ajanta pharma limited

SAFETY DATA SHEET

Clomipramine Hydrochloride Capsules, USP 25 mg, 50 mg and 75 mg

EMERGENCY OVERVIEW

Clomipramine Hydrochloride Capsules, USP contain active drug substances clomipramine hydrochloride and pharmaceutical excipients generally considered safe, non-toxic and non-hazardous. The quantities of the excipients used in the product are well within the IID (Inactive Ingredient Database) limits prescribed by USFDA for oral route.

WARNING: Accidental ingestion of large amounts may be harmful.

Section 1. Identification

Identification of the product

Product name	:	CLOMIPRAMINE HYDROCHLORIDE CAPSULES, USP 25 mg, 50 mg and 75 mg
Chemical Formula	:	Clomipramine hydrochloride: $C_{19}H_{23}ClN_2 \cdot HCl$
Chemical Name	:	**Clomipramine hydrochloride:** 3-chloro-5-[3-(dimethylamino)propyl]-10,11-dihydro-5*H*-dibenz[b,*f*]azepine monohydrochloride
Therapeutic Category	:	Antidepressant
Marketed by	:	**Ajanta Pharma USA Inc.** 440 US Highway 22 East, Bridgewater, NJ 08807. Made in India
Contact Information	:	1-855-664-7744

Section 2. Hazard (s) Identification

Potential Health Effects :

Inhalation: Not expected to be hazardous in final pharmaceutical form.

Eye Contact: Not expected to be hazardous in final pharmaceutical form.

Skin Contact: Not expected to be hazardous in final pharmaceutical form.

Indigestion: Health injuries are not known or expected under normal use. Exposures above clinical dosage could

result in adverse effects. Minor occupational exposures are not expected to be harmful.

Effects of Overexposure : The potential for exposure is reduced in finished pharmaceutical dosage form.

Section 3. Composition / information on ingredients

Active ingredient	Exposure Limit	CAS No.
Clomipramine hydrochloride	Not Found	[17321-77-6]

Inactive ingredients:
Pregelatinized starch, colloidal silicon dioxide and magnesium stearate. Additionally hard gelatin capsule shell contains FD&C Red 40 (25 mg), FD&C Blue 1 (50 mg), titanium dioxide, gelatin, D&C Yellow 10 and FD& Yellow 6 (25 mg, 50 mg and 75 mg). The capsule is imprinted with black pharmaceutical ink which contains shellac, propylene glycol, ammonia, black iron oxide and potassium hydroxide.

Section 4. First-aid measures

General :

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately. Never give anything by mouth to an unconscious person.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Overdose Treatment : Consult with a Certified Poison Control Center (1-800-222-1222) for up-to-date guidance and advice

Section 5. Fire-fighting measures

Flash Point : Not Reported

Extinguishing Media : Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.

Fire and Explosion Hazard	:	This material is assumed to be combustible. Keep it away from the open fires.
Fire Fighting Procedures	:	As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.
Hazardous Combustion by Products	:	Carbon dioxide, carbon monoxide, oxides of nitrogen, oxides of sulfur, oxides of sodium, hydrogen chloride

Section 6. Accidental release measures

Personal Precautions	:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Environmental Protections	:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Clean-up Methods	:	Wipe up with a damp cloth and place in container for disposal. Avoid generating airborne dust. Clean spill area thoroughly. Prevent discharge to drains.
Additional Consideration for Large Spills	:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Section 7. Handling and storage

General Handling	:	Minimize dust generation and accumulation. If capsule are crushed and/or broken, avoid breathing dust and avoid contact to eyes, skin and clothing. When handling, use appropriate personal protective equipment.
Storage	:	Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].

Section 8. Exposure controls / personal protection

Respiratory Protection	:	Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.

Skin Protection : Skin protection is not normally necessary, however it is good practice to avoid direct contact with chemical to use suitable gloves when handling.

Eye protection : Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.

Protective Clothing : Protective clothing is not normally necessary, however it is good practice to use apron.

Section 9. Physical and chemical properties

Appearance : **25 mg:** melon-yellow opaque / ivory opaque hard gelatin size "2" capsules imprinted with "ap" logo on cap and "CLM 25" on body in black.

50 mg: aqua blue opaque / ivory opaque hard gelatin size "1" capsules imprinted with "ap" logo on cap and "CLM 50" on body in black ink containing white to off-white colored powder.

75 mg: yellow opaque / ivory opaque hard gelatin size "1" capsules imprinted with "ap" logo on cap and "CLM 75" on body in black ink containing white to off-white colored powder.

Presentations and NDC Codes	Strengths		
	25 mg	50 mg	75 mg
Bottles of 30's pack	27241-210-30	27241-211-30	27241-212-30
Bottles of 100's pack	27241-210-01	27241-211-01	27241-212-01

Solubility in water : No Data Available
Odor : Odorless
Boiling point : No Data Available
Melting Point : No Data Available
Evaporation rate : No Data Available
Specific gravity : No Data Available
Vapor density : No Data Available
Reactivity in water : No Data Available
Evaporation rate : No Data Available
Percentage Volatile by volume : No Data Available

Vapor pressure	:	No Data Available
Other information	:	No Data Available

Section 10. Stability and reactivity

Condition to avoid	:	Avoid exposure to extreme heat, light and moisture.
Stable	:	Stable under normal ambient and anticipated storage and handling conditions.
Decomposition Products	:	No data available
Hazardous Reaction	:	No data available. In finished dosage form there is least possibility that product will undergo any hazardous reaction.
Incompatibilities	:	No data available.

Section 11. Toxicological information

General	:	Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.
Target organ	:	Eye contact, Skin contact and inhalation is not great risk as this product is orally administered capsule formulation.
Acute Toxicity	:	No Data Available

Section 12. Ecological information

No data available on Ecotoxicity of API. In the finished product form there is no potential for air borne contamination since the product is in capsule form.

Section 13. Disposal Consideration

Waste Disposal Considerations: Dispose of material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended.
At home: Discard away from children's reach.

Section 14. Transport information

This product is authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals.
DOT: Not Regulated
IATA: Not Regulated
IMDG: Not Regulated

Section 15. Regulatory information

DEA: Doxepine Hydrochlorideis not a controlled substance.
FDA: Doxepine Hydrochloride is an approved prescription medication.

Section 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.

Ajanta shall not be held liable for any damage resulting from handling or from contact with the above product.

Date: Apr 22, 2022

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION