Safety Data Sheet
Levofloxacin Tablet

Strength: 250/500/750 mg. **Pack Size:** 50/100/500 Tablets per bottle (250/750mg)

50/100/500/1000Tablet/bottle (500mg) **Revision No.:** 02

EMERGENCY OVERVIEW

Levofloxacin Tablets contain Levofloxacin and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Section 1. Identification

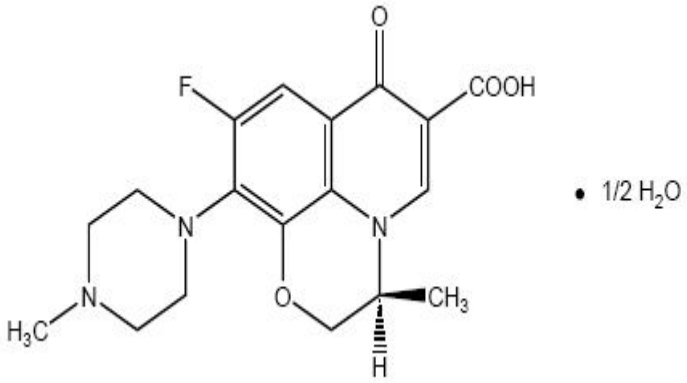
Identification of the product

Product name: Levofloxacin Tablet

Formula: $C_{18}H_{20}FN_3O_4 \cdot ½ H_2O$

Chemical Name: (-)-(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.

Therapeutic Category Antibacterial



Manufacturer / supplier identification

Company: **Cadila Healthcare Ltd. Ahmedabad, India**

Address: Sarkhej – Bavla. N.H. 8A, Moraiya. Tal. Sanand. Dist. Ahmedabad – 382210. State: Gujarat. India

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Recommended use / Therapeutic Category Antibacterial

Restriction on Use / Contraindications: Levofloxacin tablet is contraindicated in persons with known hypersensitivity to levofloxacin, or other quinolone antibacterials.

Section 2. Hazard(s) Information

Dose and Administration

Dosage in Adult Patients with Normal Renal Function

The usual dose of levofloxacin tablets is 250 mg, 500 mg, or 750 mg administered orally every 24 hours, as indicated by infection and described in below Table.

These recommendations apply to patients with creatinine clearance ≥ 50 mL/min. For patients with creatinine clearance < 50 mL/min, adjustments to the dosing regimen are required

Type of Infection*	**Dose Every 24 hours**	**Duration (days)†**
Nosocomial Pneumonia	750 mg	7 to 14
Community Acquired Pneumonia‡	500 mg	7 to 14
Community Acquired Pneumonia§	750 mg	5
Acute Bacterial Sinusitis	750 mg	5
	500 mg	10 to 14
Acute Bacterial Exacerbation of Chronic Bronchitis	500 mg	7
Complicated Skin and Skin Structure Infections (SSSI)	750 mg	7 to 14
Uncomplicated SSSI	500 mg	7 to 10
Chronic Bacterial Prostatitis	500 mg	28
Complicated Urinary Tract Infection or Acute Pyelonephritis (AP)¶	750 mg	5
Complicated Urinary Tract Infection or Acute Pyelonephritis (AP)#	250 mg	10
Uncomplicated Urinary Tract Infection	250 mg	3
Inhalational Anthrax (Post-Exposure) Adults and Pediatric Patients > 50 kg and ≥ 6 months of age Þ,ß Pediatric Patients < 50 kg and ≥ 6 months of age Þ,ß	500 mg 8 mg/kg BID (not to exceed 250 mg/dose)	60 ß 60 ß

* Due to the designated pathogens.

† Sequential therapy (intravenous to oral) may be instituted at the discretion of the physician.

‡ Due to methicillin-susceptible Staphylococcus aureus, Streptococcus Pneumonia (including multi-drug-resistant strains [MDRSP]), Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Moraxella catarrhalis, Chlamydophila pneumoniae, Legionella pneumophila, or Mycoplasma pneumoniae

§ Due to Streptococcus pneumoniae (excluding multi-drug-resistant Strains [MDRSP]), Haemophilus influenzae, Haemophilus parainfluenzae, Mycoplasma pneumoniae, or Chlamydophila pneumoniae [see Indications and Usage.

¶ This regimen is indicated for cUTI due to Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis and AP due to E. coli, including cases with concurrent bacteremia.

This regimen is indicated for cUTI due to Enterococcus faecalis, Enterococcus cloacae, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa; and for AP due to E. coli.

Þ Drug administration should begin as soon as possible after suspected or confirmed exposure to aerosolized B. anthracis. This indication is based on a surrogate endpoint. Levofloxacin plasma concentrations achieved in humans are reasonably likely to predict clinical benefit.

ß The safety of levofloxacin tablets in adults for durations of therapy beyond 28 days or in pediatric patients for durations beyond 14 days has not been studied. An increased incidence of musculoskeletal adverse events compared to controls has been observed in pediatric patients [see Warnings and Precautions, Use in Specific Populations and Clinical Studies. Prolonged levofloxacin tablets therapy should only be used when the benefit outweighs the risk.

