



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	
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GHS Product identifier	Lopinavir and Ritonavir Tablets USP 200 mg / 50 mg & 100 mg / 25 mg
Trade Name	Not applicable
Recommended use	Lopinavir and ritonavir tablet is an HIV-1 protease inhibitor indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients (14 days and older)
Manufacturer	Hetero Labs Limited, Unit III, 22-110, IDA, Jeedimetla, Hyderabad-500055, India.
Distributor	Camber Pharmaceuticals, Inc, Piscatway, NJ 08854
Section 2: Hazard(s) Identification	
Section 2, Hazard(s)identification	Not considered hazardous when handled under normal conditions with good house keeping.
Fire and Explosion	
Label precautionary statements	S36/37 Wear suitable protective clothing and gloves. R20/21/22 Harmful by inhalation, in contact with skin and if swallowed
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Lopinavir USP	192725-17-0
Ritonavir USP	155213-67-5
Section 4: First-Aid Measures	
Section 4, First-aid measures	
Eye Contact:	Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention.
Skin Contact:	Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention.



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Inhalation:	Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult give oxygen. Seek medical attention.
Ingestion	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Signs and Symptoms:	None known from occupational exposure. Clinical data suggests the following: vomiting, nausea, diarrhea, headaches, weakness, rash, abnormal liver function, altered acid/ base balance, abnormal thyroid function, taste alterations, alterations in serum lipid concentrations.
Medical Conditions Aggravated by Exposure:	None known from occupational exposure. Data suggest any pre-existing ailments in the following organs: gastrointestinal system, liver, eyes, thyroid.
Notes To Physician:	See Package Insert for drugs that are contraindicated, drugs that should not be co-administered and/or established and other potentially significant drug interactions.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures

Suitable Extinguishing Media:	Use extinguishing agent suitable for type of surrounding fire.
Protective Equipment and Precautions for Firefighters:	As in any fire, wear self-contained breathing apparatus and full protective gear

Section 6: Accidental Release Measures

Section 6, Accidental release measures

Personal precautions	Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.
Environmental precautions	Contain material and prevent release to waterways or soil.
Clean-up Methods	Recover product and place in an appropriate container for disposal.

Section 7: Handling and Storage

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Handling	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
Storage	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].



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Sorbitan monoloaurate	33600 mg/kg (rat)	Not available	Not available
Lopinavir	2500 mg/kg (rat)	Not available	Not available
Ritonavir	1030 – 1970 mg/kg (mice)	2000 mg/kg (rat)	Not available
Sodium stearyl fumarate	Not available	Not available	Not available
opadry yellow	Not available	Not available	Not available

Section 12: Ecological Information

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Do not allow product to enter drinking water supplies, waste water or soil.

Section 13: Disposal Considerations

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Disposal should be made in accordance with country, federal, state and local regulations.

Section 14: Transport Information

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DOT - Not Regulated

UN-Number

Not applicable

Section 15: Regulatory Information

Section 15: Regulatory Information

U.S State regulations

Present

California Proposition 65: This product does not content any proposition 65 chemicals

Not listed

Section 16: Other Information

Section 16, Other information

Issue Date : 05-04-2019

Version : 00

Further information

Revision note: New issue

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.

Hetero Labs Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited reserves the right to revise this SDS.