

DATE: 12/10/2009

GENERIC NAME: Ciprofloxacin Tablets 250mg, 500mg and 750mg

BRAND EQUIVILANT: CIPRO®

SECTION 1: CHEMICAL PRODUCT & COMPANY IDENTIFICATION

Common Name Ciprofloxacin Tablets USP

Synonyms Ciprofloxacin Hydrochloride Tablets

Formula $C_{17}H_{18}FN_3O_3.HCl.H_2O$

CAS Number 86393-32-0

Therapeutic Category Antibiotic

Chemical Name 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-

piperazinyl)-3-quinolinecarboxylic acid monohydrochloride, monohydrate

Additional Names N/A

Manufacturer Name & Address Unique Pharmaceutical Laboratories

(A Div. of J. B. Chemicals & Pharmaceuticals Ltd)

Meelam Centre

Worli, Mumbai 400016, INDIA

Distributor Name & Address PACK Pharmaceuticals, LLC

1110 W. Lake Cook Rd., Ste. 301

Buffalo Grove, IL 60089

Emergency Telephone No. (800) 521-5340

Adverse Reactions/Product Compliant/Inquires (866) 562-4597

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

This material is not subject to the Fedral OSHA Hazard Communication Standard 29 CFR 1910.1200

LD50/(Oral) Not Applicable

SECTION 3: HAZARDS IDENTIFICATOIN

N/A





FIRST AID MEASURES **SECTION 4:**

> Use only as directed. See product packaging for General

> > further information concerning adverse effects and

drug interactions.

Eyes In case of contact flush with plenty of water for at

least 15 minutes. Contact a physician.

Skin Contact a physician if irritation develops. In case of

skin contact, wash affected areas with soap and

water.

SECTION 5: FIRE AND EXPLOSION DATA

> Flash Point Not Applicable

Explosion Sensitivity to Impact None Known

None Known **Explosion Sensitivity to Static Electricity**

Combustible Material Not Applicable

Explosive Material Not Applicable

Flammable Material None Known

Pyrophoric Material Not Applicable

Hazardous Combustion Products Will not occur

SECTION 6: ACCIDENTAL RELEASE MEASURES

> Spills/Leaks Spills should be swept up and placed in appropriate

> > containers for disposal. Prevent from entering open

drains and waterways. Avoid creating dusty

conditions.

SECTION 7: HANDLING & STORAGE

> Handling Keep this and all drugs out of reach of children. Wash

> > thoroughly for handling. Store in a dry place away from excessive heat. Containers should be kept tightly

closed to prevent contamination. Use normal

precautions for storage of a drug. Avoid contact with

eyes, with skin or clothing.

Storage Store at 86° F (30°C)



SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Engineering Control Not Applicable

Respiratory Protection A NIOSH approved dust respirator should be worn if

inhalation of dust is a problem.

Skin Protection Lab coat. Employees should wash their hands and

face before eating, drinking or using tobacco products. Gloves, long sleeved shirts and pants

Eye Protection None for Normal use.

SECTION 9: PHYSICAL DATA

Melting Point Not Applicable

Solubility in Water Soluble

Solubility in org. solvents

Not Established

Molecular Weight Not Applicable

Appearance White to slightly yellowish

Odor Odorless

SECTION 10: STABILITY & REACTIVITY

Stability Stable

Hazardous Decomposition Products These products are carbon oxides (CO, CO2),

nitrogen oxides (NO, NO2...), halogenated

compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

Reproductive Effects No adequate and well-controlled studies in pregnant

women

Carcinogenicity Long-term carcinogenicity studies in rats and mice

resulted in no carcinogenic or tumorigenic effects due to ciprofloxacin at daily oral dose levels up to 250 and 750 mg /kg to rats and mice, respectively (approximately 1.7- and 2.5- times the highest recommended therapeutic dose based upon mg/m2).

Mutagenicity In vitro resistance to ciprofloxacin develops slowly

by multiple step mutations.





Ecotoxicity No data available for this product

SECTION 12: ECOLOGICAL INFORMATION

Acute Aquatic Toxicity None Known

Degradability Not Applicable

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal Method Incineration is recommended. Waste disposal should

be in accordance with existing federal, state and local

environment control laws.

SECTION 14: TRANSPORTATION INFORMATION

This material is not classified as hazardous for transport.

SECTION 15: REGULATORY INFORMATION

Prescription only medication

NDCNumber/s: 250mg:

16571-141-10 (100ct)

500mg:

16571-142-10 (100ct) 16571-142-50 (500ct)

750mg:

16571-143-05 (50ct)

SECTION 16: OTHER INFORMATION

MSDS Preparation Information Created: 12/10/2009

Updated: 02/01/2011 **Updated: 06/06/2011**

DISCLAIMER

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