VKT Pharma

VKT Pharma Private Limited
Survey No. 21-27, Derasam (Village)
Ranasthalam (Mandalam), Srikakulam (District)
AP, India - 532 409

Material Safety Data Sheet
Ranolazine Extended Released Tablets

Section 1: Identification

Product Name: Ranolazine Extended Released Tablets 500 mg and1,000 mg.
Category : Anti- Anginal.
Manufacturer: VKT Pharma Private Limited,
Survey No: 21-27, Derasam village,
Ranasthalam Mandal,
Srikakulam District,
Andhra Pradesh-532409
India.

Section 2: Hazards Identification

Fire and Explosion : Expected to be non-combustible.
Health Environment : Ranolazine is contraindicated in patients:

- Taking strong inhibitors of CYP3A
- Taking inducers of CYP3A
- With liver cirrhosis.

No information is available about the potential of this product to produce adverse environmental effects

Section 3: Composition and Information on Ingredients

Ingredients	CAS	Strength
Ranolazine	95635-55-5	500 mg and 1,000 mg

Section 4: First - Aid Measures

Ingestion: Flush out mouth with water, consult a physician immediately.

Inhalation: In case of inhalation remove to fresh air and seek medical aid.

Skin Contact: Remove immediately contaminated clothes wash affected skin with plenty of water.

Eye Contact: In case of contact with eyes rinses thoroughly with plenty of water and gets medical advice

NOTES TO HEALTH PROFESSIONALS
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. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.

OVER DOSAGE: High oral doses of ranolazine produce dose-related increases in dizziness, nausea, and vomiting. High intravenous exposure also produces diplopia, paresthesia, confusion, and syncope. In addition to general supportive measures, continuous ECG monitoring may be warranted in the event of overdose. Severe tremor, unsteady gait/incoordination, dysphasia, and hallucinations have been reported in cases of overdose with ranolazine extended-release tablets.

Since ranolazine is about 62% bound to plasma proteins, hemodialysis is unlikely to be effective in clearing ranolazine.

Section 5: Fire - fighting measures

Fire and Explosion Hazards: Assume that this product is capable of sustaining combustion.

Extinguishing Media: Use extinguishing media appropriate to surrounding fire conditions, such as water, fog, spray, dry chemical, regular foam, carbon dioxide.

Special Firefighting Procedures: For single units (packages): No special requirements needed.
For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.

Hazardous Combustion Products Hazardous combustion or decomposition products are expected when the product is exposed to fire

Section 6: Accidental Release Measures

Personal Precautions: Avoid excessive contact and contact with eyes. Wear safety goggles or shield.

Environmental Precautions: For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

Clean-up Methods: This material is not known to possess additional hazards when spilled beyond those of other non-hazardous solids.

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

Section 8: Exposure Controls/Personal Protection

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling

Section 9: Physical and Chemical Properties

Physical Form: **Ranolazine Extended Released Tablets,** 500 mg are Beige colored, oval shaped film coated tablet debossed with "V" on one side and "09" on the other side.

60's Count in 75CC HDPE container

Ranolazine Extended Released Tablets, 1,000 mg are pale yellow colored, oval shaped film coated tablet debossed with "V" on one side and "09" on the other side.

60's Count in 150CC HDPE container

Section 10: Stability and Reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Carcinogenesis, Mutagenesis, Impairment of Fertility: Ranolazine tested negative for genotoxic potential in the following assays: Ames bacterial mutation assay, Saccharomyces assay for mitotic gene conversion, chromosomal aberrations assay in Chinese hamster ovary (CHO) cells, mammalian CHO/HGPRT gene mutation assay, and mouse and rat bone marrow micronucleus assays.

There was no evidence of carcinogenic potential in mice or rats. The highest oral doses used in the carcinogenicity studies were 150 mg/kg/day for 21 months in rats (900 mg/m2/day) and 50 mg/kg/day for 24 months in mice (150 mg/m2/day). These maximally tolerated doses are 0.8 and 0.1 times, respectively, the daily maximum recommended human dose (MRHD) of 2000 mg on a surface area basis. A published study reported that ranolazine promoted tumor formation and progression to malignancy when given to transgenic APC (min/+) mice at a dose of 30 mg/kg twice daily. The clinical significance of this finding is unclear.

In male and female rats, oral administration of ranolazine that produced exposures (AUC) approximately 3-fold or 5-fold higher, respectively, than the MRHD had no effect on fertility

Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

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Section 14: Transport Information

IATA/ICAO - Not Regulated

IATA Proper shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

IMDG - Not Regulated

IMDG Proper shipping Name	:	N/A
IMDG UN/ID/No	:	N/A
IMDG Hazard class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

DOT - NOT Regulated

DOT Proper shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT packing group	:	N/A
DOT Label	:	N/A

Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

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Prepared by: 24/03/2022

Verified by: 24/03/2022