

SAFETY DATA SHEET

Amitriptyline HCl Tablet (10/25/50/75/100/150 mg)

1. IDENTIFICATION

Product identifier: Amitriptyline HCl Tablets

Product code: #

Chemical Description: *N,N*-dimethyl-3-(2-tricyclo[9.4.0.0^{3,8}] pentadeca-1(15),3,5,7,11,13-hexaenylidene)propan-1-amine hydrochloride

Other means of identification: ---

Recommended use of the tablet:

Amitriptyline tablets are indicated for:

- the treatment of major depressive disorder in adults
- the treatment of neuropathic pain in adults
- the prophylactic treatment of chronic tension type headache (CTTH) in adults
- the prophylactic treatment of migraine in adults

Restrictions on use: The product should be used only for the above mentioned uses and may not be used for any other purpose than stated above.

Manufactured by:

Mankind Pharma Ltd.,
Unit III, Opp. Dental College, Rampur Ghat,
Teh. -Paonta Sahib (HP-173025), India.
CIN No.: U74899DL1991PLC044843

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2. HAZARDS IDENTIFICATION

Classification	NA
Signal Word	Warning
Hazard Statements:	H302 : Harmful if swallowed, in excess H332 : Harmful if inhaled, in excess H370: Causes damage to organs H315: Causes skin irritation H361: Suspected of damaging fertility or the unborn child . H335: May cause respiratory irritation H410: Toxic to aquatic life with long lasting effects
Precautionary Statements:	P260: Do not breathe dust P305 + P351 + P338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P280: Wear protective gloves/protective clothing/eye protection/face protection. P332+P313: If skin irritation occurs: Get medical advice/attention. P337+P313: If eye irritation persists: Get medical advice/attention. P362: Take off contaminated clothing. P273: Avoid release to the environment.

	P405: Store locked up.
Other hazards	None.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical nature: Mixture containing Amitriptyline HCl

Hazardous ingredients	CAS	Content
Amitriptyline Hydrochloride	549-18-8	Approx 10-25%

4. FIRST-AID MEASURES

Inhalation

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

Skin contact

Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician

Ingestion

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician

Overdose Treatment

Obtain an ECG and immediately initiate cardiac monitoring. Protect the patient's airway, establish an intravenous line and initiate gastric decontamination. A minimum of six hours of observation with cardiac monitoring and observation for signs of CNS or respiratory depression, hypotension, cardiac dysrhythmias and/or conduction blocks, and seizures is necessary. If signs of toxicity occur at any time during the period extended monitoring is required. There are case reports of patients succumbing to fatal dysrhythmias late after overdose; these patients had clinical evidence of significant poisoning prior to death and most received inadequate gastrointestinal decontamination. Monitoring of plasma drug levels should not guide management of the patient. Gastrointestinal Decontamination All patients suspected of tricyclic antidepressant overdose should receive gastrointestinal decontamination. This should include, large volume gastric lavage followed by activated charcoal. If consciousness is impaired, the airway should be secured prior to lavage. Emesis is contraindicated.

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Fire/explosion hazard

No data available.

Specific hazards arising from the chemical

Carbon oxides, Nitrogen oxides (NOx), Hydrogen chloride gas.

Personal protection

Self-contained breathing apparatus. Fire-fighters must wear self-contained breathing apparatus for firefighting if necessary.

Special exposure hazards

Do not release chemically contaminated water into drains, soil or surface water. Dispose of contaminated water and soil according to local regulations.

6. ACCIDENTAL RELEASE MEASURES

Personal protection

Wear Goggles, gloves, protective clothing, respiratory protection. Avoid breathing dust.

Remove ignition sources and provide sufficient ventilation.

Environmental precautions

Prevent contamination of soil, drains and surface waters.

Spillage procedure

Take up mechanically and collect in suitable container (Adequately labelled) for disposal.

7. HANDLING AND STORAGE

Handling

Occupational hygiene

Avoid ingestion, inhalation, skin and eye contact. Avoid formation of dust and aerosols. Handle in accordance with good industrial hygiene practice and any legal requirements.

