darunavir (Prezista)

WHAT IS DARUNAVIR?

Darunavir, also known as darunavir ethanolate or DRV (brand name Prezista), is a drug used as part of antiretroviral therapy (ART). The FDA approved darunavir in 2006 as an antiretroviral drug (ARV) for people with HIV infection. Generic versions have been approved under PEPFAR. Darunavir is manufactured by Janssen Therapeutics.

Darunavir is a type of drug called a protease inhibitor (PI). PIs block protease (an HIV enzyme). By blocking protease, PIs prevent new (immature) HIV from becoming a mature virus that can infect other CD4 cells.

When used in combination with other ARVs to treat HIV infection, darunavir may help:

- Reduce the amount of HIV in your blood. This is called viral load.
- Increase the number of CD4 cells in your blood, that help fight off other infections.

Reducing the amount of HIV and increasing the CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting opportunistic infections (OIs) that can happen when your immune system is weak. Read more about viral suppression.

Darunavir does not cure HIV infection or AIDS. You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

WHO SHOULD TAKE DARUNAVIR?

Darunavir is a prescription HIV medicine used in combination with other ARVs to treat HIV infection in adults and children 3 years of age and older. Darunavir must be co-administered with ritonavir (Norvir) and other ARVs.

The safety and effectiveness of darunavir has not been established in children under 3 years of age. Darunavir has not been carefully studied in the elderly (65 years of age and older).

All people with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. Read more about U.S. ART guidelines.

WHO SHOULD NOT TAKE DARUNAVIR?

Do not take darunavir if you are allergic to darunavir or any of the ingredients in this drug.

Darunavir is a sulfa drug. If you are allergic to sulfa drugs, be sure to tell your healthcare provider, as some people who are allergic to sulfa may also be allergic to darunavir.

Do not take darunavir if you are taking any of the following medicines. Taking darunavir with these medicines may affect how darunavir works. Darunavir may cause serious or life-threatening side effects or death when used with these medicines:

- Alpha 1-adrenoreceptor antagonist: alfuzosin
- Anti-gout medicine: colchicine (if you have liver or kidney problems)
- Anti-psychotic medicines: lurasidone, pimozide
- Tuberculosis (TB) medicine: rifampin
- Benzodiazepines: midazolam (when taken by mouth), triazolam
- Cholesterol medicines: lomitapide, lovastatin, simvastatin
- Ergot-containing medicines: dihydroergotamine, ergotamine tartrate, methylergonovine
- Heart medicines: dronedarone, ivabradine, ranolazine
- Heartburn and reflux medicines: cisapride
- Hepatitis C virus (HCV) medicines: elbasvir, grazoprevir, glecaprevir, pibrentasvir
- Herbal product: St. John’s Wort (*Hypericum perforatum*)
- Opioid antagonist: naloxegol
- PDE-5 inhibitor: sildenafil (when used for the treatment of pulmonary arterial hypertension [PAH])

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. If you have taken any of these medicines in the past four weeks, talk to your healthcare provider or pharmacist before starting treatment with darunavir.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING DARUNAVIR?

Before you take darunavir, tell your healthcare provider about all of your medical conditions, and in particular if you:

- Have liver problems, including hepatitis B virus (HBV) or HCV infection
- Are allergic to sulfa medicines
- Have high blood sugar (diabetes)
- Have hemophilia

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with darunavir. There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry Read more about pregnancy and HIV.

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with darunavir. It is not known if darunavir can pass to your baby in your breastmilk. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. These new copies 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. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. Read more about HIV drug resistance.

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS DARUNAVIR TAKEN?

Darunavir must be co-administered with **ritonavir (Norvir)** to exert its therapeutic effect. Failure to correctly co-administer darunavir with ritonavir will result in plasma levels of darunavir that will be insufficient to achieve the desired antiviral effect and will alter some drug interactions.

Darunavir is taken by mouth as a tablet or oral suspension. The recommended dosage of darunavir for adults is 800 mg once daily or 600 mg twice daily, **in combination with 100 mg of ritonavir (Norvir).** The recommended dosage of darunavir for children varies based on the child's weight, age, and other medications they are taking and is given in combination with ritonavir. Your healthcare provider will determine the correct dosage.

For adults who have difficulty swallowing tablets, darunavir oral suspension is taken once daily along with ritonavir at the same recommended adult dosage as the tablets.

Darunavir should be taken at the same time each day with food.

Darunavir is also available in 2 combination medications. Combination HIV medicines contain 2 or more HIV medicines from 1 or more drug classes.

- darunavir/cobicistat (Prezcobix)
- darunavir/cobicistat/emtricitabine/ tenofovir AF (Symtuza)

WHAT ARE THE SIDE EFFECTS?

When you start any ARV, you may have temporary side effects such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of darunavir are diarrhea, nausea, rash, headaches, stomach-area (abdominal) pain, and vomiting.

Darunavir can cause serious side effects including:

Liver problems. Some people taking darunavir in combination with ritonavir (Norvir) have developed liver problems, which may be life-threatening. Your healthcare provider should do blood tests before and during your darunavir and ritonavir combination treatment. If you have chronic HBV or HCV infection, your healthcare provider should check your blood tests more often because you have an increased chance of developing liver problems. Tell your healthcare provider if you have any of the following signs and symptoms of liver problems.

- Dark or "tea colored" urine
- Yellowing of your skin or whites of your eyes
- Pale colored stools (bowel movements)
- Nausea/vomiting

- Pain or tenderness on your right side below your ribs
- Loss of appetite
- Tiredness

Severe or life-threatening skin reactions or rash. Sometimes these skin reactions and skin rashes can become severe and require treatment in a hospital. Tell your healthcare provider right away if you develop a rash. Stop taking darunavir and ritonavir combination treatment and tell your healthcare provider right away if you have any skin changes with the symptoms below:

- Fever
- Tiredness
- Muscle or joint pain
- Blisters or skin lesions
- Mouth sores or ulcers
- Red or inflamed eyes, like “pink eye” (conjunctivitis)

Rash occurs more often in people taking darunavir and raltegravir (Isentress, Isentress HD) together than with either drug separately but is generally mild.

Diabetes and high blood sugar (hyperglycemia). Some people who take PIs including darunavir can get high blood sugar, develop diabetes, or their diabetes can get worse. Tell your healthcare provider if you notice an increase in thirst or urinate often while taking darunavir.

Changes in body fat. Changes in body fat distribution or accumulation have happened in some people taking HIV medicines, including an increased amount of fat in the upper back and neck (buffalo hump), in the breasts, and around the trunk. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these body fat changes are not known.

Immune Reconstitution Inflammatory Syndrome (IRIS). IRIS is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting darunavir.

Increased bleeding for hemophiliacs. Some people with hemophilia have increased bleeding with protease inhibitors including darunavir.

These are not all the possible side effects of darunavir. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW DOES DARUNAVIR REACT WITH OTHER DRUGS?

All ARVs can interact with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take darunavir with other medicines.

See above for a list of medicines that you should not take with darunavir.

MORE INFORMATION

Visit the Prezista website

Visit the Prezista healthcare professional website

Download the full Prescribing Information

Visit the Janssen CarePath website for Prezista

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