Adverse Effects

The following serious and otherwise important adverse drug effects,

- Tendon Disorders
- Exacerbation of Myasthenia Gravis
- Hypersensitivity Reactions
- Hepatotoxicity
- Convulsions, dizziness, lightheadedness
- Peripheral Neuropathies
- Prolongation of the QT Interval
- Musculoskeletal Disorders in Pediatric Patients
- Photosensitivity/Phototoxicity
- Blood Glucose Disturbances
- Photosensitivity/Phototoxicity
- Development of Drug Resistant Bacteria

Crystalluria and cylindruria have been reported with quinolones, including levofloxacin. Therefore, adequate hydration of patients receiving levofloxacin should be maintained to prevent the formation of a highly concentrated urine.

Over Dose Effect

In the acute overdosage, the stomach should be emptied .The patient should be observed and appropriate hydration maintained. following clinical signs after receiving a single high dose of levofloxacin: ataxia, ptosis, decreased locomotor activity, dyspnea, prostration, tremors, and convulsions.

Medical Conditions

Do not take levofloxacin if you have ever had a severe allergic reaction to an antibiotic known as a fluoroquinolone, or if you are allergic to any of the ingredients in levofloxacin tablets

- have tendon problems
- have a disease that causes muscle weakness (myasthenia gravis)
- have central nervous system problems (such as epilepsy)
- have nerve problems
- have or anyone in your family has an irregular heartbeat, especially a condition called “QT prolongation.”
- have low blood potassium (hypokalemia)
- have a history of seizures
- have bone and joint problems
- have kidney problems. You may need a lower dose of levofloxacin if your kidneys do not work well.
- have liver problems
- have rheumatoid arthritis (RA) or other history of joint problems
- are pregnant or planning to become pregnant. It is not known if levofloxacin will harm your unborn child.
- are breastfeeding or planning to breastfeed. Levofloxacin is thought to pass into breastmilk. You and your healthcare provider should decide whether you will take levofloxacin or breastfeed.

Contraindications

Levofloxacin tablet is contraindicated in persons with known hypersensitivity to levofloxacin, or other quinolone antibacterials

Pregnancy Comments

levofloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers:levofloxacin will be excreted in humanmilk Because of the potential for serious adverse reactions from levofloxacin in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pregnancy Category

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Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Levofloxacin hemihydrate equivalent to levofloxacin	Not Found	138199-71-0
Inactive ingredients :		
Crospovidone	Not Found	9003-39-8
Hypromellose	Not Found	9004-65-3
Magnesium stearate	Not Found	577-04-0
Microcrystalline cellulose	Not Found	9004-34-6
Polyethylene glycol 6000	Not Found	25322-68-0
Talc	Not Found	14807-96-6
Titanium dioxide.	Not Found	13463-67-7

Section 4. First aid measures

General

Inhalation

Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

contact with skin

Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

contact with eyes
Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice

Ingestion
If swallowed, wash out mouth with water, provided person is concious. Seek medical advice

Remove and wash/dispose of contaminated clothing promptly.

Overdose Treatment

In the event of an acute overdosage, the stomach should be emptied. The patient should be observed and appropriate hydration maintained.

Section 5. Fire – fighting measures

Flash point	Not Found	**Upper Flammable Limit:**	Not Found
Auto-Ignition Temperature:	Not Found	**Lower Flammable Limit:**	Not Found
Extinguishing Media	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	**Fire and Explosion Hazard**	This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build up of static electricity.

Fire Fighting Procedure As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

Spill Response Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

Section 7. Handling and Storage

Storage Store at 20° to 25° C (68° to 77° F)

Incompability No data available.

Section 8. Exposure controls / personal protection

Respiratory Protection Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.

Skin Protection Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.

Eye protection Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.

Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.

Section 9. Physical and chemical properties

Appearance	Levofloxacin Tablets, **250 mg** are white to off white, modified capsule shaped, biconvex, film-coated tablets debossed with logo of 'ZC55' on one side and plain on other side Levofloxacin Tablets, **500 mg** are white to off white, modified capsule shaped, biconvex, film-coated tablets debossed with logo of 'ZC56' on one side and plain on other side Levofloxacin Tablets, **750 mg** are white to off white, modified capsule shaped, biconvex, film-coated tablets debossed with logo of 'ZC57' on one side and plain on other side

Solubility in water	No Data Available	**Odour**	Odourless
Boiling point	No Data Available	**Melting Point**	No Data Available
Evaporation rate	No Data Available	**Vapour density**	No Data Available
Reactivity in water	No Data Available	**Evaporation rate**	No Data Available
Percentage Volatile by volume	No Data Available	**Specific gravity**	No Data Available
Vapour pressure	No Data Available		
Other information	Not Applicable		

Section 10. Stability and Reactivity

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	**Stable**	Stable under normal ambient and anticipated storage and handling conditions.
Decomposition Products	No Data Available	**Hazardous Reaction**	No data available.
Incompatibilities	No data available.		

Section 11. Toxicological information

General Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.

Target organ Eye contact, Skin contact and inhalation is not great risk as this product is tablet.

Other Not Applicable

Section 12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil

Section 13. Disposal Consideration

Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea(IMDG).

Section 15. Regulatory Information

Generic Medicine. Approved by USFDA & the ANDA Number is 077652

Section 16. Other information

None

Date of issue: 28/05/2015 **Supersedes edition of:** 01

The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.