ScieGen Pharmaceuticals, Inc.
89 Arkay drive
Hauppauge, New York 11788
Tel: 631-434-2723
Fax: 631-357-3178

SAFETY DATA SHEET

Date: 03/15/2019

Generic Name: Ranolazine extended-release tablets, 500 mg and 1000 mg.

Brand Equivalent: Ranexa® (Ranolazine) extended-release Tablets, 500 mg and 1000 mg

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SECTION 1: IDENTIFICATION	
Product Name	Ranolazine extended-release tablets
Active substance	Ranolazine
Synonyms	N/A
Formula	C24H33N3O4
Intended Use	indicated for the treatment of chronic angina
Chemical Name	1-piperazineacetamide, N-(2,6-dimethylphenyl)-4-[2-hydroxy-3-(2-methoxyphenoxy)propyl]-, (±)-.
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723

2. HAZARDS IDENTIFICATION	
Fire and explosion	Expected to be non-combustible
Health	Ranolazine is contraindicated in patients • Taking strong inhibitors of CYP3A • Taking inducers of CYP3A • With liver cirrhosis
Environment	No information is available about the potential of this product to produce adverse environmental effects.

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3. Composition/Information on ingredients		500 mg	1000 mg
Components	**CAS-No**	**Concentration (%w/w)**	
Ranolazine	95635-55-5	72.78	
Microcrystalline Cellulose, NF (Avicel PH 101)	9004346	*	
Methacrylic Acid and Ethyl Acrylate copolymer-NF (EUDRAGIT L 100-55)	25212888	*	
Hypromellose USP (Methocel E5 Premium LV)	9004653	*	
Sodium Hydroxide pellets, NF	1310732	*	
Magnesium Stearate, NF	557040	*	
SheffCoat Peach (L 30705064)	Mixture	*	
SheffCoat Yellow (L 30705062)	Mixture	*	

* Proprietary, In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST AID MEASURES	
Eye contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
	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 dosages	High oral doses of ranolazine produce dose-related increases indizziness, nausea, and vomiting. High intravenous exposure alsoproduces 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.

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5. FIRE-FIGHTING MEASURES	
Suitable extinguishing media	Extinguish fires with CO2, extinguishing powder, foam, or Water.
Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire.
Fire Fighting Procedures	During all fire fighting activities, wear appropriate protective equipment, including selfcontained breathing apparatus.
Fire / Explosion Hazards:	Fine particles (such as dust and mist) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES	
Health and Safety Precautions	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Measures for Cleaning / Collecting	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Measures for Environmental Protections	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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.

7. HANDLING AND STORAGE	
General Handling	Minimize dust generation and accumulation. Avoid breathing dust and avoid contact with eyes, skin, and clothing. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Storage Conditions	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

8. Exposure controls/Personal protection	
Environmental Exposure Controls	Refer to available public information for specific Member State Occupational Exposure Limits.
Engineering Controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure

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	limits listed above in this section.
Personal Protective Equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations- preferred, Maintain eyewash facilities in the work area.
Eyes	Wear safety glasses or goggles if eye contact is possible.
Skin	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection	If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
Appearance **Physical State** **Color** **Form**	Film coated tablets 500 mg –peach oblong shape tablets 1000 mg-yellow oblong shape tablets
Molecular Weight	Mixture

10. Stability and Reactivity	
Reactivity	No data available
Chemical Stability	Stable under normal conditions
Oxidizing Properties	No data available
Conditions to Avoid	Fine particles (such as dust and mists) may fuel fires/explosions.
Hazardous Decomposition Products	No data available
Incompatible Materials	As a precautionary measure, keep away from strong oxidizers

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

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	carcinogenic potential in mice or rats. The highest oral doses used in the carcinogenicity studies were150 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
Short Term Known Clinical Effects	Ingestion of this material may cause effects similar to those seen in clinical use including dizziness, drowsiness, muscle weakness, gastrointestinal disturbances, liver effects, and hypersensitivity reactions.
Acute Toxicity (Species, Route, End Point, Dose) Alginic acid	Due to lack of data the classification is not possible
Repeated Dose Toxicity	Due to lack of data the classification is not possible
Reproduction & Development Toxicity	No route specified Dose not specified, Not teratogenic, Negative
Genetic Toxicity	Due to lack of data the classification is not possible
Carcinogenicity	Not listed as a carcinogen by IARC, NTP or US OSHA
Other Toxicity Information	Due to lack of data the classification is not possible

12. Ecological Information	
Toxicity	No data available
Environmental Overview	Environmental properties have not been investigated. Releases to the environment should be avoided.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available
Mobility in soil	Not available
Other adverse effects	Not available

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13. Disposal considerations	
Waste treatment method	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. Transport Information
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations

15. Regulatory Information	
EU Indication of danger	Harmful

16. Other information	
Recommended Restrictions for Use:	Not available
Prepared on	*03/15/2019*
Revision	00
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