Quixin

Levofloxacin

COMPOSITION

Quixin: Each tablet contains Levofloxacin Hemihydrate INN equivalent to Levofloxacin 500 mg.

PHARMACOLOGICAL INFORMATION

Pharmacological Action

Quixin (Levofloxacin) is a synthetic, broad-spectrum, third generation fluoroquinolone antibiotic with proven activity against bacteria. It acts by inhibiting bacterial DNA gyrase enzyme.

Mechanism of Action

Quixin (Levofloxacin) blocks bacterial DNA synthesis by inhibiting bacterial topoisomerase II (DNA gyrase) and topoisomerase IV. Inhibition of DNA gyrase prevents the relaxation of positively supercoiled DNA that is required for normal transcription and replication. Inhibition of topoisomerase IV interferes with the separation of replicated chromosomal DNA into respective daughter cells during cell division.

Pharmacokinetic properties

Levofloxacin is rapidly and completely absorbed after oral administration. Peak plasma concentration are usually attained one to two hours after oral administration. The absolute bioavailability of a 500mg Levofloxacin tablet is approximately 99%, demonstrating complete oral absorption of Levofloxacin. Levofloxacin reaches its peak levels in skin tissues of healthy subjects at approximately 3 hours after dosing. After oral administration, approximately 87% of an administrated dose as recovered as unchanged drug in urine within 48 hours. No Levofloxacin crystals were found in any of the urine samples freshly collected from subjects receiving Levofloxacin.

CLINICAL INFORMATION

Therapeutic Indications

Quixin (Levofloxacin) is used for the treatment of single or mixed infections caused by two or more susceptible organisms. It is recommended for the following indications:

- Acute maxillary sinusitis
- Acute bacterial exacerbation of chronic bronchitis
- Community-acquired pneumonia
- Complicated urinary tract infections
- Acute pyelonephritis
- Uncomplicated & complicated skin and soft tissue infections
- Uncomplicated & complicated urinary tract infections

Dosage and Administration

Indications	Daily Dose	Duration
Acute sinusitis	500 mg	10-14 days
Acute Exacerbation of chronic bronchitis	250-500 mg	7 days
Community-acquired pneumonia	500 mg	7-14 days
Complicated urinary-tract infections and acute pyelonephritis	250 mg	7-10 days
Uncomplicated skin and soft-tissue infections	500 mg	7-10 days
Complicated skin and soft-tissue infections	750 mg	7-14 days

Use in Pregnancy & Lactation

Pregnant women: In animal studies Levofloxacin does not appear to be teratogenic but it may damage developing cartilage. Levofloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactating mother: Levofloxacin does cross into the breast milk and its use during lactation is not advised.

Use in Children

Not recommended for children.

Use in Elderly

Although higher Levofloxacin serum levels is found in elderly, no dosage adjustment is necessary.

Use in patient with impaired liver function

In studies in patients with stable chronic cirrhosis, no significant changes in Levofloxacin pharmacokinetics have been observed. The kinetics of Levofloxacin in patients with acute hepatic insufficiency, however, has not been fully evaluated.

Use in patient with impaired renal function

Dosage adjustments are usually not required, except in patients with severe renal impairment (creatinine clearance <20 ml/minute). If adjustment is necessary, this may be achieved by reducing the total daily dose by half.

Side Effects

Levofloxacin is generally well tolerated. However, a few side effects can usually be seen. Side effects include: nausea, vomiting, diarrhea, abdominal pain, flatulence and rare occurrence of photo-toxicity (0.1%). Side effects that may be seen very rarely include tremors, depression, anxiety, confusion etc.

Contraindications

Levofloxacin is contraindicated in patients with a history of hypersensitivity to Levofloxacin, quinolones or any other components of this product.

Drug Interaction

Antacids, Iron and Adsorbents-reduce absorption of Levofloxacin. NSAIDs may increase the risk of CNS stimulation. Concomitant administration of Levofloxacin and Warfarin may increase the risk of bleeding.

Over Dosage & Treatment

In the event of acute, excessive oral overdosage, reversible renal toxicity has been reported in some cases. Therefore, apart from routine emergency measures, it is recommended to monitor renal function and to administer Mg or Ca-containing antacids which reduce the absorption of Levofloxacin.

PHARMACEUTICAL INFORMATION

Storage Conditions

Store below 30°C and dry place, away from light. Keep out of the reach of children.

Presentation & packaging

Quixin: Each commercial box contains 30 tablets in Alu-PVDC blister pack.

Manufactured By
BEACON®
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