**Material Safety Data Sheet**

**PREPARATION DATE:** December 30, 2002
This revision replaces the last update of March 21, 1996

## SECTION 1: Chemical Product and Company Identification

| | |
|---|---|
| Common Name: (used on the label) | NORPRAMIN Tablets |
| (Trade Names & Synonyms) | desipramine hydrochloride |
| Chemical Name: | 5*H*-Dibenz[*bf*]azepine-5-propanamine, 10,11-dihydro-N-methyl-,monohydrochloride |


| | |
|---|---|
| **Manufacturer:** | **Aventis Pharmaceuticals, Inc.** |
| **Address:** | **Route 202-206**<br>**Bridgewater, NJ 08807-0800** |

**Technical Information, M-F, 8 AM – 5 PM EST:** **(908) 231-4829**
**24-Hour Transport Emergency, US (Chemtrec):** **(800) 424-9300**
**24-Hour Transport Emergency, outside US (Chemtrec) :** **(703) 527-3887**
**24-Hour Emergency, Aventis:** **(908) 231-2666**


## SECTION 2: Composition/Information on Ingredients

| | |
|---|---|
| Material: | NORPRAMIN tablets |
| Concentration: | Each capsule contains 10, 25, 50 75, 100 or 150 mg of desipramine hydrochloride. |
| Nature of Hazard: | Pharmaceutical Product. |

## SECTION 3: Hazards Identification

Appearance :

10 mg blue coated tablets imprinted with 68-7
25 mg yellow coated tablets imprinted NORPRAMIN 25
50 mg green coated tablets imprinted NORPRAMIN 50
75 mg orange coated tablets imprinted NORPRAMIN 75
100 mg peach coated tablets imprinted NORPRAMIN 100
150 mg white coated tablets imprinted NORPRAMIN 150

NORPRAMIN is indicated for the treatment of depression.

**SECTION 4: First Aid Measures**

Signs and symptoms of toxicity with tricyclic antidepressants most often involve the cardiovascular and central nervous systems. Overdosage with this class of drugs has resulted in death. Within a few hours of ingestion, the patient may become agitated, restless, confused, delirious or stuporous, and then comatose. Mydriasis, dry mucous membranes, vomiting, urinary retention, and diminished bowel sounds may occur. Hypotension, shock, respiratory depression, and renal shutdown may ensue. Generalized seizures, both early and later after ingestion, have been reported. Hyperactive reflexes, hyperpyrexia, and muscle rigidity can occur. ECG evidence of impaired conduction and serious disturbances of cardiac rate, rhythm, and output may occur. The duration of the QRS complex on ECG may be a helpful guide to the severity of tricyclic overdose. Physicians should be aware that relapse may occur after apparent recovery.

In humans, doses at 10-30 times the usual daily dosage have been considered within the lethal range. The lethal dose for children and geriatric patients would be lower than that for the general adult population. Serious adverse events in general are more frequently associated with plasma levels in excess of 1000 ng/ml.

There is no specific antidote for desipramine overdosage, nor are there specific phenomena of diagnostic value characterizing poisoning by the drug. Because CNS involvement, respiratory depression, and cardiac arrythmia can occur suddenly, hospitalization and close observation are generally advisable, even when the amount ingested is thought to be small or the initial degree of intoxication appears slight or moderate. Aggressive supportive therapy of cardiac, neurologic, or acid-base disturbances may be necessary.

The initial phase of therapy in a tricyclic antidepressant overdose should be devoted to protection of the patients airway, stabilization of the vital signs, establishing an intravenous line, obtaining an ECG, and initiating continuous cardiac monitoring, and maintaining renal output. It should be remembered that rapid deterioration of vital signs, seizures, respiratory failure, and ventricular arryhthmias are common during the first 24 hours after ingestion.

Ventricular arrhythmias and intraventricular conduction abnormalities may respond to administration of sodium bicarbonate to correct the metabolic acidosis. During alkalinization, the patient's electrolytes and renal function must be closely monitored with frequent laboratory determinations. Arryhthmias may be treated with standard antiarrhythmic therapy (e.g., lidocaine). Physostigmine may be used with caution to reverse severe cardiovascular abnormalities or coma; too rapid administration may result in seizures.

If the patient is hypotensive, supportive measures (e.g., intravenous fluids) should be used. Vasopressor agents may be used with caution if necessary. If the patient develops seizures,

intravenous diazepam may be used. In addition, longer acting anticonvulsants (e.g., barbiturates) may be necessary for repetitive seizures.

Once the patient is stabilized, gastric lavage with a large bore orogastric tube should be used to evacuate the stomach. The physician must be prepared to protect the airway by endotracheal intubation if seizures or loss of consciousness occur prior to completion of the lavage procedure. Because of the potential for rapid onset of life-threatening events, emesis should not be used to empty the stomach. Activated charcoal (as single or repeated doses) in a water slurry should be given by mouth or instilled through the lavage tube.

Additional information regarding treatment of overdosage may be available from poison control centers.

**SECTION 5: Fire Fighting Measures**

Extinguisher media: Carbon Dioxide, Dry Chemical Powder, Alcohol or Polymer Foam. Water may be effective for cooling.

Unusual Fire and Explosion Hazards: None.

Vapor Pressure: Not applicable.

Vapor Density: Not applicable.

Flashpoint: Not applicable.

Auto-ignition Temperature: Not applicable.

**SECTION 6: Accidental Release Measures**

Shovel or sweep up spill. Place in DOT approved container and seal. Dispose of in accordance with RCRA and applicable state and local regulations.

**SECTION 7: Handling and Storage**

Incompatibility: Not applicable.
Hazardous polymerization: Will not occur.
NORPRAMIN tablets should be stored at room temperature, preferable below 86°F (30°C).
Protect from excessive heat.

**SECTION 8: Exposure Controls/Personal Protection**

OSHA Permissible Exposure Limit: Not available.

**SECTION 9: Physical and Chemical Properties**

Appearance: See section 3 for detailed information.

**SECTION 10: Stability and Reactivity**

Material is stable under normal conditions.
Hazardous polymerization: Will not occur.

**SECTION 11: Toxicological Information**

The oral $LD_{50}$ of desipramine is 290 mg/kg in male mice and 320 mg/kg in female rats.

**SECTION 12: Ecological Information**

Shovel or sweep up spill. Place in DOT approved container and seal. Dispose of in accordance with RCRA and applicable state and local regulations

**SECTION 13: Disposal Considerations**

This material should be disposed of in accordance with local, state, and/or federal regulations.

**SECTION 14: Transport Information**

This material is not regulated as hazardous by U.S.-DOT. A copy of this MSDS should accompany shipments of this material.

**SECTION 15: Regulatory Information**

No additional information.

**SECTION 16: Other Information**

The information provided in this Material Safety Data Sheet has been compiled from our experience and the data presented in various technical publications. It is the users responsibility to determine the suitability of this information for the adoption of safety precautions as may be necessary. We reserve the right to revise the Material Safety Data Sheets from time to time as new information becomes available. The user has the responsibility to contact the company to make sure the sheet is the latest one issued.