



DARUNAVIR/COBICISTAT (Prezcobix)

WHAT ARE DARUNAVIR AND COBICISTAT?

Darunavir and cobicistat are drugs used as part of antiretroviral therapy (ART). Darunavir is also called Prezista. Darunavir is manufactured by Janssen Pharmaceuticals; cobicistat is manufactured by Gilead Sciences.

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.

Cobicistat (Tybost, see fact sheet 455) is a drug used to boost the levels of other drugs that are metabolized by the liver. Darunavir requires that a booster like cobicistat or ritonavir (Novir, see fact sheet 442) be part of the HIV treatment combination.

WHO SHOULD TAKE IT?

The darunavir/cobicistat combination was approved in 2014; darunavir was approved in 2006 as an antiretroviral drug (ARV) for treatment of HIV in treatment-naïve and treatment-experienced people with virus without darunavir resistance. It should not be taken by people less than 18 years old or people with severe liver disease.

While antiretroviral therapy (ART) is now recommended for all people living with HIV, 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/cobicistat is taken by mouth as a tablet. The normal dose is one 800/150 milligram (mg) tablet taken once daily with food.

Darunavir/cobicistat should always be taken with food. This increases blood levels of darunavir. The type of food is not important.

Darunavir should be stored at room temperature.

WHAT ARE THE SIDE EFFECTS?

The more common side effects include diarrhea, headache, nausea and rash. Less common side effects include fatigue, muscle soreness and upset stomach.

Darunavir has not been carefully studied in patients over the age of 65 or those 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 cobicistat 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.

Cobicistat causes an increase in the levels of creatinine (a chemical in blood used to estimate kidney function) that is not

associated with kidney problems. This increase should not be greater than 0.4 mg/dl.

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.

THE BOTTOM LINE

Darunavir/cobicistat is the second combination boosted protease inhibitor. It's usually very well tolerated, but does have important drug interactions. Darunavir/cobicistat stops HIV by preventing the making of new proteins. This prevents the virus from making new copies of itself.

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