

DARUNAVIR

Other NAMES: Prezista®

WHY is this drug prescribed?

Darunavir is an antiretroviral (anti-HIV) drug that belongs to a class of drugs called **protease inhibitors**. Protease inhibitors interfere with the formation of mature infectious virus particles by tightly binding to the enzyme needed to produce more HIV infection.

Darunavir is always used together with ritonavir and other antiretrovirals to delay the progression of HIV infection in antiretroviral-experienced adults who have failed prior treatments. By taking this regimen, your immune system should improve (increase in CD4⁺ count) and you will be better protected against infections, by reducing viral load.

The long-term effects of darunavir are unknown at this time. Further studies are being carried out. Darunavir received Health Canada approval on the condition that the manufacturer continue to conduct trials to demonstrate safety and effectiveness of the product.

Darunavir does not cure AIDS or completely kill the virus, but helps to prevent further damage by slowing down the production of new viruses. Treatment with darunavir does not reduce the risk of passing infection on to others. You will still be able to pass HIV by sexual contact, by blood transfer or by sharing needles. You should always use appropriate precautions to prevent passing HIV on to others.

HOW should this drug be taken?

The dose of darunavir is 600 mg taken together with 100 mg ritonavir twice daily, or 800 mg taken with 100 mg ritonavir once daily.

Darunavir and ritonavir should be taken with a meal or substantial snack.

Your dosage is:

- 300 mg orange film-coated tablet
- 400 mg light orange film-coated tablet
- 600 mg orange film-coated tablet

_____ tablets (____mg) ____ times a day

plus:

- ritonavir 100 mg capsule

_____ capsule(s) ____ times a day

What should you do if you FORGET a dose?

If you miss a dose of darunavir, take it as soon as possible. However, if it is time for your next dose, do not double the dose, just carry on with your regular schedule.

Why should you not forget to take this drug?

If you miss doses of darunavir, the amount of HIV virus in your blood (known as the viral load) will start increasing again and your immune system will be further damaged. A few missed doses can be enough for darunavir to stop being active. A phenomenon known as **resistance**. When this happens, other antiretrovirals that work in a similar way as darunavir may also become inactive. **Therefore, missing doses of darunavir can decrease treatment options for the future.** Even if you do not feel well, you should always take your doses of darunavir. Please do not stop darunavir without talking to your doctor first.

What ADVERSE EFFECTS can this drug cause? What should you do about them?

Most adverse effects reported with darunavir were mild and infrequent. They included sleeplessness, fever, diarrhea, abdominal pain, nausea, vomiting, headache, loss of appetite, and fatigue. If these effects occur and bother you, please call the clinic or discuss them at your next visit.

Regular blood tests will be done to detect any changes in your liver or pancreas function. Also, your doctor will look for increases in your cholesterol, triglyceride and blood sugar level.

Abnormal weight gain or changes in body shape have been reported with other protease inhibitors. It is uncertain if darunavir will cause these changes.

It is important that you keep your doctor appointments and come for your laboratory tests so that your progress can be followed.

What other PRECAUTIONS should you follow while using this drug?

You must make sure that you are taking the right dose. Studies have indicated taking higher doses of darunavir than what is prescribed does not provide any additional benefit and may increase the chance of having adverse effects. If you take lower doses of darunavir than what is prescribed, the HIV virus may become resistant to the anti-retroviral.

Certain drugs can increase or decrease the effect of darunavir. Also, darunavir might influence the effect of other drugs you are taking. Inform your doctor and pharmacist of all prescribed, and non-prescribed drugs you are taking. As well, you should inform them of natural products and recreational (street) drugs you are taking. If you wish to start a new drug or

natural product, please consult with your pharmacist before doing so.

Do NOT take the following drugs with darunavir:

- Amiodarone (Cordarone®)
- Ergot derivatives [Ergotamine (Cafergot®, Bellergal®, Ergodryl™, Gravergol®), ergo-novine, dihydroergotamine (Migranal®), methylergonovine (Methergine®)]
- Lidocaine (systemic)
- Midazolam (Versed®)
- Quinidine
- Pimozide (Orap®)
- Rifampin (e.g. Rifadin®, Rimactane®, Rofact™)
- Triazolam (Halcion®)

The safety of darunavir has not been established during pregnancy. Darunavir should only be used in pregnancy if the potential benefit outweighs the potential risk. A registry has been established to monitor patients on darunavir while pregnant. Please inform your doctor if you are pregnant, as he/she is able to register your exposure at 1-800-258-4263. Your doctor can recommend the appropriate treatment to help reduce the risk of passing the HIV virus on to your baby. Breastfeeding is NOT recommended if you have HIV as you can transmit the virus to your baby through your breast milk.

How should this drug be STORED?

Darunavir film-coated tablets should be stored in a cool (15 - 30°C), dry place, out of the reach of children.

If you have any questions or concerns about this drug or if you are experiencing adverse effects, please discuss them with your pharmacist, doctor or nurse.

Write questions or concerns down to ensure they are addressed.

The following pharmacist is available to answer questions:

Pharmacist: _____

Telephone: _____

DARUNAVIR

(PREZISTA®)

MEDICATION

FACT SHEET

Reference: Product monograph *Prezista™* (darunavir). Janssen-Ortho Inc., Toronto, On, Canada: 2008. Prepared by the Ontario HIV Pharmacy Professional Specialty Group, 2009.

Additional medication fact sheets and updates may be found at: www.hivclinic.ca