



MSDS: Levofloxacin Injection, 25 mg/mL

Manufacture: Akorn Incorporated
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Section 1 - IDENTIFICATION

Common/Trade Name: Levofloxacin Injection

Chemical Name of Active Ingredient: (-)-(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
Molecular Formula = $C_{18}H_{20}FN_3O_4 \cdot \frac{1}{2}H_2O$
Molecular Weight = 370.38 g/mole

Date Prepared: 08-09-11

Category: Prescription Only. Levofloxacin Injection is a synthetic broad spectrum antibacterial agent for intravenous administration.

Section 2 – HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

Component	CAS#	Amount
Levofloxacin	138199-71-0	25.0 mg/mL
Sodium Hydroxide, NF	1310-73-2	QS
Hydrochloride Acid, NF	7647-01-0	QS
Water for Injection, USP	7732-18-5	QS

Section 3 – HEALTH HAZARD DATA

Routes of Entry: Intended for parenteral use. Levofloxacin Injection is contraindicated in persons with a history of hypersensitivity to levofloxacin, quinolone antimicrobial agents or any other component of the drug product.

Carcinogenicity: *NTP:* No *IARC:* No *OSHA Regulated:* No

Section 4 – FIRST AID MEASURES

Eyes: May cause irritation. Flush with copious amounts of water. Seek medical advice.

Skin: May cause irritation. Flush with copious amounts of water. Seek medical advice.

Inhalation: May cause irritation. Remove to fresh air. Seek medical advice.

Ingestion: May cause irritation. Flush out mouth with copious amounts of water.
Levofloxacin is rapidly absorbed from the gastrointestinal tract. Seek medical advice.

Section 5 – FIRE FIGHTING MEASURES**FIRE AND EXPLOSION DATA**

Closed Cup Flash Point:	Not Established
Open Cup Flash Point:	Not Established
Fire Point:	Not Established
Auto ignition:	Not Established
Lower Explosion Limit:	Not Established
Upper Explosion Limit:	Not Established
General Hazard:	Evacuate personnel to a safe area. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.
Fire Fighting Instructions:	Use water spray, dry chemical, carbon dioxide or foam extinguishing media as appropriate for surrounding fire and materials.
Fire Fighting Equipment:	Firefighters should use self-contained breathing equipment and protective clothing to prevent contact with skin and eyes.
Hazardous Combustion Products:	May emit toxic fumes

Section 6 – ACCIDENTAL RELEASE MEASURES

Clean-Up: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using an absorbent material. Place in a appropriately-labeled container for proper disposal according to applicable local, state, and federal regulations. Wash the spill site thoroughly but do not allow large amounts of waste materials to enter drains or water courses.

Section 7 – HANDLING AND STORAGE

General Handling: Care should be taken to prevent contact with eyes and skin and from contaminating personal clothing. Use of gloves and safety glasses is recommended. Wash thoroughly after handling.

Storage Conditions: Store at controlled room temperature and protected from light.

Section 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: Use adequate ventilation. No extra accommodations are required in the home, hospital or clinical setting.

Personal Protective Equipment

Eye Protection:	Safety glasses or goggles
Hand Protection	Chemically-compatible gloves (ex: latex)
Respiratory Protection:	Adequate ventilation
Skin Protection:	Lab coat or other mechanism to protect exposed skin

Exposure Limits: Levofloxacin Injection should be used only as prescribed by a physician. Possible eye, skin, gastrointestinal and/or respiratory tract irritation can occur. Hypersensitivity reactions can be serious.

