

Prezcobix

Generic Name: darunavir + cobicistat

Abbreviation: DRV/c

Other Market Name: Rezolsta

Drug Class: Protease Inhibitors (PIs)

Company: Janssen Therapeutics

Approval Status: Approved

Generic Version Available: No

Drug Indication

A component of alternative treatment regimens for antiretroviral-naive people living with HIV, as indicated by the U.S. Department of Health and Human Services (DHHS) Panel on Antiretroviral Guidelines for Adults and Adolescents. Visit

https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/0 for the full DHHS guidelines.

General Info

Prezcobix is an HIV medication. It is in a category of HIV medicines called protease inhibitors. Prezcobix was approved by the U.S. Food and Drug Administration for use by people living with HIV in January 2015.

Prezcobix is a combination of two drugs: Prezista (darunavir) and Tybost (cobicistat). Both of these drugs can be purchased individually for use in combination with other HIV drugs.

Prezcobix must be combined with other HIV drugs.

Dosage

Adult Dose: One tablet once a day. Each tablet contains 800 mg Prezista (darunavir) + 150 mg

Tybost (cobicistat).

Pediatric Dose: N/A

Dosing Info: Take with food.

Side Effects

Common side effects associated with Prezcobix include diarrhea, nausea, headache, and abdominal pain.

Rash is another common side effect of Prezcobix. If a severe rash occurs while taking Prezcobix, contact your health care provider immediately. The darunavir in Prezcobix is a sulfa-containing drug and should be used with caution in patients with a known sulfa allergy.

Some people may experience increases in their lipid levels (triglycerides and cholesterol) or diabetes risk while being treated with protease inhibitors. These problems are much less common with duranavir-based regimens compared with most other protease inhibitors.

Drug-induced hepatitis (liver injury) has been reported in people taking protease inhibitors. This usually occurred in people who had extremely low CD4 cells, were taking multiple other medications and who were also infected with hepatitis B virus (HBV) or hepatitis C virus (HCV). Lab tests to monitor liver function is an important component of routine follow-up care and important for people using protease inhibitors.

The cobicistat in Prezcobix can cause minor increases in serum creatinine, a potential sign of kidney toxicity. These increases do not appear to affect creatinine clearance (CrCl), an even better indicator of kidney health. However, Prezcobix should not be used in combination with regimens containing tenofovir disoproxil fumarate (e.g., Viread or Truvada) by people with CrCL below 70 mL/min. CrCl should be tested before and during treatment with regimens containing Prezcobix and tenofovir disoproxil fumarate.

Drug Interactions

The following medications should not be taken while you are being treated with Prezcobix:

Acid reflux/heartburn medications: Propulsid (cisapride)

Antibiotics: Rifadin (rifampin)

Antimigraine medications: Methergine, Methylergometrine (methylergonovine); Ergostat, Cafergot, Ercaf, Wigraine (ergotamine); Ergotrate, Methergine (ergonovine); or D.H.E. 45,

Migranal (dihydroergotamine)

Anti-gout: Colcrys (colchicine)

Cholesterol-lowering drugs (statins): Zocor (simvastatin) and Mevacor (lovastatin)

Heart medications: Ranexa (ranolazine) and Multag (dronedarone)

Antipsychotics: Latuda (lurasidone) and Orap (pimozide) **Sedatives:** Versed (midazolam) and Halcion (triazolam)

Enlarged prostate: Uroxatral (alfuzosin)

Pulmonary Hypertension: Revatio (sildenafil)

Herbal products: St. John's wort

Prezcobix should not be combined with any HIV medications that contain any of the active ingredients in Prezcobix. These include: Evotaz, Prezista, Tybost, Stribild, and Genvoya.

Important hepatitis C treatment drug-drug interactions: Prezcobix can be combined with Sovaldi (sofosbuvir), Harvoni (ledipasvir/sofosbuvir), ribavirin, and pegylated interferon alfa. Do not use with Olysio/Sovriad (simeprevir) or Viekira Pak (ombitasvir/paritaprevir/ritonavir/dasabuvir).

Prezcobix, particularly its cobicistat component, can increase the levels of many other drugs in the body, potentially increasing the risk of serious side effects. Dosage adjustments or substitutions may be necessary if you are prescribed certain medications from any of the following drug classes: antiarrhythmics, antibiotics, cancer chemotherapeutic drugs, anticoagulants, anticonvulsants, antidepressants, antifungals, anti-gout medications, antimalarial drugs, beta-blockers, calcium channel blockers, corticosteroids (oral and inhaled), endothelin receptor antagonists, hepatitis C medications, statins, hormonal contraceptives, immune-suppressants, inhaled beta agonists, narcotic medications (for pain and opioid dependence), neuroleptics/anti-seizure medications, erectile dysfunction drugs, and sedatives/hypnotics. Consult the Prezcobix package insert for more details:

http://www.janssentherapeutics.com/shared/product/prezcobix/prescribing-information.pdf

Other Info

Before taking this medication, tell your doctor if you have kidney disease or liver disease (including hepatitis B). In addition, tell your doctor if you are pregnant or planning to become pregnant, if you are breastfeeding, and all your medical conditions, including all prescription and over-the-counter medications and supplements you are taking.

For More Info:

http://www.janssentherapeutics.com/shared/product/prezcobix/prescribing-information.pdf

Co-Pay Program Info: https://www.poz.com/basics/hiv-basics/drug-assistance-programs

Patient Assistance Program Info:

https://www.poz.com/basics/hiv-basics/drug-assistance-programs

Last Reviewed: July 15, 2016