darunavir

**Actions**

Initiates HIV-1 protease, selectively inhibiting the cleavage of HIV-1-encoded polyproteins in infected cells. This prevents the formation of mature virus particles. Inhibits HIV-1 protease, selectively inhibiting the cleavage of HIV-encoded specific polyproteins in infected cells. This prevents the formation of mature virus particles.

**Therapeutic Effects:** Increased CD4 cell counts and decreased viral load with subsequent slowed progression of HIV infection and its sequelae.

**Indications**

HIV infection (must be used with ritonavir and with other antiretrovirals).

**Contraindications/Precautions**

Contraindicated in: Concurrent use with ritonavir.

**Adverse Reactions/Side Effects**

Drug-Drug: Darunavir and ritonavir are both inhibitors of CYP3A and are metabolized by CYP3A. Multiple drug-drug interactions can be expected with drugs that share, inhibit, or induce these pathways. Consult product information for more specific details.

**Interactions**

Concurrent use with ritonavir is contraindicated. Concurrent use with indinavir may result in increased ritonavir levels; blood level monitoring recommended. May lower levels of ritonavir.

**Dosage**

**Adult**: 800 mg b.i.d. dosed with 100 mg ritonavir daily.

**Pediatric Use:** Safety and efficacy not established.

**Geriatric Use:** Age-related dose adjustment.

**Dosage Adjustments**

**Renal Impairment:** No adjustment required.

**Liver Impairment:** Use with caution, no dose adjustment recommended.
Therapy-naive—

Therapy-experienced (with no darunavir resistance associated substitution) or if genotypic testing not performed)—600 mg twice daily with monitor 100 mg once daily.

Therapy-experienced (with 1 darunavir resistance associated substitution or if genotypic testing not performed)—600 mg twice daily with monitor 100 mg once daily.

PO (oral suspension or tablets) (Children 3–17 yr and 50–59.9 kg): Therapy-naive—675 mg once daily with monitor 150 mg once daily; Therapy-experienced (with no darunavir resistance associated substitution)—675 mg once daily with monitor 150 mg once daily; Therapy-experienced (with 1 darunavir resistance associated substitution or if genotypic testing not performed)—450 mg twice daily with monitor 100 mg once daily.

PO (oral suspension or tablets) (Children 3–17 yr and 15–29.9 kg): Therapy-naive—450 mg once daily with monitor 100 mg once daily; Therapy-experienced (with no darunavir resistance associated substitution)—450 mg once daily with monitor 100 mg once daily; Therapy-experienced (with 1 darunavir resistance associated substitution or if genotypic testing not performed)—375 mg twice daily with monitor 100 mg once daily.

PO (oral suspension only) (Children 3–17 yr and 14–14.9 kg): Therapy-naive—450 mg once daily with monitor 100 mg once daily; Therapy-experienced (with no darunavir resistance associated substitution or if genotypic testing not performed)—375 mg twice daily with monitor 100 mg once daily.

PO (oral suspension only) (Children 3–17 yr and 13–13.9 kg): Therapy-naive—450 mg once daily with monitor 100 mg once daily; Therapy-experienced (with no darunavir resistance associated substitution or if genotypic testing not performed)—375 mg twice daily with monitor 100 mg once daily.

PO (oral suspension only) (Children 3–17 yr and 12–12.9 kg): Therapy-naive—420 mg once daily with monitor 100 mg once daily; Therapy-experienced (with no darunavir resistance associated substitution or if genotypic testing not performed)—300 mg twice daily with monitor 100 mg once daily.

PO (oral suspension only) (Children 3–17 yr and 11–11.9 kg): Therapy-naive—385 mg once daily with monitor 100 mg once daily; Therapy-experienced (with no darunavir resistance associated substitution or if genotypic testing not performed)—280 mg twice daily with monitor 100 mg once daily.

PO (oral suspension only) (Children 3–17 yr and 10–10.9 kg): Therapy-naive—350 mg once daily with monitor 100 mg once daily; Therapy-experienced (with no darunavir resistance associated substitution or if genotypic testing not performed)—250 mg twice daily with monitor 100 mg once daily.

PO (oral suspension only) (Children 3–17 yr and 9–9.9 kg): Therapy-naive—300 mg once daily with monitor 100 mg once daily; Therapy-experienced (with no darunavir resistance associated substitution or if genotypic testing not performed)—200 mg twice daily with monitor 100 mg once daily.

PO (oral suspension only) (Children 3–17 yr and 8–8.9 kg): Therapy-naive—240 mg once daily with monitor 100 mg once daily; Therapy-experienced (with no darunavir resistance associated substitution or if genotypic testing not performed)—150 mg twice daily with monitor 100 mg once daily.

PO (oral suspension only) (Children 3–17 yr and 7–7.9 kg): Therapy-naive—180 mg once daily with monitor 100 mg once daily; Therapy-experienced (with no darunavir resistance associated substitution or if genotypic testing not performed)—100 mg twice daily with monitor 100 mg once daily.

