

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Identification

Material	Darunavir Tablets 800 mg and 600 mg
Manufacturer	Lupin Limited Nagpur - 441108 Maharashtra, India
Distributor	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221
Use of the Substance/mixture	Pharmaceuticals

Section 2: Hazard(s) Identification

Hazard(s) identification

Classification

Danger	May be harmful if swallowed. Causes eye irritation.
Physical Hazard	Combustible Dust May form combustible dust concentrations in air.

Section 3: Composition/Information on Ingredients

Drug Substance:

Name	CAS No.	Quantity in 800 mg Tablet		Quantity in 600 mg Tablet	
		Quantity mg/tablet	% w/w	Quantity mg/tablet	% w/w
Darunavir Ethanolate*	206361-99-1	867.297	74.946	650.473	50.522
Microcrystalline Cellulose	9004-34-6	176.303	15.235	549.527	42.681
Hypromellose	9004-65-3	33.000	2.852	--	--
Crospovidone	9003-39-8	30.000	2.592	30.000	2.330
Colloidal Silicon Dioxide	7631-86-9	5.600	0.484	5.000	0.388
Magnesium Stearate	557-04-0	5.600	0.484	10.000	0.776

Note *: 650.473 mg of Darunavir Ethanolate equivalent to 600 mg of Darunavir,
867.297 mg of Darunavir Ethanolate equivalent to 800 mg of Darunavir

Section 4: First-Aid Measures

First-aid measures

General advice	Consult a physician. Show this safety data sheet to the doctor in attendance.
Eye contact	If this product comes in contact with the eyes: Wash out immediately with fresh running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Seek medical attention without delay; if pain persists or recurs seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin or hair contact occurs: Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.
Inhalation	If fumes, aerosols or combustion products are inhaled remove from contaminated area.
Ingestion	If swallowed do NOT induce vomiting. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Observe the patient carefully. Never give liquid to a person showing signs of being sleepy or with reduced awareness, i.e., becoming unconscious. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Seek medical advice.
Note to physicians	Treat symptomatically

Section 5: Fire-Fighting Measures

Fire-fighting measures

Suitable extinguishing media	Foam, Dry chemical powder, Carbon dioxide Alert Fire Brigade and tell them location and nature of hazard.
Advise for fire fighters Hazardous combustion products	Wear breathing apparatus plus protective gloves. carbon monoxide (CO), carbon dioxide (CO ₂), nitrogen oxides (NO _x) sulfur oxides (SO _x), other pyrolysis products typical of burning organic material. May emit poisonous fumes. May emit corrosive fumes.

Section 6: Accidental Release Measures

Accidental release measures

Personal precautions, protective equipment and emergency procedures	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure. Avoid raising and breathing dust and provide adequate ventilation. Gloves must be inspected prior to use. Use proper glove removal technique (without touching gloves outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
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Environmental precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Methods and material containment and cleaning up	<p>Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.</p> <p>Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.</p>
Disposal Methods	Dispose of in accordance with local, state, and national regulations.

Section 7: Handling and Storage

Handling and storage	
Precautions for safe handling	<p>Avoid all personal contact, including inhalation.</p> <p>Wear protective clothing when risk of exposure occurs.</p> <p>Use in a well-ventilated area.</p> <p>Prevent concentration in hollows and sumps.</p> <p>Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions)</p> <p>Minimize airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame.</p> <p>Establish good housekeeping practices.</p> <p>Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.</p>
Advice on safe handling	Handle in accordance with good industrial hygiene and safety practices.
Conditions for safe storage, including any incompatibilities	
Storage conditions	Store in original containers.
Storage	Keep containers securely sealed. Avoid reaction with oxidizing agents.

Section 8: Exposure Controls/Personal Protection

Exposure controls/personal protection	
Personal protection	Use appropriate personal protective equipment for protection.
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 / fumes.
Individual protection measures, such as personal protective equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands	<p>Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.</p> <p>Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference. Double gloving should be considered. PVC gloves.</p>

Eyes	Wear safety glasses or goggles if eye contact is possible. Chemical goggles and Face shield.
Skin	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. wear disposable coverall of low permeability and disposable shoe covers.
Respiratory protection	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties

Appearance	Tablet
HOW SUPPLIED	<p>Darunavir Tablets, 600 mg are supplied as orange colored, oval shaped, film-coated tablets debossed with 'LU' on one side and 'A42' on the other side.</p> <p>Darunavir Tablets, 800 mg are supplied as dark red colored, oval shaped, film-coated tablets debossed with 'LU' on one side and 'A46' on the other side.</p> <p>Darunavir Tablets are packaged in bottles in the following configuration:</p> <ul style="list-style-type: none"> • 600 mg tablets - bottles of 60 (NDC 68180-345-07) • 800 mg tablets - bottles of 30 (NDC 68180-346-06), bottles of 90 (NDC 68180-346-09)
Odour	Not available
Odour threshold	Not available
Melting point/Freezing Point	103-105 (°C)
Boiling point	Not available
Flash point	Not available
Evaporation rate	Not available
Flammability (solid, gas)	Not available
Flammability Limit in Air	Not available
Explosive properties	Not available
Explosive properties	Not available
Oxidising properties	Not available
Vapour pressure	Negligible
Vapour density	Not available
Specific Gravity	Not available
Water solubility	Partly Miscible
Solubility in other solvent	Not available
Partition coefficient	Not available
Auto-ignition temperature	410 (Dust Cloud)
Decomposition temperature	Not available
Viscosity, kinematic	Not available
Viscosity, dynamic	Not available
Upper flammability limit	Not available
Lower flammability limit	Not available

Section 10: Stability and Reactivity

Reactivity	Avoid reaction with oxidizing agents
Chemical stability	Stable under normal conditions of use
Possibility of hazardous reactions	None known.
Incompatible materials	As a precautionary measure, keep away from strong oxidizers. Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result.
Hazardous decomposition products	Carbon monoxide (CO), carbon dioxide (CO ₂), nitrogen oxides (NO _x) sulfur oxides (SO _x), other pyrolysis products typical of burning organic material. May emit poisonous fumes. May emit corrosive fumes.

Section 11: Toxicological Information

Toxicological information

Acute toxicity

Chemical Name	Oral LD50.	Dermal LD50	Inhalation LC50	Intravenous LD50
Darunavir	Oral (Dog) LD50; >320 mg/kg[2]	-	-	-

Information on toxicological effects

The toxicological effects of this product have not been thoroughly studied.

Section 12: Ecological Information

Avoid release into the environment. Runoff from fire control or dilution water may cause pollution

Eco toxicity	Not available.
Persistence and degradability	Not available.
Bioaccumulation	Not available.
Mobility	Not available.
Other adverse effects	Not available.

Section 13: Disposal Considerations

Disposal Considerations

Disposal of wastes: Disposal should be in accordance with applicable regional, national and local laws and regulations. Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

Hierarchy of Controls seems to be common - the user should investigate:

Reduction

Reuse

Recycling

Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use.

DO NOT allow wash water from cleaning or process equipment to enter drains.

It may be necessary to collect all wash water for treatment before disposal.
In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
Where in doubt contact the responsible authority.
Recycle wherever possible.
Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.
Dispose of by burial in a landfill specifically licensed to accept chemical and / or pharmaceutical wastes or Incineration in a licensed apparatus (after admixture with suitable combustible material)
Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

Section 14: Transport Information

Transport Information

Not Regulated

Land transport (UN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Section 15: Regulatory Information

Regulatory Information

Not available

Section 16: Other Information

Other information

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.

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