



HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018, A.P., INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
e-mail : contact@heterodrugs.com URL : http://www.heterodrugs.com

SAFETY DATA SHEET

Section 1: Identification	
Material	Droxidopa capsules 300 mg
Other means of identification	--
Recommended use	Pharmaceutical product
Recommended restrictions	NA
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	Camber Pharmaceuticals, Inc. , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Not classified
Classification according to Directive 67/548/EEC or 1999/45/EC	Not classified
Adverse physicochemical, human health and environmental effects	No additional information available
Label Elements	
GHS Signal Word:	None
Hazard statements (CLP)	H312 - Harmful in contact with skin H312+H332 - Harmful in contact with skin or if inhaled
Precautionary statements (CLP)	P101 - If medical advice is needed, have product container or label at hand P102 - Keep out of reach of children P103 - Read label before use P201 - Obtain special instructions before use P202 - Do not handle until all safety precautions have been read and understood P233 - Keep container tightly closed P420 - Store away from other materials
Section 3: Composition/Information on Ingredients	
Active Ingredient	
Droxidopa	
CAS	23651-95-8
Section 4: First-Aid Measures	
First-aid measures general	Allow the victim to rest in a well ventilated area. Seek immediate Medical attention.
In Case of Inhalation:	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
In Case of Skin Contact:	Immediately wash skin with soap and copious Amounts of water for at least 15 minutes. If Irritation persists seek medical attention.



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In Case of Eye Contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
In Case of Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water provided person is conscious. Do NOT induce vomiting unless directed to do so by medical personnel. Get medical attention.

Section 5: Fire-Fighting Measures

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO ₂ .
Fire hazard	Flammable with air within explosion limits Indirect fire hazard may be ignited by sparks Gas/vapour spreads at floor level ignition hazard.
Explosion hazard	Not expected for the product although the packaging is combustible.
Reactivity	Product is not explosive.
Precautionary measures fire	Fight fire from a safe distance. Wear full protective clothing. Use water spray to keep exposed containers and equipment cool. Toxic, corrosive of flammable thermal decomposition products are expected when the product is exposed to fire. Self-contained breathing apparatus and full protective equipment is recommended for firefighters.
Protection during firefighting	As with all fires evacuate personnel to safe area fire fighters should use self-contained breathing equipment and protective clothing.

Section 6: Accidental Release Measures

General measures	Keep upwind-Mark the danger area-Consider evacuation-Seal off low-lying area-Close doors and windows of adjacent premises.
Environmental precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Methods and materials for containment and cleaning up	Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions. Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly.
Other information	Wash clothing and equipment after handling.

Section 7: Handling and Storage

Precautions for safe handling	Gloves.
Conditions for safe storage, including any incompatibilities	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Section 8: Exposure Controls/Personal Protection

Exposure controls	
Appropriate 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.



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Personal protective equipment	Face shield, Gas mask, Gloves, Protective clothing, Protective goggles.
Eye/face protection	Safety glasses with side-shields.
Protective Gloves:	Compatible chemical-resistant gloves
Other Protective Clothing	Lab coat

Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties	
Physical State	Solid
Description	White opaque size '1e1' hard gelatin capsule imprinted with 'V' on cap and '32' on body filled with white to light brown color powder. 300 mg 90-count bottle NDC code# 31722-010-90

Section 10: Stability and Reactivity

Reactivity	Product is not explosive.
Chemical stability	Stable under normal use and storage conditions.
Possibility of hazardous reactions	No data available
Conditions to avoid	No data available
Incompatible materials	As a precautionary measure. Keep away from strong oxidizers.
Hazardous decomposition products	No data available

Section 11: Toxicological Information

Acute toxicity	Not classified
Skin corrosion/irritation	Not classified
Serious eye damage/irritation	Not classified
Respiratory or skin sensitisation	Not classified
Germ cell mutagenicity	Not classified
Carcinogenicity	Not classified
Reproductive toxicity	Not classified
Specific target organ toxicity (single exposure)	Not classified
Specific target organ toxicity (repeated exposure)	Not classified
Aspiration hazard	Not classified

Section 12: Ecological Information

Ecology - air	Not dangerous for the ozone layer (1999/45/EC).
Persistence and degradability	No data is available.
Bioaccumulative potential	
Droxldopa	The substance has low potential for bioaccumulation



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Mobility in soil Droxidopa	The substance has moderate mobility in groundwater. The substance has moderate mobility in soil.
Results of PBT and vPvB assessment	No additional information available.
Other adverse effects	No other effects known.
Section 13: Disposal Considerations	
Waste treatment methods	Wash clothing and equipment after handling. Take up liquid spill into absorbent material-Scoop absorbed substance into closing containers.
Section 14: Transport Information	
DOT (US)	Not dangerous goods
IMDG	Not dangerous goods
IATA	Not dangerous goods
Transport in accordance with local, state, and federal regulations.	
Section 15: Regulatory Information	
U.S State regulations	
Section 16: Other Information, including date of preparation or last revision	
Issue Date: 23-01-2021	
Version: 00	
Further information	
Revision date: New issue	
Revision note: New issue	
<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>	
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