis of tuberculosis, exposed to ultraviolet light such as sunlight through window glass of longer wavelength ultraviolet (UVA) from sun beds, in order to prevent photosensitization.

INTERACTIONS

The absorption of Levopyx [Levofloxacin] is significantly reduced when administered with iron salts, antacids and sucralfate. It is recommended that preparations containing iron salts, sucralfate, magnesium- or aluminium-containing antacids should not be taken two hours before or after Levopyx [Levofloxacin] tablet administration.

Levopyx [Levofloxacin] is known to inhibit hepatic medicine metabolism and may interfere with the clearance of medicines, such as theophylline, fenbufen or similar non-steroidal anti-inflammatory medicines that lower the seizure threshold.

SIDE EFFECTS

Adverse reactions with Levofloxacin therapy include fungal overgrowth and proliferation of other resistant micro-organisms, eosinophilia, leucopenia, neutropenia, thrombocytopenia, Agranulocytosis, haemolytic anaemia, pancytopenia, anaphylactic-like shock hypoglycaemia, particularly in diabetic patients, insomnia, agitation, anxiety, confusion, depression, psychotic reactions, hallucinations, psychotic headache, dizziness/vertigo, drowsiness paraesthesia, tremor, convulsions hypoaesthesia, disturbances of taste and smell, visual and auditory disturbances, visual disturbances, auditory disturbances, hypotension allergic pneumonitis, nausea, diarrhea anorexia, vomiting, abdominal pain, dyspepsia, hepatitis, pruritus, rash, angio-oedema, photosensitivity reactions, arthralgia, myalgia, rhabdomyolysis, acute renal failure, interstitial nephritis.

DOSAGE AND DIRECTIONS FOR USE

Levopyx [Levofloxacin] tablets should be swallowed whole, without crushing. Levopyx [Levofloxacin] may be taken on an empty stomach or with meals. Levopyx [Levofloxacin] is to be taken once or twice daily in a usual dose of 250 or 500 mg.

PRESENTATION

1X10 Alu-Alu blister pack.

STORAGE

Store in a cool & dry place
Protected from light.

Keep all medicines out of reach of Children