

PRESCRIBING INFORMATION

**Gen-Levo 250mg & 500mg Tablets
(Levofloxacin) IV Infusion**

Composition:

Gen-Levo 250mg Tablets
(Levofloxacin Tablets USP)
Each film coated tablet contains:
Levofloxacin (as Levofloxacin Hemihydrate) ...USP ...250mg

Gen-Levo 500mg Tablets
(Levofloxacin Tablets USP)
Each film coated tablet contains:
Levofloxacin (as Levofloxacin Hemihydrate) ...USP ...500mg

Gen-Levo IV Infusion
Each 100ml contains:
Levofloxacin (as Levofloxacin Hemihydrate) ...USP ...500mg
Mfg. Specs. Brookes

Description:
Gen-Levo (Levofloxacin) is a synthetic broad spectrum anti-bacterial agent. Chemically it is a chiral fluorinated carbonylquinolone. Gen-Levo acts by inhibiting DNA-gyrase. Gen-Levo is bactericidal and has activity against many gram +ve, gram -ve and Anaerobic bacteria.

Indications:

- Acute & Chronic Sinusitis
- Community acquired pneumonia
- Complicated Skin & Soft tissue Infections
- Acute Pyelonephritis
- Acute & Chronic Bronchitis
- Nosocomial pneumonia
- Complicated & Uncomplicated UTI
- Typhoid & paratyphoid fever

Dosage:
Gen-Levo Tablets are administered once or twice daily depending on type and severity of infection. Gen-Levo Infusion is given intravenous slowly depending on the dosage. Gen-Levo infusion is administered IV in one hour to avoid complication. The dosage schedule of Gen-Levo Tablets and Infusion is given below as per indications.

Indications	Daily Dose	Its Duration
Acute & Chronic Sinusitis	250mg Twice Daily 500mg Once Daily	18-34 Days
Acute & Chronic Bronchitis	250mg Twice Daily 500mg Once Daily	7-Days
Community acquired pneumonia	750mg Once Daily	7-8Days
Nosocomial pneumonia	750mg Once Daily	7-8 Days
Complicated Skin & Soft tissue infections	750mg Once Daily	7-10 Days
Complicated & Uncomplicated UTI	250mg Twice Daily 500mg Once Daily	5-7 Days
Acute Pyelonephritis	250mg Twice Daily 500mg Once Daily	20-Days
Typhoid & paratyphoid fever	250mg Twice Daily 500mg Once Daily	30-Days

Contra-Indications:
Gen-Levo (Levofloxacin) is contraindicated in cases of hypersensitivity to the active ingredient or any other quinolone. Gen-Levo (Levofloxacin) is also not used in Children & Adolescence below the age of 18years.

Side-Effects:

Gen-Levo is usually well tolerated. Following are the few adverse effects reported during therapy with Gen-Levo (Levofloxacin). Allergic reactions (anaphylactic/anaphylactoid reactions), Skin reactions e.g. itching and rash, Nausea, diarrhoea, loss of appetite, abdominal pain, dyspepsia, Headache, vertigo, dizziness, sleeping problems, paraesthesia e.g. like tingling in the hands, restlessness, anxiety, and confusions, drop of blood pressure, tendon pain, tendon rupture (Achilles Tendon), this side effect may occur within 48 hours after starting treatment and may be bilateral. Muscular weakness, which may be of special importance in patients with Myasthenia Gravis (a rare disease of nervous systems), increased levels of liver enzymes (e.g. ALT, AST), increased level of bilirubin and serum creatinine, up to kidney failure, Eosinophilia, decrease in the number of white blood cells (leucopenia).

Precautions:

General:

- Serious and occasionally hypersensitivity and/or anaphylactic reactions have been reported in patients receiving therapy with quinolone, including Gen-Levo and should be discontinued immediately.
- Excessive exposure to sunlight should be avoided. Therapy should be discontinued if skin eruptions occurs.
- Although Gen-Levo is more soluble than other quinolones, adequate hydration of patients receiving Gen-Levo should be maintained to prevent the formation of highly concentrated urine.

Renal Insufficiency:

Gen-Levo should be administered with caution in the presence of renal insufficiency. Careful clinical observation and appropriate laboratory studies should be performed prior to and during therapy since elimination of Gen-Levo may be reduced. In patients with impaired renal function (creatinine clearance <50ml/min) adjustment of the dose regimen is necessary to avoid the accumulation of Gen-Levo due to decreased clearance.

Paediatric use:

Safety and effectiveness of Gen-Levo in individuals below 10years of age have not been established.

Pregnancy:

There are no adequate and well-controlled studies available for Gen-Levo use in pregnant women.

Drug Interactions:

Concurrent Antacids, Sucralfate, Metal Cations, Multivitamins may interfere with the gastrointestinal absorption of Gen-Levo Tablets. These agents should be taken at least 2 hours before or after Gen-Levo administration. The concomitant administration of a NSAID's with a quinolone, including Gen-Levo, may increase the risk of CNS stimulation and convulsive seizures.

Overdosage:

Gen-Levo (Levofloxacin) exhibits a low potential for acute toxicity. In the event of an acute overdosage, the stomach should be emptied. The patient should be observed and appropriate hydration maintained. Gen-Levo is not efficiently removed by hemodialysis or peritoneal dialysis.

Storage:

Gen-Levo 250mg Tablets:

Gen-Levo 500mg Tablets:

Store at temperature below 30 °C away from light and moisture.

Gen-Levo IV Infusion:

Store at temperature below 30 °C away from light.

Presentation:

Gen-Levo 250mg Tablets are available in blister pack of 30 Tablets
 Gen-Levo 500mg Tablets are available in blister pack of 30 Tablets
 Gen-Levo IV Infusion is available in 100ml Glass vial with carton.



Manufactured by:

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