

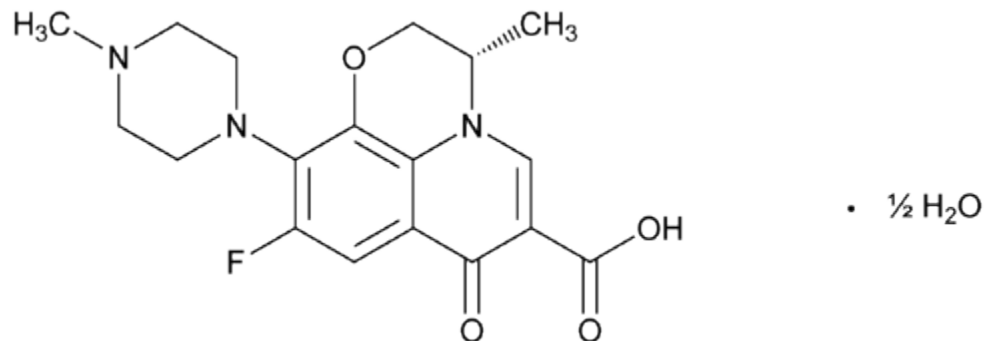
1. PRODUCT AND COMPANY INFORMATION

Distributed By: WG Critical Care, LLC.
120 Route 17 North
Suite 115
Paramus, NJ 07652 USA

Product Name: **Levofloxacin Injection in 5% Dextrose**

**Common name/
Trade Name:** Levofloxacin

Structure:



Chemical Name: (1) 7HPyrido[1,2,3-de]1,4-benzoxazine-6-carboxylic acid, 9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxohydrate(2:1), (S);
(2) (-)-(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:** C₁₈H₂₀FN₃O₄·1/2H₂O

UNII Code: UNII6GNT3Y5LMF; UNIIIRIX4E89Y14[anhydrous].

CAS Number: 138199-71-0; 100986-85-4 [anhydrous]

Chemical Family: Anti-infective (Antibacterial)

Product Use: Pharmaceutical

Product Type: Prescription Drug

**Container
Information:** Plastic Bags

Customer Service Phone Number: +1-888-493-0861

Emergency Phone Number: +1-866-562-4708 (Prosar)

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2. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>Weight %</u>	<u>CAS No.</u>
Levofloxacin	5mg/ml	138199-71-0; 100986-85-4 [anhydrous]

3. HAZARDS IDENTIFICATION

ROUTES OF ENTRY: Skin Contact: Causes skin irritation; Skin Absorption: May be harmful if absorbed through the skin. Eye Contact: Causes eye irritation. Inhalation: Material is irritating to mucous membranes and upper respiratory tract. May be harmful, if inhaled; Ingestion: Harmful if swallowed.

CHEMICAL LISTED AS CARCINOGEN: NTP: NO IARC: NO OSHA: NO

4. FIRST AID MEASURES

EYE EXPOSURE: Flush eyes with copious amounts of water

SKIN EXPOSURE: Rinse the exposed area with copious amount of water for 15 minutes

INGESTION: If swallowed, do not induce vomiting unless directed by the physician. Never give anything by mouth to an unconscious person. Loosen tight clothing such as collar, tie, belt or waistband. Get medical attention immediately

INHALATION: If inhaled, remove to fresh air. Get medical attention if symptoms appear

5. FIRE FIGHTING MEASURES

FLASH POINT: Not Available

AUTO-IGNITION TEMPERATURE: Not Available

FLAMMABLE LIMITS IN AIR: Not Available

FLAMMABLE LIMITS: Not Available

EXTINGUISHING MEDIA: Water spray, Carbon Dioxide, foam or dry powder

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**UNUSUAL FIRE / EXPLOSION
HAZARDS:**

Levofloxacin Hemihydrate is assumed to be combustible.

6. ACCIDENTAL RELEASE MEASURE

- SPILL:** Collect all of the material with protective equipment. Place this material in a clean and dry container. Wear appropriate personal equipment as described in Section 8.
- RELEASE TO AIR:** Ventilate area of leak or spill
- RELEASE TO WATER:** Refer to local water authority. Drain disposal is not recommended. Please refer to all local, state, and federal disposal guidelines.

7. HANDLING AND STORAGE

- GENERAL HANDLING:** Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical and home environment.
- STORAGE CONDITIONS:** Store product or below 25 °C (77°F): however, brief exposure up to 40°C (104°F) does not adversely affect the product. Protect from light. Avoid excessive heat and protect from freezing .

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

RESPIRATORY PROTECTION: Respiratory Protection: When working with small quantities in a well-ventilated area, respiratory protection may not be required. The use of an approved dust mask is recommended.

EYE PROTECTION: Safety goggles.

VENTILATION Provide exhaust ventilation or other engineering controls.

SKIN PROTECTION: Protective gloves.

OTHER PROTECTIVE EQUIPMENT: Vapor respirator, rubber boots and rubber gloves.

ADDITIONAL EXPOSURE PRECAUTIONS: None.

9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE:	Liquid	EVAPORATION RATE:	Not Available
APPEARANCE AND ODOR:	Light yellow solution, free from any particulates	MELTING POINT:	224 ⁰ – 229 ⁰ C
BOILING POINT:	Not Available	pH:	3.8 – 5.8
VAPOR PRESSURE:	Not Available		
VAPOR DENSITY:	Not Available		

10. STABILITY AND REACTIVITY

STABILITY: Stable under normal conditions of temperature and pressure.

INCOMPATIBILITY : (MATERIALS TO AVOID) Strong oxidizing agents.

HAZARDOUS POLYMERIZATION: Not available.

HAZARDOUS DECOMPOSITION: High temperatures can cause the release of fumes containing toxic gases of COx, NOx and HF

CONDITIONS TO AVOID: Heat, moisture and incompatible materials.

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11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY

COMPONENT	TYPE	ROUTE	SPECIES	DOSAGE
Levofloxacin	LD50	Oral	Rat	503 mg/kg
Levofloxacin	LD50	Oral	Mouse	285 mg/kg
Levofloxacin	LD50	Oral	Monkey	>250 mg/kg

12. ECOLOGICAL INFORMATION

No applicable ecological information found or determined for ecotoxicity, bioaccumulative potential, mobility in soil, persistence and degradability.

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL: Dispose all materials and waste residue in accordance with all applicable Federal, State and Local regulations.

14. TRANSPORT INFORMATION

REGULATORY ORGANIZATIONS:

DOT: Not Regulated

ICAO / IATA: Not Regulated

IMO: Not Regulated

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15. REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible WG Critical Care use. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your city / state / country.

US Regulations

TSCA – No

CERCLA-No

SARA 302 – No

SARA 313 – No

OSHA Substance Specific - No

16. OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

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