Safety Data Sheet

Darunavir Tablets

Strength: 600 mg and 800 mg

Pack Size: 600 mg HDPE Bottle 60's
800 mg HDPE Bottle 30's

Revision No.: 00

EMERGENCY OVERVIEW

Each Darunavir Tablet intended for oral administration contains Darunavir and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

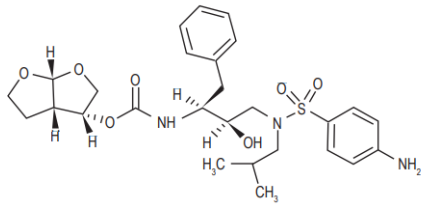
Section 1. Identification

Identification of the product

Product Name: **Darunavir Tablets**

Formula: $C_{27}H_{37}N_3O_7S$

Chemical Name:



Manufacturer / supplier identification

Company:	**Zydus Lifesciences Ltd., Matoda, India**
Address:	Zydus Lifescience Limited, Plot No- 1A/1 & 2, Pharmez Special Economic Zone, Sarkhej- Bavla N.H. No. 8A, Near Village Matoda, Tal. Sanand, Dist. Ahmedabad-382 213, India
Contact for information:	Tel: +91-79-26868100 Fax: +91-79-26868533
Emergency Telephone No.	Tel: +91-79-26868101
US Customer Service:	1 (877) 993 8779
Recommended use / Therapeutic Category	Darunavir is a human immunodeficiency virus (HIV-1) protease inhibitor indicated for the treatment of HIV-1 infection in adult and pediatric patients 3 years of age and older.
Restriction on Use / Contraindications:	Co-administration of darunavir/ritonavir is contraindicated with drugs that are highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events.

Safety Data Sheet

Darunavir Tablets

Strength: 600 mg and 800 mg

Pack Size: 600 mg HDPE Bottle 60's
800 mg HDPE Bottle 30's

Revision No.: 00

Section 2. Hazard(s) Identification

Dose and Administration

- Testing:
  - In treatment-experienced patients, treatment history genotypic and/or phenotypic testing is recommended prior to initiation of therapy with darunavir/ritonavir to assess drug susceptibility of the HIV-1 virus.
  - Monitor serum liver chemistry tests before and during therapy with darunavir/ritonavir.
- Treatment-naïve adult patients and treatment-experienced adult patients with no darunavir resistance associated substitutions: 800 mg (one 800 mg tablet) taken with ritonavir 100 mg once daily and with food.
- Treatment-experienced adult patients with at least one darunavir resistance associated substitution: 600 mg (one 600 mg tablet) taken with ritonavir 100 mg twice daily and with food.
- Pregnant patients: 600 mg (one 600 mg tablet) taken with ritonavir 100 mg twice daily and with food.
- Pediatric patients (3 to less than 18 years of age and weighing at least 10 kg): dosage of darunavir and ritonavir is based on body weight and should not exceed the adult dose. Darunavir should be taken with ritonavir and with food.
- Darunavir/ritonavir is not recommended for use in patients with severe hepatic impairment.

Adverse Effects

The following serious adverse reactions are described elsewhere in the prescribing information:

- Hepatotoxicity
- Bone Marrow Effects/Immunosuppression Potential/Infections Hypersensitivity Reactions
- Serious Skin Reactions
- Drug Reaction with Eosinophilia and Systemic Symptoms
- Peripheral Neuropathy
- Increased Blood Pressure
- Respiratory Effects

	• Pancreatitis in Paediatric Patients
Overdosage	Human experience of acute overdose with darunavir is limited. No specific antidote is available for overdose with darunavir. Treatment of overdose with darunavir consists of general supportive measures including monitoring of vital signs and observation of the clinical status of the patient. Since darunavir is highly protein bound, dialysis is unlikely to be beneficial in significant removal of the active substance.
Pregnancy Comments	There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to darunavir during pregnancy. Healthcare providers are encouraged to register patients by calling the Antiretroviral Pregnancy Registry (APR) 1-800-258-4263.
Pregnancy Category	Category B

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component:		
Darunavir Tablets	1.0 mg/day	206361-99-1
Inactive ingredients:		
Colloidal Silicon Dioxide	Not Found	112926-00-8
Sodium starch Glycolate	Not Found	9063-38-1
Microcrystalline Cellulose	Not Found	9004-34-6
Magnesium Stearate	Not Found	557-04-0

Section 4. First -aid measures

In Case of Inhalation	Remove to fresh air, if not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.
In Case of Skin Contact	Immediately wash skin with soap and plenty water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur, wash clothing before reuse.
In Case of Eye Contact	Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eye examined and tested by medical person. Seek medical attention immediately.

In Case of Ingestion	Wash out mouth with water provided person in conscious. Never give anything by mouth to an unconscious person.
Section 5. Fire -fighting measures	
Fire Fighting instruction	wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.
Special hazards arising from the substance or mixture	No further relevant information available.
Extinguishing agent	Use firefighting measures that suit the environment. A solid water stream may be inefficient.
Section 6. Accidental release measure	
Contamination and cleaning	Contain spill and collect, as appropriate.
Clean-up Procedures	Wearing appropriate protective gear as outlined under "Protective Equipment" wipe up spill and Transfer to a chemical waste container for disposable in accordance with local regulation.
Section 7. Handling and Storage	
Precaution to be taken in handling	Avoid breathing dust/ fumes/ gas/ mist/ vapour/ spray. Avoid prolong and repeated exposure.
Precaution to be taken in storing	Keep container tightly closed. Store in accordance with information listed on product insert.
Section 8. Exposure control / Personal Protection	
Engineering Control	Use process enclosures, local exhausted ventilation, or other engineering control to control airborne levels below recommended exposure limit.
Eye Protection	Safety glasses.
Protective Gloves	Compatible chemical resistance gloves.
Other protective Clothing	Lab coat
Respiratory Equipment	NISHO Approved respirator, as condition warrant.

Safety Data Sheet

Darunavir Tablets

Strength: 600 mg and 800 mg

Pack Size: 600 mg HDPE Bottle 60's
800 mg HDPE Bottle 30's

Revision No.: 00

Section 9. Physical and chemical properties

Physical States	Description of **Darunavir Tablets 600 mg** is Brown, oval, film coated tablets debossed "1215" on one side and plain on other side. Description of **Darunavir Tablets 800 mg** is Beige, oval, film coated tablets debossed "1217" on one side and plain on other side.		
Solubility in water	No Data	**Decomposition Temperature:**	No Data
Boiling point	No Data	**Melting Point**	No Data
Evaporation rate	No Data	**Vapour density**	No Data
Reactivity in water	No Data	**Vapour pressure**	No Data
% Volatile by volume	No Data	**Specific gravity**	No Data

Section 10. Stability and Reactivity

Stability	This material is stable of store in accordance with information listed on product insert.
Condition to avoid	No data available
Incompatibles	Strong oxidizing agents

Section 11. Toxicological information

Information on toxicological effects:	The toxicological efforts of this product have not been thoroughly studied.
Chronic Toxicological Effect	Darunavir Toxicity data : Unreported TDLO (rat): 1000 mg/ KG.

Section 12. Ecological information

Toxicity	Avoid release into environment. Run off fire control or dilution water may cause pollution.

Section 13. Disposal Consideration

Dispose in accordance with local, state, and federal regulations

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG). In

accordance with ADR / RID / IMDG / IATA / AND.

Section 15. Regulatory Information

Approved by USFDA & the ANDA Number is 214085.

Section 16. Other information

None

Date of issue: 22/12/23 **Supersedes edition:** New Edition

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.