

**SAFETY DATA SHEET**

Section 1: Identification	
<b>Material</b>	<b>Darunavir Tablets 600 mg and 800 mg</b>
<b>Recommended use</b>	Pharmaceutical Product
<b>Manufacturer</b>	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
<b>Distributor</b>	<b>Camber Pharmaceuticals, Inc.</b> , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
<b>Hazard statements</b>	Harmful if swallowed.
<b>Precautionary statements</b>	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	
<b>Ingredients</b>	<b>CAS</b>
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 Yellow	--
Section 4: First-Aid Measures	
<b>Description of first aid measures</b> <b>General information</b>	Symptoms of poisoning may even occur after several hours; therefore, medical observation for at least 48 hours after the accident
<b>After Inhalation</b>	Supply fresh air; consult doctor in case of complaints
<b>After Skin contact</b>	Generally, the product does not irritate the skin.
<b>After Eye contact</b>	Rinse opened eye for several minutes under running water
<b>After swallowing</b>	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.

**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	Tablet
<b>Description</b>	<p>Darunavir 600 mg tablets are available as yellow, oval shaped, biconvex, film-coated tablets debossed with 'V' on one side and '5' on the other side. Each 600 mg tablet contains darunavir amorphous equivalent 600 mg of darunavir.</p> <p style="text-align: center;">Bottles of 60 <span style="float: right;">NDC 31722-088-60</span></p> <p>Darunavir 800 mg tablets are available as yellow, oval shaped, biconvex, film-coated tablets debossed with 'V' on one side and '7' on the other side. Each 800 mg tablet contains darunavir amorphous equivalent 800 mg of darunavir</p> <p style="text-align: center;">Bottles of 30 <span style="float: right;">NDC 31722-089-30</span></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:**

**Darunavir - Oral LD50** - Oral (Dog) LD50; >320 mg/kg[2]

- **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

<b>Transport hazard class(es)</b> · DOT, ADN, IMDG, IATA <b>Class</b>	Not regulated
<b>Packing group</b> <b>DOT, IMDG, IATA</b>	Not regulated
<b>Environmental hazards:</b>	Not applicable
<b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
<b>UN "Model Regulation":</b>	Not regulated

### Section 15: Regulatory Information

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

No further relevant information available.

- **Sara**
- **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:** 25-06-2025

**Version:** 00

**Further information**

**Revision date:** NA

**Revision notes:** NA

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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