

**SAFETY DATA SHEET**

Section 1: Identification	
<b>Material</b>	Ivabradine Tablets 5 mg and 7.5 mg
<b>Recommended use</b>	Pharmaceutical
<b>Manufacturer</b>	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
<b>Distributor</b>	<b>Camber Pharmaceuticals, Inc.</b> , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Nonhazardous	
If exposed or concerned: Get medical advice/ attention	
Do not breathe dust/fume/gas/mist/vapors/spray	
Section 3: Composition/Information on Ingredients	
Ingredients	CAS-No
Ivabradine	148849-67-6
Corn starch	9005-25-8
Lactose monohydrate	10039-26-6
Maltodextrin	9050-36-6
Colloidal silicon dioxide	7631-86-9
Magnesium stearate	557-04-0
Opadry Tan	NA
Opadry white	NA
Section 4: First-Aid Measures	
<b>Eye contact</b>	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice
<b>Skin contact</b>	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Consult a physician if necessary.
<b>Inhalation</b>	Move to fresh air. If symptoms persist, call a physician
<b>Ingestion</b>	If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person

<b>Notes to Physician</b>	Treat symptomatically
<b>Section 5: Fire-Fighting Measures</b>	
<b>Flammable Properties</b>	No information available.
<b>Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment
<b>Hazardous Combustion Products</b>	No information available
<b>Protective Equipment and Precautions for Firefighters</b>	As in any fire, wear self-contained breathing apparatus pressure-demand, NIOSH (approved) and full protective gear
<b>Section 6: Accidental Release Measures</b>	
<b>Spill Procedures</b>	If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment in cleaning up a spill. If in powder form, wet down spilled material to minimize airborne dispersion. Soak up material with absorbent e.g., paper towels, and wash spill area thoroughly with appropriate cleaning materials. Dispose of collected material in accordance with applicable waste disposal regulations. Avoid release to the environment.
<b>Section 7: Handling and Storage</b>	
<b>Handling and Storage</b>	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke in work areas. Use adequate ventilation to minimize exposure. Wash hands, face and other potentially exposed areas immediately after handling this material. Remove contaminated clothing prior to entering eating areas. Clean protective equipment thoroughly after each use. Store in a well ventilated area.
<b>Section 8: Exposure Controls/Personal Protection</b>	
<b>Engineering Controls</b>	When practicable, handle material in enclosed processes or in processes with effective local exhaust ventilation or within a chemical hood.
<b>Eye/face Protection</b>	Wear safety glasses with side shields, chemical splash goggles, or safety glasses with side shields and a full-face shield to prevent contact with eyes. The choice of protection should be based on the job activity and potential for exposure to the eyes and face.
<b>Skin Protection</b>	Use gloves or other appropriate personal protective equipment if skin contact with formulation is possible. Wear lab coat or other protective over garment if splashing is possible. The choice of protection should be based on the job activity and potential for skin contact.

<b>Respiratory Protection</b>	When possible, handle material in enclosed processes or containers. If it is properly handled with effective local exhaust ventilation or containment, respiratory protection may not be needed. For procedures involving larger quantities or dust/aerosol generating procedures such as weighing or a large transfer of liquids, an air-purifying respirator with NIOSH approval for dusts and mists may be needed. The choice of protection should be based on the job activity and the potential for exposure
<b>Other</b>	Wash hands, face and other potentially exposed areas after handling material (especially before eating, drinking or smoking). Clean protective equipment thoroughly after each use
<b>Environmental exposure controls</b>	Avoid release to the environment

## Section 9: Physical and Chemical Properties

<b>Physical form</b>	Tablet
<b>Description</b>	<p>Ivabradine 5 mg tablets are formulated as white to off white-colored, oval-shaped, film-coated tablet, functionally scored on both edges, debossed with "V" on one side and "9" bisected "1" on other side. They are supplied as follows:</p> <ul style="list-style-type: none"> <li>• Bottles of 60 tablets with child-resistant closure NDC 31722-053-60</li> </ul> <p>Ivabradine 7.5 mg tablets are formulated as tan colored oval shaped, film-coated tablet debossed with "V" on one side and "92" on other side. They are supplied as follows:</p> <ul style="list-style-type: none"> <li>• Bottles of 60 tablets with child-resistant closure NDC 31722-054-60</li> </ul>