PO (oral suspension only) (Children 3–17 yr and 6–6.9 kg): Therapy-naive—120 mg once daily with monitor 100 mg once daily; Therapy-experienced (with no darunavir resistance associated substitution or if genotypic testing not performed)—60 mg twice daily with monitor 100 mg once daily.

PO (oral suspension only) (Children 3–17 yr and 5–5.9 kg): Therapy-naive—60 mg once daily with monitor 100 mg once daily; Therapy-experienced (with no darunavir resistance associated substitution or if genotypic testing not performed)—30 mg twice daily with monitor 100 mg once daily.

PO (oral suspension only) (Children 3–17 yr and 4–4.9 kg): Therapy-naive—40 mg once daily with monitor 100 mg once daily; Therapy-experienced (with no darunavir resistance associated substitution or if genotypic testing not performed)—20 mg twice daily with monitor 100 mg once daily.
CONTINUED

darunavir

Associated substitution or if genotypic testing not performed—200 mg twice daily with ritonavir 32 mg twice daily.

PO (oral suspension only) (Children 3–17 yr and 10–10.9 kg): Therapy-naive—350 mg once daily with ritonavir 64 mg once daily; Therapy-experienced (with no darunavir resistance associated substitution)—350 mg once daily with ritonavir 64 mg once daily; Therapy-experienced (with a darunavir resistance associated substitution or if genotypic testing not performed)—200 mg twice daily with ritonavir 32 mg twice daily.

NURSING IMPLICATIONS

Assessment

● Assess for change in severity of HIV symptoms and for symptoms of opportunistic infections during therapy.

● Assess for allergy to sulfonamides.

● Monitor patient for development of rash; usually maculopapular and self-limited. May cause Stevens-Johnson syndrome or toxic epidermal necrolysis. Discontinue therapy if severe or if accompanied with fever, general malaise, fatigue, muscle or joint aches, blisters, oral lesions, conjunctivitis, hepatitis and/or eosinophilia.

● Lab Test Considerations: Monitor viral load and CD4 counts regularly during therapy.

● May cause serum AST, ALT, GGT, total cholesterol, triglycerides, total bilirubin, alkaline phosphatase, pancreatic amylase, pancreatic lipase, uric acid concentrations.

Potential Nursing Diagnoses

Risk for infection (Indications)

Implementation

PO: Must be administered with a meal or light snack along with ritonavir 100 mg to be effective. The type of food is not important. Tablets should be swallowed whole with water or milk, do not chew.

Administer oral suspension 9 ml dose and two 4–ml doses using syringe provided along with ritonavir and food.

Patient/Family Teaching

● Emphasize the importance of taking darunavir with ritonavir exactly as directed, at evenly spaced times throughout day. Do not take more than prescribed amount and do not stop taking without consulting health care professional. If dose of darunavir or ritonavir is missed by more than 6 hr, wait and take next dose at regularly scheduled time. If missed for less than 6 hr, take darunavir and ritonavir immediately and then take next dose at regularly scheduled time. If dose is skipped, do not double doses. Advise patient to read the Patient Information sheet before starting therapy and with each Rx renewal in case changes have been made.

● Instruct patient to notify health care professional of all Rx or OTC medications, vitamins, or herbal products being taken and consult health care professional before taking any new medications.

● Inform patient that darunavir does not cure AIDS or prevent associated or opportunistic infections. Ritonavir does not reduce the risk of transmission of HIV to others through sexual contact or blood contamination. Caution patient to use a condom during sexual contact and to avoid sharing needles or donating blood to prevent spreading the HIV virus to others. Advise patient that the long-term effects of darunavir are unknown at this time.

● Inform patient that darunavir may cause hyperglycemia, hyperlipidemia, and severe skin reactions. Advise patient to notify health care professional promptly if signs of hyperglycemia (increased thirst or hunger; unexplained weight loss; increased urination; fatigue; or dry, itchy skin), hyperlipidemia (unexplained fatigue, nausea, jaundice, abdominal pain or dark urine), or rash occur.

● Advise patients taking oral contraceptives to use a nonhormonal method of birth control during darunavir therapy. Advise female patients to avoid breast feeding during therapy with darunavir.

● Instruct patient that redistribution and accumulation of body fat may occur, causing central obesity, dorsocervical fat enlargement (buffalo hump), peripheral
Wasting, breast enlargement, and cushingoid appearance. The cause and long-term effects are not known.

- Emphasize the importance of regular follow-up exams and blood counts to determine progress and monitor for side effects.

Evaluation/Desired Outcomes
- Delayed progression of AIDS and decreased opportunistic infections in patients with HIV.
- Decrease in viral load and improvement in CD4 cell counts.

Why was this drug prescribed for your patient?