ajanta pharma limited

SAFETY DATA SHEET

Ranolazine Extended-Release Tablets 500 mg and 1000 mg

EMERGENCY OVERVIEW

Ranolazine Extended-Release Tablets contain active drug substances ranolazine 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 of the substance

Identification of the product

Product name	**:**	RANOLAZINE EXTENDED-RELEASE TABLETS 500 mg and 1000 mg
Chemical Formula	**:**	Ranolazine : $C_{24}H_{33}N_3O_4$
Chemical Name	**:**	Ranolazine: 1-piperazineacetamide,N-(2,6 dimethylphenyl)-4-[2-hydroxy-3-(2-methoxyphenoxy)propyl]-, (±)-
Therapeutic Category	**:**	Antianginal Agent indicated in treatment of chronic angina
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.
Ranolazine	Not Found	95635-55-5

Inactive ingredients:
Hypromellose, magnesium stearate, methacrylic acid and ethyl acrylate copolymer (sodium lauryl sulfate and polysorbate 80), microcrystalline cellulose, polyethylene glycol and sodium hydroxide.

The color coating contains titanium dioxide, polyvinyl alcohol, talc, hypromellose, polyethylene glycol, Iron Oxide Yellow, and Iron Oxide Red.

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 tablets 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 between 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 : **Ranolazine Extended-Release Tablets 500 mg**: Orange colored, oval-shaped, biconvex, film-coated, extended-release tablets debossed with "RZ1" on one side and plain on other side.
Ranolazine Extended-Release Tablets 1000 mg: Yellow colored, oval-shaped, biconvex, film-coated, extended-release tablets debossed with "RZ2" on one side and plain on other side.

Presentations and NDC Codes	**Strengths**	
	500 mg	**1000 mg**
Bottles of 60's pack	27241-125-02	27241-126-02
Bottles of 500's pack	27241-125-05	27241-126-05

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 tablet formulation.
Acute Toxicity	**:**	(LD50): 980 mg/kg [Rat].

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 tablet 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: Ranolazine is not a controlled substance.
FDA: Ranolazine 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: Apr 01, 2022

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