



# DARUNAVIR (Prezista)

## WHAT IS DARUNAVIR?

Darunavir is a drug used as part of antiretroviral therapy (ART). It is also called Prezista and used to be called TMC114. It is manufactured by Tibotec Pharmaceuticals.

Darunavir is a protease inhibitor. These drugs prevent the protease enzyme from working. HIV protease acts like a chemical scissors. It cuts the raw material for HIV into specific pieces needed to build a new virus. Protease inhibitors "gum up" these scissors.

## WHO SHOULD TAKE IT?

Darunavir was approved in 2006 as an antiretroviral drug (ARV) for people with HIV infection. It should not be used in children younger than 3 years old and has not been studied in children between 3 and 6 years old.

There are no absolute rules about when to start ART. You and your health care provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your attitude about taking ART. Fact Sheet 404 has more information about guidelines for the use of ART.

If you take darunavir with other ARVs, you can reduce your viral load to extremely low levels, and increase your CD4 cell counts. This should mean staying healthier longer.

## WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. They are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called "developing resistance" to the drug. See Fact Sheet 126 for more information on resistance.

Sometimes, if your virus develops resistance to one drug, it will also have resistance to other ARVs. This is called "cross-resistance." **Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.**

Darunavir was specifically developed to control HIV that is already resistant to some other protease inhibitors. It has shown low levels of cross-resistance to other protease inhibitors.

## HOW IS IT TAKEN?

Darunavir is taken by mouth as a tablet. The normal adult dose is 600 milligrams (mg) taken with one 100 mg capsule of ritonavir, two times a day. The original tablets are 300 mg. However, there are also 400 mg and 600 mg tablets. This cuts down the pill count.

Also in 2008 the FDA approved darunavir for use as the first regimen for people with HIV. This regimen is 800 mg (two 400 mg tablets) taken with ritonavir 100 mg once daily, with food. In 2010, this once-daily dosing pattern was approved for treatment-experienced patients (those who have been taking ART for some time), provided that a genotypic test of their virus does not show any relevant protease inhibitor mutations.

In 2011 Tibotec announced an agreement with Gilead Sciences to develop a combination medication (see fact sheet 409) of darunavir and cobicistat, a booster. The new medication would be a single tablet taken just once a day.

Darunavir is also approved for children ages 3 years old or older who have already used ART. There are 75 mg and 150 mg tablets. A new liquid formulation was approved by the FDA in December 2011 for use by children and adults.

Darunavir should be taken with food. This increases blood levels of darunavir. The type of food does not matter.

Darunavir should be stored at room temperature.

## WHAT ARE THE SIDE EFFECTS?

The most common side effects include diarrhea, nausea, headache, and a common cold. Some people may get a skin rash. In rare cases, this could be serious.

Darunavir has not been carefully studied in patients with hepatitis B or hepatitis C, or people with existing liver disease. Their

condition should be carefully monitored. Some cases of severe liver damage have been reported.

Darunavir taken with ritonavir can cause increases in cholesterol and triglycerides (blood fats). See Fact Sheet 123 for more information on blood fats. High levels of blood fats can increase the risk of heart disease. Be sure that your health care provider checks your blood fat levels before you start taking darunavir, and regularly after that.

Darunavir is a sulfa drug. If you are allergic to sulfa drugs, be sure to tell your health care provider.

## HOW DOES IT REACT WITH OTHER DRUGS?

Darunavir with ritonavir can interact with other drugs or supplements that you are taking. **These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are being identified all the time.**

Drugs to watch out for include other ARVs, drugs to treat tuberculosis (see fact sheet 518), for erectile dysfunction (such as Viagra), antidepressants, drugs for heart rhythm (antiarrhythmics), and for migraine headaches. Interactions are also possible with several antihistamines (allergy medications), sedatives, drugs to lower cholesterol, and anti-fungal drugs. **Make sure that your health care provider knows about ALL drugs and supplements you are taking.**

Some **birth control pills** may not work if you are taking darunavir. Talk to your health care provider about how to prevent an unwanted pregnancy.

Darunavir lowers blood levels of **methadone**. Watch for signs of excessive sedation if you take darunavir with **buprenorphine**.

The herb **St. John's Wort** (See Fact Sheet 729) lowers the blood levels of some protease inhibitors. Do not take it while taking darunavir.

Revised December 20, 2011