## Section 10: Stability and Reactivity

<b>Reactivity</b>	No information available
<b>Chemical stability</b>	No information available
<b>Possibility of hazardous reactions</b>	No information available
<b>Incompatible materials</b>	No information available
<b>Hazardous decomposition products</b>	No information available

Section 11: Toxicological Information	
<b>Acute toxicity</b>	Ivabradine oral LD50 in rats is 840 mg/kg (GHS Category 4).
<b>Skin corrosion/irritation</b>	Based on available data, the GHS classification criteria are not met
<b>Serious eye damage/eye irritation</b>	Based on available data, the GHS classification criteria are not met
<b>Respiratory or skin sensitization</b>	Based on available data, the GHS classification criteria are not met
<b>Germ cell mutagenicity</b>	Based on available data, the GHS classification criteria are not met
<b>Carcinogenicity</b>	Based on available data, the GHS classification criteria are not met
<b>Reproductive toxicity</b>	Ivabradine oral exposure to pregnant rats and rabbits resulted in embryo-fetotoxicity and teratogenicity (GHS Category 1B).
<b>Aspiration Hazard</b>	No information available
Section 12: Ecological Information	
<b>Ecotoxicity effects</b>	Algae Growth Inhibition test, Scenedesmus subspicatus (72 hrs) ErC50 = 14.9 mg/L
	Acute Mobilization test, Daphnia magna (48 hrs) EC50 = 88.6 mg/L
	Acute toxicity on fish, Rainbow Trout, Oncorhynchus mykiss (96 hrs) LC50 > 500 mg/L
	Reproduction test, water flea Daphnia magna (21 days) NOEC = 1.58 mg/L
	Early-life Stage Toxicity on Fish, Rainbow Trout, Oncorhynchus mykiss (64 days) NOEC = 10 mg/L
	Activated sludge test, Respiration inhibition EC50 > 1000 mg/L
	GHS Category Acute 3
	GHS Category Chronic 2
<b>Persistence/Degradability</b>	Ready biodegradability test - Approximately 0% degradation over a 28 day test period (does not biodegrade)
	Water sediment Study - Rapid dissipation from water column: 6.9 to 8.6% at day 4, 76 to 90% at day 14 in sediment (DT50 sediment > 100 days). No transformation products > or = 10% or with increasing concentrations
<b>Bioaccumulation/ Accumulation</b>	N-octanol: water partition coefficient (Log Kow) 2.1 at pH 7.4
<b>Mobility in Environmental Media</b>	Adsorption coefficient (log Koc) 1.34 and 4.00 at pH 1.51 and 10.58, respectively.
	Water Solubility 47 g/L
<b>Results of PBT and vPvB assessment</b>	Does not meet criteria of PBT or vPvB compound
<b>Other Adverse Effects</b>	No information available

Section 13: Disposal Considerations	
<b>Waste Disposal Method</b>	Dispose of waste according to prescribed federal, state, local and competent authority guidelines.
Section 14: Transport Information	
<b>DOT</b>	Not regulated by U.S. DOT, IATA, or IMDG
Section 15: Regulatory Information	
<b>TSCA</b>	United States Toxic Substances Control Act Section 8(b) Inventory
<b>EINECS/ELINCS</b>	European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
<b>DSL/NDSL</b>	Canadian Domestic Substances List/Non-Domestic Substances List
<b>PICCS</b>	Philippines Inventory of Chemicals and Chemical Substances
<b>ENCS</b>	Japan Existing and New Chemical Substances
<b>IECSC</b>	China Inventory of Existing Chemical Substances
<b>AICS</b>	Australian Inventory of Chemical Substances
<b>KECL</b>	Korean Existing and Evaluated Chemical Substances
<b>California Proposition 65</b>	This product does not contain any Proposition 65 chemicals
<b>Chemical safety assessment</b>	No CSA has been conducted
Section 16: Other Information	
<p><b>Issue Date : 04-07-2024</b></p> <p><b>Version : 00</b></p> <p><b>Further information</b></p> <p><b>Revision date: New issue</b></p> <p><b>Revision note: New issue</b></p> <p>The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. 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.</p> <p>Annora Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Annora Pharma Private Limited reserves the right to revise this SDS.</p>	