



SAFETY DATA SHEET

Section 1: Identification	
Material	Darunavir Tablets 400 mg and 600mg
Recommended use	Pharmaceutical Product
Manufacturer	Hetero Labs Limited, Unit-III 22-110, IDA, Unit III, Jeedimetla, Hyderabad-500055, India.
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Hazard statements	Harmful if swallowed.
Precautionary statements	Wash thoroughly after handling Do not eat, drink or smoke when using this product. If swallowed: Call a poison center/doctor if you feel unwell Rinse mouth. Dispose of contents/container in accordance with local/regional/national/international regulations.
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Darunavir	206361-99-1
Magnesium Stearate	557-04-0
Crospovidone	9003-39-8
Silicified Microcrystalline Cellulose	9004-34-6
Colloidal Silicon Dioxide	7631-86-9
Opadry II Orange	--
Section 4: First-Aid Measures	
Description of first aid measures General information	Symptoms of poisoning may even occur after several hours; therefore, medical observation for at least 48 hours after the accident
After Inhalation	Supply fresh air; consult doctor in case of complaints
After Skin contact	Generally, the product does not irritate the skin.
After Eye contact	Rinse opened eye for several minutes under running water
After swallowing	Immediately call a doctor.

**Most important symptoms and effects, both acute and delayed.**

May cause anemia, cough, CNS depression, drowsiness, headache, heart damage, lassitude (weakness, exhaustion), liver damage, narcosis, reproductive effects, teratogenic effects.
No further relevant information available.

Indication of any immediate medical attention and special treatment needed

No further relevant information available.

Section 5: Fire-Fighting Measures**Extinguishing media****Suitable extinguishing agents:**

Use firefighting measures that suit the environment.

A solid water stream may be inefficient.

Special hazards arising from the substance or mixture No further relevant information available.

Advice for firefighters

Protective equipment: No special measures required.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures Not required.

· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

· **Methods and material for containment and cleaning up:** Pick up mechanically.

· **Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

· **Protective Action Criteria for Chemicals**

· **PAC-1:** Substance is not listed.

· **PAC-2:** Substance is not listed.

· **PAC-3:** Substance is not listed

Section 7: Handling and Storage**Handling:****Precautions for safe handling**

No special precautions are necessary if used correctly.

Avoid breathing dust/fume/gas/mist/vapours/spray.

Avoid prolonged or repeated exposure.

Keep away from sources of ignition.

Take precautionary measures against static discharge.re.

Information about protection against explosions and fires: No special measures required.

Conditions for safe storage, including any incompatibilities**Storage:**

Requirements to be met by storerooms and receptacles: No special requirements.

Information about storage in one common storage facility: Not required.

Further information about storage conditions: None.

Specific end use(s) No further relevant information available.



Section 8: Exposure Controls/Personal Protection

Additional information about design of technical systems: No further data; see item 7.

- **Control parameters**
- **Components with limit values that require monitoring at the workplace:** Not required

Additional information: The lists that were valid during the creation were used as basis.

- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Breathing equipment:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Not required.

Section 9: Physical and Chemical Properties

Physical Form	Solid
Description	<p>Darunavir 400mg tablets are supplied as orange, oval shaped, bevel edged biconvex, film-coated tablets de-bossed with “H” on one side and “189” on the other side.</p> <p>Bottles of 60 NDC31772-567-60</p> <p>Darunavir 600mg tablets are available as orange, oval shaped, biconvex, film-coated tablets de-bossed with “J” on one side and “7” on the other side.</p> <p>Bottles of 60 NDC31772-568-60</p>



Section 10: Stability and Reactivity

Reactivity No further relevant information available.

· **Chemical stability**

· **Thermal decomposition / conditions to be avoided:**

No decomposition if used according to specifications.

· **Possibility of hazardous reactions** No dangerous reactions known.

· **Conditions to avoid** No further relevant information available.

· **Incompatible materials:** strong oxidizing agents

· **Hazardous decomposition products:**

carbon dioxide, carbon monoxide, nitrogen oxides, sulfur oxides

Section 11: Toxicological Information

Information on toxicological effects

· **Acute toxicity:**

· **Primary irritant effect:**

· **on the skin:** No irritant effect.

· **on the eye:** No irritating effect.

· **Sensitization:** No sensitizing effects known.

· **Additional toxicological information:**

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)** Substance is not listed.

· **NTP (National Toxicology Program)** Substance is not listed.

· **OSHA-Ca (Occupational Safety & Health Administration)** Substance is not listed.

Section 12: Ecological Information

Toxicity

· **Aquatic toxicity:** No further relevant information available.

· **Persistence and degradability** No further relevant information available.

· **Behavior in environmental systems:**

· **Bioaccumulative potential** No further relevant information available.

· **Mobility in soil** No further relevant information available.

Section 13: Disposal Considerations

Waste treatment methods

· **Recommendation:**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.



Section 14: Transport Information	
UN-Number	
· DOT, IMDG, IATA	Not regulated
UN proper shipping name	
DOT, IMDG, IATA	Not regulated
Transport hazard class(es)	
· DOT, ADN, IMDG, IATA	
Class	Not regulated
Packing group	
DOT, IMDG, IATA	Not regulated
Environmental hazards:	Not applicable
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
UN "Model Regulation":	Not regulated

Section 15: Regulatory Information	
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Safety, health and environmental regulations/legislation specific for the substance or mixture
 No further relevant information available.

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- **Section 355 (extremely hazardous substances):** Substance is not listed.
- **Section 313 (Specific toxic chemical listings):** Substance is not listed.
- **TSCA (Toxic Substances Control Act):** Substance is not listed.
- **Hazardous Air Pollutants** Substance is not listed.
- Proposition 65**
- **Chemicals known to cause cancer:** Substance is not listed.
- **Chemicals known to cause reproductive toxicity for females:** Substance is not listed.
- **Chemicals known to cause reproductive toxicity for males:** Substance is not listed.
- **Chemicals known to cause developmental toxicity:** Substance is not listed.
- **Carcinogenic categories**
- **EPA (Environmental Protection Agency)** Substance is not listed.
- **TLV (Threshold Limit Value)** Substance is not listed.
- **NIOSH-Ca (National Institute for Occupational Safety and Health)** Substance is not listed.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.



Section 16: Other Information

Issue Date: 14-08-2023

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Further information

Revision date: NA

Revision notes: NA

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