

Darunavir

dar-UE-na-vir

Brand Name: Prezista

Drug Class: Protease Inhibitors

Darunavir, also known as Prezista or TMC114, is a type of medicine called a protease inhibitor (PI). PIs work by blocking protease, a protein that HIV needs to make more copies of itself.

HIV/AIDS-Related Uses

Darunavir, to be coadministered with ritonavir, was approved by the FDA on June 23, 2006, for use with other antiretroviral agents in the treatment of HIV infection in adults. Darunavir does not cure or prevent HIV infection or AIDS and does not reduce the risk of passing the virus to other people.

Tibotec provides darunavir through an expanded access program for international patients who have limited or no treatment options because of virologic failure or who cannot tolerate certain anti-HIV drug regimens. Patients and health care professionals can visit <http://www.tibotec.com> or call 1-866-889-2074 for more information.

Dosage Form/Administration

Darunavir comes in tablet form and is taken by mouth with food.

Recommended Daily Dose

The recommended daily dose of darunavir for treatment-naïve adults is 800 mg (two 400-mg tablets) taken with ritonavir 100 mg once a day with food. The recommended daily dose of darunavir for treatment-experienced adults is 600 mg taken with ritonavir 100 mg twice a day with food. Some patients may benefit from different doses of darunavir. Patients should always take darunavir as prescribed by their doctor.

Contraindications

Individuals should tell a doctor about any medical problems before taking this medicine.

Possible Side Effects

Along with its desired effects, darunavir may cause some unwanted effects. Although not all of these effects are known, diarrhea, nausea, headache, and cold-like symptoms, including runny nose or sore

throat, have been reported as the most common side effects. Individuals should tell a doctor if they have any of these side effects. Inflammation of the liver, abnormal liver function tests, severe skin rash, fever, and abnormally high cholesterol and triglyceride levels have also been reported. Liver injury, specifically drug-induced hepatitis, may occur when darunavir and ritonavir are taken together. Signs and symptoms of liver injury include abnormal liver function tests, dark urine, jaundice, and liver tenderness. Patients who have hepatitis coinfection or who already have abnormal liver function tests should be followed closely during the first few months of darunavir and ritonavir treatment. Rare cases of hypersensitivity including facial swelling and rhabdomyolysis have been reported.

Drug and Food Interactions

A doctor should be notified of any other medications being taken, including prescription, nonprescription (over-the-counter), or herbal medications.

Clinical Trials

For information on clinical trials that involve Darunavir, visit the ClinicalTrials.gov web site at <http://www.clinicaltrials.gov>. In the Search box, enter: Darunavir AND HIV Infections.

Manufacturer Information

Darunavir
Tibotec
1029 Stony Hill Road
Suite 300
Yardley, PA 19067
(877) 732-2488

Darunavir



Manufacturer Information (cont.)

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For More Information

Contact your doctor or an AIDSinfo Health Information Specialist:

- Via Phone: 1-800-448-0440 Monday - Friday, 12:00 p.m. (Noon) - 5:00 p.m. ET
- Via Live Help: http://aidsinfo.nih.gov/live_help Monday - Friday, 12:00 p.m. (Noon) - 4:00 p.m. ET