MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Material **Imipramine Pamoate Capsules**
75 mg, 100 mg, 125 mg & 150 mg

Manufacturer
Lupin Limited
Goa 403 722
INDIA

Distributor
Lupin Pharmaceuticals, Inc.
Harborplace Tower, 21st 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 Pamoate	10075-24-8	75 mg, 100 mg, 125 mg & 150 mg
Non-hazardous ingrédients	----------	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 Pamoate 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 Pamoate . 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 Store at 20°C to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Dispense in tight container (USP) with a child-resistant closure.

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 Imipramine Pamoate Capsules 75 mg are size “2” capsule with brown cap and brown body, imprinted with “LU” in black ink on cap and “U01” in black ink on body, containing pale yellow to yellow granular powder.

They are supplied as follows:
NDC 68180-314-06 Bottles of 30’s
NDC 68180-314-01 Bottles of 100’s

Imipramine Pamoate Capsules 100 mg are size “1” capsule with brown cap and dark yellow body, imprinted with “LU” in black ink

on cap and “U02” in black ink on body, containing pale yellow to yellow granular powder.

They are supplied as follows:
NDC 68180-315-06 Bottles of 30’s
NDC 68180-315-01 Bottles of 100’s

Imipramine Pamoate Capsules 125 mg are size “1” capsule with brown cap and light yellow body, imprinted with “LU” in black ink on cap and “U03” in black ink on body, containing pale yellow to yellow granular powder.

They are supplied as follows:
NDC 68180-316-06 Bottles of 30’s
NDC 68180-316-01 Bottles of 100’s

Imipramine Pamoate Capsules 150 mg are size “0” capsule with brown cap and brown body, imprinted with “LU” in black ink on cap and “U04” in black ink on body, containing pale yellow to yellow granular powder.

They are supplied as follows:
NDC 68180-317-06 Bottles of 30’s
NDC 68180-317-01 Bottles of 100’s

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

ANIMAL PHARMACOLOGY & TOXICOLOGY

A. *Acute:* Oral LD_{50}:
Mouse 2185 mg/kg
Rat (F) 1142 mg/kg
(M) 1807 mg/kg
Rabbit 1016 mg/kg
Dog 693 mg/kg (Emesis ED_{50})

B. *Subacute:*

Two three-month studies in dogs gave evidence of an adverse drug effect on the testes, but only at the highest dose level employed, i.e., 90 mg/kg (10 times the maximum human dose). Depending on the histological section of the testes examined, the findings consisted of a range of degenerative changes up to and including complete atrophy of the seminiferous tubules, with spermatogenesis usually arrested.

Human studies show no definitive effect on sperm count, sperm motility, sperm morphology or volume of ejaculate.

Rat
One three-month study was done in rats at dosage levels comparable to those of the dog studies. No adverse drug effect on the testes was noted in this study, as confirmed by histological examination.

C. *Reproduction/Teratogenic:*
Oral: Imipramine pamoate was fed to male and female albino rats for 28 weeks through two breeding cycles at dose levels of 15 mg/kg/day and 40 mg/kg/day (equivalent to 2 1/2 and 7 times the maximum human dose).

No abnormalities which could be related to drug administration were noted in gross inspection. Autopsies performed on pups from the second breeding likewise revealed no pathological changes in organs or tissues; however, a decrease in mean litter size from both matings was noted in the drug-treated groups and significant growth suppression occurred in the nursing pups of both sexes in the high group as well as in the females of the low-level group. Finally, the lactation index (pups weaned divided by number left to nurse) was significantly lower in the second litter of the high-level group.

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.