



Conditional Approval Of PREZISTA*

FACT SHEET

- What is PREZISTA?** PREZISTA is a type of anti-HIV (Human Immunodeficiency Virus) drug called a protease inhibitor.
- Health Canada has approved PREZISTA with conditions, under the Notice of Compliance with Conditions policy. This authorization reflects the promising nature of the clinical evidence which must be verified and/or extended with further studies. Products approved under Health Canada's NOC/c policy, have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment.
- What is PREZISTA used for?** PREZISTA is an oral tablet used for the treatment of HIV infection in adults. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).
- How does PREZISTA work?** PREZISTA blocks HIV protease, an enzyme that is needed for HIV to multiply. When used with other anti-HIV medicines, PREZISTA may reduce the amount of HIV in your blood (called “viral load”) and increase your CD4+ (T) cell count. HIV infection destroys CD4+ (T) cells, which are important to the immune system. The immune system helps fight infection. Reducing the amount of HIV and increasing the CD4+ (T) cell count may help your immune system fight infections.
- PREZISTA does not cure HIV infection or AIDS. At present, there is no cure for HIV infection. People taking PREZISTA may still develop infections or other conditions associated with HIV infection. Because of this, it is very important for you to remain under the care of a doctor.
- What other treatments have been used to treat HIV infection?** HIV-infected patients are treated with antiretroviral (ARV) drugs. ARV's currently consist of four classes of drugs:
- Nucleoside reverse transcriptase inhibitors (NRTIs)
 - Protease Inhibitors (PIs)
 - Non-nucleoside reverse transcriptase inhibitors (NNRTIs)
 - Fusion Inhibitors (FIs)

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Most HIV-infected patients on therapy take a combination of three drugs from at least two classes of ARVs. This type of regimen is known as a highly active antiretroviral therapy (HAART). The focus of treatment is maximum durable suppression of HIV with the ideal objective of achieving undetectable viral load.

What are the advantages of PREZISTA over other therapies?

PREZISTA has proven to be effective in significantly reducing viral load and increasing CD4+ cell counts in HIV-infected patients who have failed or who could not tolerate their current antiretroviral regimen.

What do patients need to know about using PREZISTA?

Together with your doctor, you need to decide whether taking PREZISTA is right for you.

Do not take PREZISTA if you are allergic to darunavir or any of the other ingredients in PREZISTA or ritonavir (Norvir®)

Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins, and herbal supplements, including St. John's wort (*Hypericum perforatum*). PREZISTA and many other medicines can interact. Sometimes serious side effects will happen if PREZISTA is taken with certain other medicines.

BEFORE you use PREZISTA talk to your doctor or pharmacist if you have diabetes, liver problems, hemophilia, are pregnant, are planning to get pregnant or are breastfeeding.

Tell your doctor if you are taking estrogen-based contraceptives. PREZISTA might reduce the effectiveness of estrogen-based contraceptives. You must take additional precautions for birth control such as a condom.

Tell your doctor if you take other anti-HIV medicines. PREZISTA can be combined with some other anti-HIV medicines while other combinations are not recommended.

What are the side effects and how serious are they?

Like all prescription drugs, PREZISTA can cause side effects. The following is **not** a complete list of side effects reported with PREZISTA when taken either alone or with other anti-HIV medicines. Do not rely on this fact sheet alone for information about side effects. Your doctor can discuss with you a more complete list of side effects.

The most common side effects include diarrhea, nausea, headache, abdominal pain, constipation, and vomiting.

As with other protease inhibitors, PREZISTA may cause side effects, including high blood sugar and diabetes, increased bleeding in patients with hemophilia, changes in body fat, and immune reconstitution syndrome.

Tell your doctor promptly about these or any other unusual symptoms. If the condition persists or worsens, seek medical attention.

Who can be treated with PREZISTA?

PREZISTA has been approved for the treatment of HIV-infected patients who have failed prior antiretroviral therapy.

How is PREZISTA taken?

Take PREZISTA tablets every day exactly as prescribed by your doctor. You must take ritonavir (NORVIR[®]) at the same time as PREZISTA. The usual dose is 600 mg (two 300 mg tablets) of PREZISTA, together with 100 mg (one 100 mg capsule) of ritonavir (NORVIR[®]), twice daily *every day*. It may be easier to remember to take PREZISTA and ritonavir (NORVIR[®]) if you take them at the same time every day. If you have questions about when to take PREZISTA and ritonavir (NORVIR[®]), your doctor can help you decide which schedule works for you.

You should always take PREZISTA and ritonavir (NORVIR[®]) together with food. The type of food is not important.

Continue taking PREZISTA and ritonavir (NORVIR[®]) unless your doctor tells you to stop. Take the exact amount of PREZISTA and ritonavir (NORVIR[®]) that your doctor tells you to take, right from the very start. To help make sure you will benefit from PREZISTA and ritonavir (NORVIR[®]), you must not skip doses or interrupt therapy. If you don't take PREZISTA and ritonavir (NORVIR[®]) as prescribed, the beneficial effects of PREZISTA and ritonavir (NORVIR[®]) may be reduced or even lost.

Where can I learn more about PREZISTA?

<http://www.janssen-ortho.com>
Contact the Janssen-Ortho Medical Information Department at 1-800-567-3331.