Section 9 – PHYSICAL/CHEMICAL CHARACTERISTICS

Physical Form / Appearance:	Clear, yellow to greenish-yellow solution
Boiling Point / Boiling Range:	Aqueous
Melting Point / Melting Range:	Not Applicable
Freezing Point:	Aqueous
Vapor Pressure:	Aqueous
Relative Vapor Density:	Not Established
Percent Volatiles:	Not Established
pH:	3.8 to 5.8
Specific Gravity:	~1.01 @ 25°C
Solvent Solubility:	Miscible with water
Latex Free:	Yes

Section 10 – STABILITY AND REACTIVITY

Stability:	Stable
Conditions to Avoid:	Prolonged light exposure
Hazardous Polymerization:	Will not occur

Section 11 – TOXICOLOGICAL INFORMATION

Signs & Symptoms of Exposure & Overexposure:

Convulsions and toxic psychoses have been reported in patients receiving quinolones, including levofloxacin. Quinolones may also cause increased intracranial pressure and central nervous system stimulation which may lead to tremors, restlessness, anxiety, lightheadedness, confusion, hallucinations, paranoia, depression, nightmares, insomnia, and, rarely, suicidal thoughts or acts. These reactions may occur after the first dose.

Serious and occasionally fatal hypersensitivity or anaphylactic reactions have been reported in patients receiving therapy with quinolones, including levofloxacin. Some reactions have been accompanied by cardiovascular collapse, hypotension/shock, seizure, loss of consciousness,

tingling, angioedema (including tongue, laryngeal, throat, or facial edema/swelling), airway obstruction (including bronchospasm, shortness of breath, and acute respiratory distress), dyspnea, urticaria, itching and other serious skin reactions.

Clinical manifestations of sensitivity may include: fever, rash or severe dermatologic reactions, vasculitis, arthralgia, myalgia, serum sickness, allergic pneumonitis, interstitial nephritis, acute renal insufficiency or failure, hepatitis, jaundice, acute hepatic necrosis or failure, anemia (including hemolytic and aplastic), thrombocytopenia (including thrombocytopenic purpura), leukopenia, agranulocytosis, pancytopenia, and/or other hematologic abnormalities.

Medical Conditions Aggravated by Exposure:

Levofloxacin should be used with caution in patients with a known or suspected CNS disorder that may predispose to seizures or lower the seizure threshold (e.g. severe cerebral arteriosclerosis, epilepsy, certain drug therapy, renal dysfunction). Levofloxacin should be administered with caution in the presence of renal insufficiency. Levofloxacin should be avoided in patients with known prolongation of the QT interval, patients with uncorrected hypokalemia, and patients receiving class 1A or class III antiarrhythmic agents.

It can be presumed that levofloxacin will be excreted in human milk. Levofloxacin should be used by nursing mothers only if the potential benefit justifies the potential risk to the infant. No adequate and well-controlled studies have been conducted in pregnant women. Levofloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Levofloxacin should be discontinued immediately

- at the first appearance of skin rash or any other hypersensitivity
- if the patient experiences symptoms of neuropathy or alterations of sensation
- if the patient experiences pain, inflammation or rupture of a tendon
- if a hypoglycemic reaction occurs
- if photosensitivity occurs

Acute Toxicity:

In animal testing, Levofloxacin exhibited no carcinogenic potential nor did it cause impairment of fertility or reproductive performance. It was not mutagenic or teratogenic.

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dosage</u>
Levofloxacin	LD ₅₀	rat	oral	~1478 mg/kg
	LD ₅₀	mouse	oral	~1803 mg/kg
	LD ₅₀	monkey	oral	> 250 mg/kg

Section 12 – TRANSPORTATION INFORMATION

Not Restricted

Section 13 – DISPOSAL INFORMATION

Disposal Procedure: Dissolve or mix with a combustible material and burn in a chemical incinerator. Observe all federal, state and local environmental regulations.

Section 14 – ENVIRONMENTAL IMPACT INFORMATION

Not Available

Section 15 – REGULATORY INFORMATION

Hazard Code: Xn, Harmful
Risk Phrases: R20/22, R36/37/38, R42/43
Safety Phrases: S22, S24/25, S36/37/39, S46, S61
ASRA: Section 313 Not Listed
Section 355 Not Listed
TSAC: Not Listed
IARC: Not Listed

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