Conditions for safe storage

Avoid dust formation and ignition sources. Ensure good local exhaust ventilation. Keep away from heat/sparks/open flames/hot surfaces – No smoking.

Storage facilities

Store in a cool, dry area with adequate ventilation. Keep tightly closed.

Segregation

Store locked up.

Storage conditions

Keep containers / shippers closed.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits

CAS No	Name	TWA	STEL	Source
549-18-8	dimethyl(3-{tricyclo[9.4.0.0 ^{3,8}]pentadeca-1(15),3,5,7,11,13-hexaen-2-ylidene}propyl)amine hydrochloride	0.1 mg/m ³	-	-

Occupational Exposure Controls:

Appropriate engineering controls

Maintain air concentrations below occupational exposure standards. Prevent dust formation.

General Personal Protection

Goggles, gloves, protective clothing.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate, use a full-face particle respirator type N99 (US) or type P2 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection

Protective gloves.

Eye protection

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Solid

Form: Tablets

Colour: Pink (10 mg), Green (25 mg), Brown (50 mg), Blue (75 mg), Orange (100 mg) & White (150 mg)

Odour: N.A.

pH: Not available

Melting point: Not available

Boiling point: Not applicable

Flash point: Not applicable

Flammability (solid): Not available

Vapour pressure: Not applicable

Auto-ignition temperature: Not available

Decomposition temperature: Not available

Density: Not available

Solubility in water: Not available

Solubility in solvents: Not available

n-Octanol/Water Partition Coefficient: Not available

Viscosity: Not applicable

Oxidizing properties: Not available

Explosivity: Stable under ordinary conditions

10. STABILITY AND REACTIVITY

Conditions to avoid

Avoid moisture

Reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport.

Hazardous decomposition products

None under normal storage conditions

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Amitriptyline HCl active ingredient has been tested for acute toxicity.

Acute toxicity - oral

LD₅₀ (oral, rat): 240 mg/kg

100% Amitriptyline is classified in category 3 for acute toxicity.

Based on toxicity data of Amitriptyline HCl and its excipients, Amitriptyline tablet with @10%-25% Amitriptyline HCl would fall under category 4. (1714 mg/kg)

Acute toxicity - Dermal, Inhalation

Data lacking for active ingredient

Excipient data - Microcrystalline cellulose, Croscarmellose -

Dermal LD₅₀ >2000, (rabbit) - category 5

Croscarmellose, colloidal silicon dioxide -

Inhalation LC₅₀ > 0.13 mg/L (rat, 4 -hr)
Data insufficient to classify for dermal/inhalation

Primary Irritation

Skin

Amitriptyline HCl -

Data is not available

Magnesium stearate-

Based on the available data mixture will be classified as cat 2

Eye

Amitriptyline - Data lacking

Respiratory or Skin sensitization

- Respiratory: Data not available.

CMR consideration:

Germ cell mutagenicity:

- Data not available

Carcinogenicity

Not classifiable as human carcinogen.

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Specific target organ toxicity single exposure:

Amitriptyline HCl -

Specific target organ toxicity - single exposure (STOT-SE) 1

Affects central nervous system, cardiovascular system, autonomic system

- Data not available

Specific target organ toxicity repeated exposure:

- Data not available

Additional information: None

12. ECOLOGICAL INFORMATION

Ecotoxicity

Poorly soluble in water. No data available on ecotoxicity.

Additional information

Do not discharge product uncontrolled into the environment.

13. DISPOSAL CONSIDERATIONS

Dispose the waste in accordance with all applicable federal, state and local laws.

14. TRANSPORT INFORMATION

Pharmaceutical Agent : Transportation of this product in its final form does not pose any risk.

15. REGULATORY INFORMATION

Generic medicine. Under approval by USFDA and the ANDA number is 213999.

16. OTHER INFORMATION**Recommended restrictions on use**

This product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with any legal regulation. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should not therefore be construed as guaranteeing specific properties.

MSDS Changes

Prepared on 24/12/20