

**SAFETY DATA SHEET**

Section 1: Identification	
<b>Material</b>	<b>Prucalopride tablets 1mg and 2 mg</b>
<b>Recommended use</b>	Treatment of major depressive disorder (MDD)
<b>Manufacturer</b>	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sanga Reddy, Telangana 502313, India (IND)
<b>Distributor</b>	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
<b>Classification</b> Classification according to WHIMIS	
Acute toxicity - Oral Category 4	Category 4
Chronic aquatic toxicity	Category 3
<b>Hazard statements</b> Classification according to WHIMIS	
<b>Precautionary Statements - Prevention</b>	Wash face, hands and any exposed skin thoroughly after handling. Do not eat, drink or smoke when using this product
<b>Precautionary Statements - Response</b>	
<b>Ingestion</b>	Call a POISON CENTER or doctor if you feel unwell Rinse mouth
<b>Precautionary Statements - Disposal</b>	Dispose of contents and container to an approved waste disposal plant
<b>Other information</b>	No information available.
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Prucalopride Succinate	179474-85-2
Microcrystalline cellulose	9004-34-6
Lactose monohydrate	10039-26-6
Colloidal silicon dioxide	7631-86-9
Magnesium Stearate	
Opadry II White	NA
Opadry II Yellow	NA

Section 4: First-Aid Measures	
<b>Description of first aid measures</b>	
<b>General advice</b>	Show this safety data sheet to the doctor in attendance
<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a doctor.
<b>Skin contact</b>	Wash skin with soap and water.
<b>Ingestion</b>	Do Not induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Call a doctor
<b>Most important symptoms and effects, both acute and delayed</b>	
<b>Symptoms</b>	No information available
<b>Indication of any immediate medical attention and special treatment needed</b>	
<b>Note to doctors</b>	Treat symptomatically
Section 5: Fire-Fighting Measures	
<b>Suitable extinguishing media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Large Fire</b>	CAUTION: Use of water spray when fighting fire may be inefficient
<b>Unsuitable extinguishing media</b>	Do not scatter spilled material with high pressure water streams.
<b>Specific hazards arising from the chemical</b>	No information available
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	None.
<b>Sensitivity to static discharge</b>	None.
<b>Special protective equipment and precautions for fire-fighters</b>	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment
Section 6: Accidental Release Measures	
<b>Personal precautions, protective equipment and emergency procedures</b>	
<b>Personal precautions</b>	Ensure adequate ventilation.
<b>Methods and material for containment and cleaning up</b>	
<b>Methods for cleaning up</b>	Pick up and transfer to properly labelled containers

## Section 7: Handling and Storage Section

### Conditions for safe storage, including any incompatibilities

<b>Storage Conditions</b>	<p>Store prucalopride tablets at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (between 59°F to 86°F) [see USP Controlled Room Temperature].</p> <p>Store prucalopride tablets in the original container to protect from moisture.</p>
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## 8. Exposure controls / personal protection

### Control parameters

<b>Exposure Limits</b>	This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region-specific regulatory bodies
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### Appropriate engineering Controls

<b>Engineering controls</b>	<p>Showers</p> <p>Eyewash stations</p> <p>Ventilation systems</p>
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### Individual protection measures, such as personal protective equipment

<b>Eye/face protection</b>	Avoid contact with eyes. Wear safety glasses with side shields (or goggles).
<b>Hand protection</b>	The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374.
<b>Skin and body protection</b>	No personal respiratory protective equipment normally required.
<b>Respiratory protection</b>	Wear appropriate thermal protective clothing, when necessary
<b>Environmental exposure controls</b>	Do not allow into any sewer, on the ground or into any body of water
<b>General hygiene considerations</b>	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection

## Section 9: Physical and Chemical Properties

<b>Physical state</b>	Tablet
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<b>Description</b>	<p>Prucalopride tablets containing 1 mg prucalopride are white to off-white colored, round biconvex, film-coated tablets debossed with “76” on one side and “V1” on other side.</p> <p>They are supplied as:</p> <p>HDPE bottle of 30 tablets, with child-resistant closure NDC 31722-391-30</p> <p>Prucalopride tablets containing 2 mg prucalopride are yellow colored, round biconvex film-coated tablets debossed with “77” on one side and “V1” on other side.</p> <p>They are supplied as:</p> <p>HDPE bottle of 30 tablets, with child-resistant closure NDC 31722-392-30</p>
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## Section 10: Stability and Reactivity

<b>Reactivity</b>	<p>No information available.</p> <p>Chemical stability</p> <p>Stable under normal conditions.</p> <p>Possibility of hazardous reactions</p> <p>None under normal processing.</p> <p>Conditions to avoid</p> <p>None known based on information supplied.</p> <p>Incompatible materials</p> <p>None known based on information supplied.</p> <p>Hazardous decomposition products None known based on information supplied.</p>
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## Section 11: Toxicological Information

<b>Information on likely routes of exposure</b>	
<b>Product Information</b>	
<b>Inhalation</b>	Specific test data for the substance or mixture is not available
<b>Eye contact</b>	Specific test data for the substance or mixture is not available
<b>Skin contact</b>	Specific test data for the substance or mixture is not available.
<b>Ingestion</b>	Specific test data for the substance or mixture is not available. Harmful if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics	
<b>Symptoms</b>	: No information available
<b>Acute toxicity</b>	<b>Numerical measures of toxicity</b> No information available
Delayed and immediate effects as well as chronic effects from short and long-term exposure	
<b>Skin corrosion/irritation</b>	No information available
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Respiratory or skin sensitisation</b>	No information available
<b>Germ cell mutagenicity</b>	No information available
<b>Carcinogenicity</b>	No information available
<b>Reproductive toxicity</b>	No information available
<b>STOT - single exposure</b>	No information available
<b>STOT - repeated exposure</b>	No information available
<b>Aspiration hazard</b>	No information available
Section 12: Ecological Information	
<b>Ecotoxicity</b>	Harmful to aquatic life with long lasting effects.
<b>Persistence and degradability</b>	No information available
<b>Bioaccumulation</b>	No information available
<b>Mobility in soil</b>	No information available
<b>Other adverse effects</b>	No information available
Section 13: Disposal Considerations	
Disposal Methods	
<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.
Section 14: Transport Information	
<b>TDG</b>	Not regulated
<b>DOT</b>	Not regulated

### Section 15: Regulatory Information

#### Safety, health and environmental regulations/legislation specific for the substance or mixture

##### International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

##### International Inventories

TSCA	Complies under research and development exemption or is regulated by a different government agency
DSL/NDSL	Contact supplier for inventory compliance status
EINECS/ELINCS	Contact supplier for inventory compliance status
ENCS	Contact supplier for inventory compliance status
IECSC	Contact supplier for inventory compliance status
KECL	Contact supplier for inventory compliance status
PICCS	Contact supplier for inventory compliance status
AIIC	Contact supplier for inventory compliance status

### Section 16: Other Information, including date of preparation or last revision

**Issue Date: 20-06-2025**

**Version: 00**

**Further information**

**Revision date: Nil**

**Revision note: Nil**

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.

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