ajanta pharma limited

SAFETY DATA SHEET

Cholestyramine for Oral Suspension, USP 4 g

EMERGENCY OVERVIEW

CHOLESTYRAMINE FOR ORAL SUSPENSION, USP contain an active drug substance cholestyramine resin, USP 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 suspension.

WARNING: Ingestion of large amounts may be harmful.

Section 1. Identification of the substance

Identification of the product

Product name	:	Cholestyramine for Oral Suspension, USP 4 g
Potencies	:	4 g
Chemical Name	:	Polyvinylbenzyltrimethyl ammonium chloride
Therapeutic Category	:	Antihyperlipidemic agent
Product Use	:	As adjunctive therapy to diet for the reduction of elevated serum cholesterol in patients with primary hypercholesterolemia who do not respond adequately to diet and for the relief of pruritus associated with partial biliary obstruction.
Marketed by	:	**Ajanta Pharma USA Inc**. Bridgewater, NJ 08807
Manufactured by	:	**Ajanta Pharma Limited** Plot No. Z-103 /A Dahej SEZ - Part II, Bharuch – 392130, Gujarat, India.
Contact Information	:	855-664-7744

Section 2. Health hazards information

Potential Health Effects	:	**Inhalation:** The quantity of active drug substance in single dose pouch may not be hazardous to inhalation. However, in case of accidental inhalation move individual to fresh air. If breathing is difficult, give artificial respiration or oxygen by trained personnel. Get immediate medical attention.

Eye Contact: Not expected to be hazardous. Do not let victim rub his/her eyes.

Skin Contact: The active content in single dose pouch may not be hazardous to skin contact.

Ingestion: 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 form.

Section 3. Composition / information on ingredients

Active ingredient	Exposure Limit	CAS No.
Cholestyramine resin, USP	Not Available	11041-12-6

Inactive ingredients: Citric acid monohydrate, colloidal silicon dioxide, propylene glycol alginate, sucrose (509.22 mg/g powder), xanthan gum, orange flavour, D&C yellow No. 10 alum lake, FD&C yellow No. 6 alum lake.

Section 4. First aid measures

This product in the final dosage form (powder) does not pose a problem of exposure to active moiety, and does not cause inhalation, skin and eye irritation problem. The lose powder exposure hazards are during the manufacturing process.

Eye Contact : Do not let victim rub his/her eyes. Immediately flush eyes with water for at least 15 minutes. Get medical attention.

Skin Contact : Immediately wash skin with soap and plenty of warm water for at least 15 minutes. Remove contaminated clothing. Get medical attention if skin reaction occur. Wash clothing before reuse.

Ingestion : Immediately contact the Poison Center or a doctor/physician. If swallowed, induce vomiting if directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation : If powder is inhaled, move individual to fresh air. If breathing is difficult, give artificial respiration or oxygen by trained personnel. Get immediate medical attention.

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.

Section 5. Fire-fighting measures

Flash Point	:	Not Available.
Extinguishing Media	:	Product is non-flammable. However use appropriate media including water spray, carbon dioxide, dry powder or appropriate foam for the surrounding fire
General Fire Hazards/ Hazardous Combustible Products	:	Though the product is non-flammable, acrid smoke and irritating fumes may emit when the product is exposed to heat.
Special Fire Fighting Procedures	:	Wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

Section 6. Accidental release measures

Personal Precautions	:	Personnel involved in clean-up should wear appropriate personal protective equipment with the degree of hazard. Minimize exposure.
Environmental Protections	:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
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	:	For bulk quantities of the material report emergency situations immediately. Non-essential personnel should be evacuated from the affected area. Spills should be cleaned up in a manner that minimizes exposure to personnel and to the environment. Personnel involved in the cleanup of spills should wear the appropriate gloves and eye protection. Clean spill area thoroughly with soap and water. Collect wash with absorbent material and transfer all waste to a labeled container for disposal. Observe all applicable regulations when disposing of this substance.

Section 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. Wear appropriate personal protective equipment and use good personal hygiene. Wash hands and exposed skin with soap and water after handling. Remove contaminated clothing and clean before reuse. Properly disposed of contaminated belts and shoes and other items that cannot be decontaminated.

Storage : Store at 25°C (77°F); excursions permitted from 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

Section 8. Exposure controls/personal protection

Exposure Limits : Not Available.

Engineering Controls : For consumer use, no unusual precaution are necessary for handling packets. In laboratory, medical or industrial setting use appropriate ventilation. Provide mechanical ventilation for confined spaces.

Respiratory Protection : For consumer use, no unusual precaution are necessary. If exposure limits are exceeded, approved respiratory protection should be worn. Seek professional assistance for proper selection of respiratory protection.

Personal Protection : For consumer use, no unusual precaution are necessary. However, for handling packets in laboratory, medical or industrial setting use gloves as recommended. Wear appropriate clothing to avoid skin contact.

Recommended Facilities : None

Section 9. Physical and chemical properties

Appearance : Cholestyramine for oral suspension, USP orange flavor is available in cartons of sixty 9 gram sachets and in HDPE bottles containing 378 grams. Nine grams of cholestyramine for oral suspension, USP contain 4 grams of anhydrous cholestyramine resin.

NDC # 27241-134-36 Carton of 60 sachets

NDC # 27241-134-51 HDPE bottle, 378 g (containing a scoop that is not interchangeable with scoops from other products)

Other Information : Cholestyramine for oral suspension, USP, the chloride salt of a basic anion exchange resin, a cholesterol lowering agent, is intended for oral administration. Cholestyramine resin is quite hydrophilic, but insoluble in water.

Section 10. Stability and reactivity

Stability : Stable under recommended storage conditions
Incompatibility : Reactive with oxidizing agents.
Hazardous Decomposition : Avoid contact with nitric acid or other strong oxidizing agents.
Conditions to Avoid : Excess heat, incompatible materials (strong oxidizing agents).

Section 11. Toxicological information

Acute toxicity : Oral LD50 (rat) : > 4,000 mg/kg

Carcinogenesis : None of the components of this product are suspected to be a carcinogen.

Mutagenesis : When processed and used as directed, this product is not expected to produce mutagenic effects.

Fertility effects : None of the components of this product are suspected to cause birth defects or reproductive harm.

Section 12. Ecological information

Eco toxicity of drug substance : Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.

In the finished product form : There is no potential for air borne contamination.

Section 13. Disposal Consideration

Waste Disposal Considerations: Dispose the material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended.

Section 14. Transport information

This product is not subject to the regulations for the safe transport of hazardous chemicals

DOT: Not regulated for transport of dangerous goods.
IATA: Not regulated for transport of dangerous goods.
IMDG: Not regulated for transport of dangerous goods.

Section 15. Regulatory information

DEA: Not a control (schedule) drug regulated by DEA.
FDA: Cholestyramine for Oral Suspension, USP 4 g is an approved prescription medication.

Section 16. Disclaimer

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: Sep 17, 2020

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION