SAFETY DATA SHEET

Droxidopa Capsules 100 mg, 200 mg and 300 mg

EMERGENCY OVERVIEW

Droxidopa Capsules contain an active drug substance droxidopa and pharmaceutical excipients generally considered safe, non-toxic and non-hazardous. The quantities of the excipients used in the product are well within the IID (Inactive Ingredient Database) limits prescribed by USFDA for oral route.

WARNING: Accidental ingestion of large amounts may be harmful.

Section 1. Identification of the substance

Identification of the product

Product name	**:**	Droxidopa Capsules
Potencies	**:**	100 mg, 200 mg and 300 mg
Chemical Name	**:**	(2S,3R)-2-Amino-3-(3,4-dihydroxyphenyl)-3-hydroxypropanoic acid.
Therapeutic Category	**:**	Symptomatic Neurogenic Orthostatic Hypotension
Product Use	**:**	Treatment of orthostatic dizziness, lightheadedness, or the "feeling that you are about to black out" in adult patients with symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy
Marketed by	**:**	**Ajanta Pharma USA Inc**. Bridgewater, NJ 08807.
Manufactured by	**:**	**Ajanta Pharma Limited** B-4/5/6, MIDC area, Paithan, Aurangabad 431148, Maharashtra, India
Contact Information	**:**	855-664-7744

Section 2. Health hazards information

Potential Health Effects **:** **Inhalation:** Not expected to be hazardous in final pharmaceutical form.

Eye Contact: Not expected to be hazardous in final pharmaceutical form.

Skin Contact: Not expected to be hazardous in final pharmaceutical form.

Ingestion: Not expected to be hazardous in final pharmaceutical form.

Fertility: Not expected to be hazardous in final pharmaceutical form.

Effects of Overexposure : The potential for exposure is reduced in finished pharmaceutical dosage form.

Section 3. Composition / information on ingredients

Active ingredient	Exposure Limit	CAS No.
Droxidopa	--	23651-95-8

Inactive ingredients: The inactive ingredients include mannitol, corn starch, and magnesium stearate. The capsule shell is printed with black ink. The black inks contain shellac, ethanol, iron oxide black, isopropyl alcohol, butyl alcohol, propylene glycol, and potassium hydroxide. The capsule shell contains the following inactive ingredients: 100 mg – gelatin, titanium dioxide, FD&C Blue No. 2, black and red iron oxide; 200 mg – gelatin, titanium dioxide, black and yellow iron oxide; 300 mg – gelatin, titanium dioxide, FD&C Blue No. 1, D&C Yellow No. 10.

Section 4. First aid measures

The product in the final dosage form (capsule) does not pose a problem of exposure to active drug substance and should not cause inhalation, skin and eye irritation problem. However, in case of exposure:

Eye Contact : Flush immediately with plenty of water for at least 15 minutes, keeping eyelids open. Obtain medical attention.

Skin Contact : Wash immediately with plenty of soap and water. Seek medical attention if symptoms occur.

Ingestion : Get immediate attention of your doctor, local health professional, or poison center.

Inhalation : Should not pose a hazard in the final pharmaceutical form. If breathing is difficult, move to fresh air. Get medical attention immediately.

Medical Treatment : There is no known antidote for droxidopa over dosage. In case of an overdose that may result in an excessively high blood pressure, discontinue droxidopa and treat with appropriate symptomatic and supportive therapy. Counsel patients to remain in a standing or seated position until their blood pressure drops below an acceptable limit.

Section 5. Fire-fighting measures

Flash Point	:	Not available.
Extinguishing Media	:	Use water spray, dry chemical, foam, carbon dioxide or material appropriate for fire in surrounding area.
General Fire Hazards/ Hazardous Combustible Products	:	Capsules will burn under fire conditions. Combustion products include oxides of carbon, nitrogen, sulfur and magnesium.
Special Fire Fighting Procedures	:	Wear self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode and full protective gear to prevent contact with skin and eyes.

Section 6. Accidental release measures

Personal Precautions	:	Wear gloves and eye protection when handling damaged capsules. Minimize exposure. If dust is present, eliminate ignition sources and wear suitable respiratory protection.
Environmental Protections	:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).
Clean-up Methods	:	Sweep up and containerize spill material in a compatible container. Take care not to generate airborne dust. Dispose according to applicable regulations.
Additional Consideration for Large Spills	:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Move containers from spill area. Clean up operations should only be undertaken by trained personnel.

Section 7. Handling and storage

Handling	:	Observe good industrial hygiene practices. No special protection required for handling intact capsules. Wear suitable protective clothing for handling damages capsules.
Storage	:	Recommended storage for Droxidopa capsules: Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

Section 8. Exposure controls/personal protection

Exposure Limits	**:**	None
Engineering Controls	**:**	Not required when handling capsules or containers. Ventilation should be matched to conditions.
Respiratory Protection	**:**	Not required when handling capsules or containers. NIOSH approved respirators should be used if respirators are found to be necessary.
Personal Protection	**:**	For consumer use, no unusual precaution are necessary. However, for handling in laboratory, medical or industrial setting use gloves as recommended. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Recommended Facilities	**:**	Eye wash, washing facilities

Section 9. Physical and chemical properties

Appearance **:**

100 mg: Hard gelatin, size 3 capsule, with an opaque light blue cap and an opaque white body, printed with "DRX100" on body and "ap" logo on cap in black ink, filled with a white to off white powder.
100 mg 90-count bottle with child-resistant closure (NDC code# 27241-199-90)

200 mg: Hard gelatin, size 2 capsule, with an opaque light yellow cap and an opaque white body, printed with "DRX200" on body and "ap" logo on cap in black ink, filled with a white to off white powder.
200 mg 90-count bottle with child-resistant closure (NDC code# 27241-200-90)

300 mg: Hard gelatin, size 1 capsule, with an opaque light green cap and an opaque white body, printed with "DRX300" on body and "ap" logo on cap in black ink, filled with a white to off white powder.
300 mg 90-count bottle with child-resistant closure (NDC code# 27241-201-90)

Other Information **:** Droxidopa (Molecular weight: 213.19) is a white to light brown crystalline powder. It is slightly soluble in water, and practically insoluble in methanol, glacial acetic acid, ethanol, acetone, ether, and chloroform. It is soluble in dilute hydrochloric acid.

Section 10. Stability and reactivity

Reactivity	**:**	Not reactive
Stability	**:**	Stable under normal condition of handling, use and transportation
Incompatibility	**:**	Incompatible with strong oxidizing agent.
Hazardous Decomposition	**:**	Combustion products include oxides of carbon, nitrogen and magnesium
Conditions to Avoid	**:**	Excessive heat and light.

Section 11. Toxicological information

Acute toxicity	**:**	Rat Oral LD50: >10,000 mg/kg
Carcinogenesis	**:**	None of the components of this product are suspected to be a carcinogen.
Mutagenesis	**:**	Droxidopa was clastogenic in Chinese hamster ovary cells (chromosome aberration assay), but was not mutagenic in bacteria (Ames assay), and was not clastogenic in a mouse micronucleus assay.
Fertility effects	**:**	Studies in rats show that droxidopa has no effect on fertility.
Teratogenicity	**:**	No potentially teratogenic effects have been observed in rats.

Section 12. Ecological information

Eco toxicity of drug substance	**:**	No data available.
In the finished product form	**:**	No data available

Section 13. Disposal consideration

Waste Disposal Considerations: Dispose the material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended. At home: Discard and away from children's reach.

Section 14. Transport information

Not classified as hazardous for transport. Therefore, regulations for hazardous materials do not apply.

DOT: Not regulated for transport of dangerous goods.
IATA: Not regulated for transport of dangerous goods
IMDG: Not regulated for transport of dangerous goods

Section 15. Regulatory information

DEA: Not classified as controlled substance.
FDA: Droxidopa Capsules 100 mg, 200 mg and 300 mg is an unapproved prescription medication.

Section 16. Disclaimer

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. 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.

Ajanta shall not be held liable for any damage resulting from handling or from contact with the above product.

Date: Jan 28, 2021

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