

FIRST TIME GENERIC APPROVAL

Brand Name	Prezista®
Generic Name	darunavir ethanolate
Drug Manufacturer	Lupin Pharmaceuticals, Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

September 29, 2022

LAUNCH DATE

June 03, 2023

REVIEW DESIGNATION

N/A

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 202073

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Darunavir is a human immunodeficiency virus (HIV-1) protease inhibitor indicated for the treatment of HIV1 infection in adult and pediatric patients 3 years of age and older. Darunavir tablets must be coadministered with ritonavir (darunavir/ritonavir) and with other antiretroviral agents.

MECHANISMS OF ACTION

Darunavir is an inhibitor of the HIV-1 protease. It selectively inhibits the cleavage of HIV1 encoded Gag-Pol polyproteins in infected cells, thereby preventing the formation of mature virus particles.

DOSE FORM AND STRENGTH

Tablets: 600 mg, and 800 mg.

DOSE & ADMINISTRATION

- 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.

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- 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 tablets should be taken with ritonavir and with food.
- Darunavir/ritonavir is not recommended for use in patients with severe hepatic impairment.

Table 1: Recommended Darunavir/Ritonavir Dosage in Treatment-Experienced Adult Patients

Baseline Resistance	Formulation and Recommended Dosing
	Darunavir tablets with ritonavir tablets or capsule
With no darunavir resistance associated substitutions ^a	One 800 mg darunavir tablet with one 100 mg ritonavir tablet/capsule, taken once daily with food.
With at least one darunavir resistance associated substitutions ^a , or with no baseline resistance information	One 600 mg darunavir tablet with one 100 mg ritonavir tablet/capsule, taken twice daily with food

^aV11I, V32I, L33F, I47V, I50V, I54L, I54M, T74P, L76V, I84V and L89V

Dosing Recommendations for Treatment-Naïve Pediatric Patients: Pediatric patients weighing at least 15 kg can be dosed with darunavir tablets using the following table:

Table 2: Recommended Dose for Pediatric Patients Weighing At Least 15 kg Who are Treatment-Naïve or Treatment-Experienced with No Darunavir Resistance Associated Substitutions^a

Body weight (kg)	Formulation: Darunavir tablet(s) and ritonavir capsules or tablets (100 mg)
	Dose: once daily with food
Greater than or equal to 15 kg to less than 30 kg	Darunavir 600 mg with ritonavir 100 mg
Greater than or equal to 30 kg to less than 40 kg	Darunavir 675 mg with ritonavir 100 mg
Greater than or equal to 40 kg	Darunavir 800 mg with ritonavir 100 mg

^adarunavir resistance associated substitutions: V11I, V32I, L33F, I47V, I50V, I54M, I54L, T74P, L76V, I84V and L89V

Dosing Recommendations for Treatment-Experienced Pediatric Patients: Pediatric patients weighing at least 15 kg can be dosed darunavir tablets using the following table:

Table 3: Recommended Dose for Pediatric Patients Weighing At Least 15 kg Who are Treatment-Naïve or Treatment-Experienced with At Least One Darunavir Resistance Associated Substitutions^a

Body weight (kg)	Formulation: Darunavir tablet(s) and ritonavir tablets, capsules (100 mg) or oral solution (80 mg/mL)
	Dose: twice daily with food
Greater than or equal to 15 kg to less than 30 kg	Darunavir 375 mg with ritonavir 0.6 mL (48 mg)
Greater than or equal to 30 kg to less than 40 kg	Darunavir 450 mg with ritonavir 0.75 mL (60 mg)
Greater than or equal to 40 kg	Darunavir 600 mg with ritonavir 100 mg

^adarunavir resistance associated substitutions: V11I, V32I, L33F, I47V, I50V, I54M, I54L, T74P, L76V, I84V and L89V

- The use of darunavir/ritonavir in pediatric patients below 3 years of age is not recommended.

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