

MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Material	Imipramine Hydrochloride Tablets USP 10 mg, 25mg and 50mg
Manufacturer	Lupin Limited Goa 403 722 INDIA
Distributor	Lupin Pharmaceuticals, Inc. Harborplace Tower, 21 st Floor 111, South Calvert Street Baltimore, MD 21202 United States Tel. 001-410-576-2000 Fax 001-410-576-2221

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS	Quantity
Imipramine Hydrochloride	113-52-0	10 mg, 25mg and 50mg
Non-hazardous ingredients	-----	q.s.

3. HAZARDOUS IDENTIFICATION

Fire and Explosion

Assume that this product is capable of sustaining combustion.

Health

The concomitant use of monoamine oxidase inhibiting compounds is contraindicated. Hyperpyretic crises or severe convulsive seizures may occur in patients receiving such combinations. The potentiation of adverse effects can be serious, or even fatal. When it is desired to substitute imipramine hydrochloride tablets in patients receiving a monoamine oxidase inhibitor, as long an interval should elapse as the clinical situation will allow, with a minimum of 14 days. Initial dosage should be low and increases should be gradual and cautiously prescribed.

The drug is contraindicated during the acute recovery period after a myocardial infarction. Patients with a known hypersensitivity to this compound should not be given the drug. The possibility of cross-sensitivity to other dibenzazepine compounds should be kept in mind.

Environment

No information is available about the potential of this product to produce adverse environmental effects.

4. FIRST AID MEASURES**Ingestion**

If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention.

Inhalation

Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.

Skin Contact

Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.

Eye Contact

Flush eyes with plenty of water. Get medical attention.

NOTES TO HEALTH PROFESSIONALS

Treat according to locally accepted protocols.

Deaths may occur from overdosage with this class of drugs. Multiple drug ingestion (including alcohol) is common in deliberate tricyclic overdose. As the management is complex and changing, it is recommended that the physician contact a poison control center for current information on treatment. Signs and symptoms of toxicity develop rapidly after tricyclic overdose. Therefore, hospital monitoring is required as soon as possible.

Children have been reported to be more sensitive than adults to an acute overdosage of imipramine hydrochloride. An acute overdose of any amount in infants or young children, especially, must be considered serious and potentially fatal.

5. FIRE-FIGHTING MEASURES**Fire and Explosion Hazards**

Assume that this product is capable of sustaining combustion.

Extinguishing Media

Water spray, carbon dioxide, dry chemical powder or appropriate foam.

Special Firefighting Procedures

For single units (packages): No special requirements needed.

Hazardous Combustion Products

Hazardous combustion or decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labeled container for recovery or disposal.

7. HANDLING AND STORAGE

Handling	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
Storage	<p>Store at 25°C (77°F); excursions permitted to 15° - 30°C (59° - 86°F) [see USP Controlled Room Temperature]. Preserve in well-closed containers.</p> <p>Dispense in tight container (USP) with a child-resistant closure.</p>

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL & CHEMICAL PROPERTIES

Physical Form	<p>Imipramine Hydrochloride Tablets USP, containing 10 mg imipramine hydrochloride, are round, biconvex, yellow film-coated tablets debossed with "LU" on one side and "V11" on the other side.</p> <p>They are supplied as follows:</p> <table><tr><td>NDC 68180-311-01</td><td>Bottles of 100's</td></tr><tr><td>NDC 68180-311-02</td><td>Bottles of 500's</td></tr></table>	NDC 68180-311-01	Bottles of 100's	NDC 68180-311-02	Bottles of 500's
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MSDS : 037/ 00
Effective Date : 07/01/2010

Imipramine Hydrochloride Tablets USP, containing 25 mg imipramine hydrochloride, are round, biconvex, green film-coated tablets debossed with "LU" on one side and "V12" on the other side.

They are supplied as follows:

NDC 68180-312-01 Bottles of 100's

NDC 68180-312-02 Bottles of 500's

Imipramine Hydrochloride Tablets USP, containing 50 mg imipramine hydrochloride, are round, biconvex, reddish brown film-coated tablets debossed with "LU" on one side and "V13" on the other side.

They are supplied as follows:

NDC 68180-313-01 Bottles of 100's

NDC 68180-313-02 Bottles of 500's

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

ANIMAL PHARMACOLOGY & TOXICOLOGY

A. Acute: Oral LD₅₀ ranges are as follows:

Rat 355 to 682 mg/kg

Dog 100 to 215 mg/kg

Depending on the dosage in both species, toxic signs proceeded progressively from depression, irregular respiration and ataxia to convulsions and death.

B. Reproduction/Teratogenic: The overall evaluation may be summed up in the following manner:

Oral: Independent studies in three species (rat, mouse, and rabbit) revealed that when imipramine hydrochloride is administered orally in doses up to approximately 2-1/2 times the maximum human dose in the first 2 species and up to 25 times the maximum human dose in the third species, the drug is essentially free from teratogenic potential. In the three species studied, only one instance of fetal abnormality occurred (in the rabbit) and in that study there was likewise an abnormality in the control group. However, evidence does exist from the rat studies that some systemic and embryotoxic potential is demonstrable. This is manifested by reduced litter size, a slight increase in the stillborn rate, and a reduction in the mean birth weight.

12. ECOLOGICAL INFORMATION

No relevant studies identified.

13. DISPOSAL CONSIDERATION

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

14. TRANSPORT INFORMATION

The Material Safety Data Sheet (MSDS) should accompany all shipments for reference in the event of spillage or accidental release. Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labeling for air, maritime, or ground transport purposes.

15. REGULATORY INFORMATION

No information found.

16. OTHER INFORMATION

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Lupin shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this MSDS.