

**DARUNAVIR TABLETS 600mg, 800mg**

S.No.	Category	Question	Answer
<b>Clinical Particulars</b>			
1	Use/Indication	What is the product indicated for?	<ul style="list-style-type: none"> <li>• Treatment of human immunodeficiency virus (HIV-1) infection</li> <li>• Patient Population: Adults and paediatric patients aged 3 years and older</li> <li>• In combination with other antiretroviral agents</li> </ul>
2	Dosage	What is the recommended dosage?	<p>For treatment-experienced HIV patients, genotypic/phenotypic testing is recommended before starting darunavir/ritonavir to assess drug resistance. Liver function should be monitored during therapy.</p> <ul style="list-style-type: none"> <li>• Treatment-naïve or no darunavir resistance: 800 mg darunavir + 100 mg ritonavir once daily with food.</li> <li>• Treatment-experienced with darunavir resistance: 600 mg darunavir + 100 mg ritonavir twice daily with food.</li> <li>• Pregnant patients: 600 mg darunavir + 100 mg ritonavir twice daily with food.</li> <li>• Paediatric patients (≥3 years, ≥10 kg): Dosage based on body weight, not exceeding adult dose.</li> </ul>
3	Administration	How do I take it?	Not recommended for patients with severe hepatic impairment.
4	Formulation	Can tablet be crushed?	Do not crush or chew the tablets
5	Administration	What do I do if I miss a dose?	If you miss a dose of Darunavir tablets continue your prescribed course of therapy, and contact your physician immediately.
6	Administration	Use in Pediatric Population	Not recommended for patients less than 3 years of age.
7	Administration	Use in Geriatric Population	Clinical studies of darunavir did not include sufficient numbers of patients aged 65 years and over to determine whether they respond differently from younger patients. In general, caution should be exercised in the administration and monitoring of darunavir in elderly patients, reflecting the greater frequency of decreased hepatic function, and of concomitant disease or other drug therapy
8	Mechanism	Mechanism of Action	Darunavir is an HIV-1 antiviral drug. Darunavir is an inhibitor of the HIV-1 protease. It selectively inhibits the cleavage of HIV-1 encoded Gag-Pol polyproteins in infected cells, thereby preventing the formation of mature virus particles.
9	Warning	Black Box Warning	Darunavir/ritonavir may cause drug-induced hepatitis (monitor

			liver function, especially in patients with liver issues). Severe skin reactions, including Stevens-Johnson Syndrome, have been reported—discontinue if severe. Use cautiously in patients with sulfonamide allergies. It may cause new-onset diabetes, hyperglycemia, or fat redistribution. Hemophilia patients may experience increased bleeding. Not recommended for children under 3 due to toxicity risks observed in juvenile rats.
10	Lactation	Use in Lactation	Women infected with HIV should be instructed not to breastfeed due to the potential for HIV transmission.
11	Pregnancy	Use in Pregnancy	Darunavir exposures during pregnancy were generally lower compared to the postpartum period, with a more significant reduction observed in patients on the once-daily dosing regimen compared to those on the twice-daily regimen.
12	Precautions	Is there any interaction between medication and alcohol?	NO
13	Interaction	Is there any interaction with food?	NO
14	Side effects	What are the common side effects?	<p>The most common side effects of darunavir tablets include:</p> <ul style="list-style-type: none"> <li>• Diarrhea</li> <li>• Headache</li> <li>• Nausea</li> <li>• stomach-area (abdominal) pain</li> <li>• rash</li> <li>• vomiting</li> </ul> <p>Tell your healthcare provider if you have any side effect that bothers you or that does not go away.</p>
15	Storage	What are the storage conditions?	Store darunavir tablets at room temperature 77°F (25°C).
16	Dispensing	How to Dispense?	As prescribed by the Physician
17	Contraindication	What are the contraindications of (medication).	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 (narrow therapeutic index).
<b>Pharmaceutical Particulars</b>			
18	Pharmaceutical Form	How is it supplied?	<p>Darunavir 600 mg tablets are supplied as Beige colored, oval-shaped, film-coated tablets debossed with “M” on one side and “600” on the other side.</p> <p>Darunavir 800 mg tablets are supplied as brown colored, oval-shaped, film-coated tablets debossed with “M” on one side and “800” on the other side.</p> <p>Darunavir tablets are packaged in bottles in the following configuration:</p> <ul style="list-style-type: none"> <li>• 600 mg tablets — bottles of 60 (NDC 72205-184-60)</li> <li>• 800 mg tablets — bottles of 30 (NDC 72205-185-30)</li> </ul>

19	Ingredients	Active and Inactive Ingredients	<b>Active:</b> Darunavir <b>Inactive:</b> <ul style="list-style-type: none"> <li>• Silicon dioxide</li> <li>• Crospovidone, unspecified</li> <li>• Hydroxypropyl cellulose, unspecified</li> <li>• Magnesium stearate</li> <li>• Polacrillin potassium</li> <li>• Microcrystalline cellulose</li> <li>• Sodium chloride</li> <li>• Polyvinyl alcohol, unspecified</li> <li>• Ferric oxide yellow</li> <li>• Ferric oxide red</li> <li>• Polyethylene glycol 3350</li> <li>• Talc</li> <li>• Titanium dioxide</li> </ul>
20	Coating	What is the type of coating?	Film-coated tablets
<b>Allergens</b>			
21	Ingredients	Is it Vegetarian?	yes
22	Ingredients	Does it contain Gluten?	No
23	Ingredients	Does it contain Dairy Products?	No.
24	Ingredients	Does it contain Casein	No
25	Ingredients	Does it contain Whey?	No
26	Ingredients	Does it contain corn?	No
27	Ingredients	Does it contain rye?	No
28	Ingredients	Does it contain sugar?	No
29	Ingredients	Does it contain Oats?	No
30	Ingredients	Does it contain wheat?	No
31	Ingredients	Does it contain spelt?	No
32	Ingredients	Does it contain barley?	No
33	Ingredients	Does it contain rennet?	No
34	Ingredients	Does it contain starch?	No
36	Ingredients	Does it contain Iodine?	No
37	Ingredients	Does it contain latex?	No
38	Ingredients	Does it contain alcohol?	Yes
39	Ingredients	Does it contain dyes?	No

40	Ingredients	Does it contain flavor?	No
41	Ingredients	Does it contain Lactose?	No
42	Ingredients	Does it contain Nuts?	No
43	Ingredients	Does it contain Preservatives?	No
44	Ingredients	Does it contain Soy products?	No
45	Ingredients	Does it contain peanut?	No
46	Ingredients	Does it contain nickel?	No
<b>Miscellaneous</b>			
47	Miscellaneous	May I know the product availability?	Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products.
48	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
49	Miscellaneous	Do you have any patient's assistance program?	Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company.
50	Miscellaneous	How do I report an adverse drug effect or reaction to Novadoz medication?	To report suspected adverse reactions, contact Novadoz Pharmaceuticals LLC at 1-855-668-2369 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
51	Miscellaneous	Why does my pharmacy that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation?	Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products.
52	Miscellaneous	Manufacturer and Distributor	<p><b>Manufactured by:</b>  <b>MSN Laboratories Private Limited,</b>  <b>Unit – II, Formulations Division,</b>  <b>Nandigama.</b></p> <p><b>Distributed by:</b>  <b>Novadoz Pharmaceuticals LLC</b>  <b>Piscataway, NJ 08854-3714</b></p>