MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Material

Imipramine Pamoate Capsules
75 mg, 100 mg, 125 mg and 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 and 150 mg

3. HAZARD IDENTIFICATION

Fire and Explosion

Expected to be non-combustible

Health

Monoamine Oxidase Inhibitors (MAOIs)
The use of MAOIs intended to treat psychiatric disorders with imipramine pamoate or within 14 days of stopping treatment with imipramine pamoate is contraindicated because of an increased risk of serotonin syndrome. The use of imipramine pamoate within 14 days of stopping an MAOI intended to treat psychiatric disorders is also contraindicated.
Starting imipramine pamoate in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue is also contraindicated because of an increased risk of serotonin syndrome.

Myocardial Infarction
The drug is contraindicated during the acute recovery period after a myocardial infarction.

Hypersensitivity to Tricyclic Antidepressants
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 MEASURE

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

Medical Treatment	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.
OVERDOSAGE	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 MEASURE

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. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this

product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters.

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.

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 AND 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 AND TOXICOLOGY

A. Acute: Oral LD50:

Mouse	2185 mg/kg
Rat (F)	1142 mg/kg
(M)	1807 mg/kg
Rabbit	1016 mg/kg
Dog	693 mg/kg (Emesis ED50)

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 nopathological 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

IATA/ICAO - Not Regulated

IATA Proper shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

IMDG - Not Regulated

IMDG Proper shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

DOT - Not Regulated

DOT Proper shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

15. REGULATORY INFORMATION

This Section Contains Information relevant to compliance with other Federal and/or state laws.

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.