



# Prezcobix

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## **WHAT IS PREZCOBIX?**

Prezcobix is a drug used as part of [antiretroviral therapy \(ART\)](#). Prezcobix contains two [antiretroviral drugs \(ARVs\)](#) combined in one tablet:

- [darunavir \(DRV, Prezista\)](#)
- [cobicistat \(COBI, Tybost\)](#)

The FDA approved Prezcobix in 2015 as an ARV for people with HIV infection. Prezcobix is manufactured by [Janssen Therapeutics](#).

One of the medications in Prezcobix, 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. The other medication in Prezcobix, cobicistat, is a type of drug called a [pharmacokinetic enhancer \(PK enhancer\)](#) or CYP3A inhibitor. PK enhancers are used to boost the effectiveness of other drugs. When the two drugs are given together, the PK enhancer interferes with the liver metabolism and breakdown of the other drug, which allows the other drug to remain in the body longer at a higher concentration. PK enhancers are included in some HIV treatment regimens. Cobicistat itself is not an ARV and does not treat HIV.

When used in combination with other ARVs to treat HIV infection, Prezcobix 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 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](#).

Prezcobix [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 PREZCOBIX?**

Prezcobix is a two-drug fixed-dose combination medication that is used in combination with other ARVs to treat HIV infection in adults and children who weigh at least 88 pounds (40 kg).

The safety and effectiveness of Prezcobix has not been established in children who weigh less than 88 pounds (40 kg). Prezcobix 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.](#)

Prezcobix provides two drugs in one pill. It can be more convenient to use Prezcobix than some other combinations of drugs that must be taken separately or at different times of the day. This could mean fewer missed doses and better control of HIV. **Prezcobix is used in combination with other ARVs for the treatment of HIV infection.**

### ***WHO SHOULD NOT TAKE PREZCOBIX?***

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

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

- Alpha 1-adrenoreceptor antagonist: alfuzosin
- Gout medicine: colchicine (if you have liver or kidney problems)
- Seizure medicines: carbamazepine, phenobarbital, phenytoin
- Antipsychotic 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 medicine: cisapride
- Herbal product: St. John's Wort (*Hypericum perforatum*)
- [Hepatitis C virus \(HCV\)](#) medicines: elbasvir, grazoprevir
- 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 Prezcobix.

Prezcobix is not recommended in people with severe liver disease.

### ***WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING PREZCOBIX?***

Before you take Prezcobix, 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
- Have [kidney problems](#)

- Are allergic to sulfa (sulfonamide)
- Have [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 Prezcoibix. It is not known if Prezcoibix will harm your unborn baby. **Prezcoibix should not be used during pregnancy** because the Prezcoibix levels in your blood may be lower during pregnancy and may not control your HIV. Your healthcare provider may prescribe different medicines if you become pregnant during treatment with Prezcoibix. Hormonal forms of birth control, such as injections, vaginal rings or implants, contraceptive patches, and some birth control pills may not work during treatment with Prezcoibix. Talk to your healthcare provider about forms of birth control that may be used during treatment with Prezcoibix.

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. [Read more about pregnancy and HIV.](#)

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with Prezcoibix. It is not known if Prezcoibix 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 PREZCOBIX TAKEN?**

Prezcoibix is taken by mouth as a tablet. Each Prezcoibix tablet contains 800 mg of darunavir and 150 mg of cobicistat. The recommended dosage of Prezcoibix for adults and children weighing at least 88 pounds (40 kg) is one tablet once daily.

Take Prezcoibix at the same time each day with food.

**You need to take Prezcoibix with other ARVs to treat HIV infection.** Your healthcare provider will tell you what other medicines to take and how to take them.

### **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 Prezcobix include [diarrhea](#), nausea, rash, headaches, stomach-area (abdominal) pain, and vomiting.

Prezcobix can cause serious side effects including:

**Liver problems.** Some people taking Prezcobix may develop liver problems which may be life-threatening. Your healthcare provider should do [blood tests](#) before and during your treatment with Prezcobix. 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 below signs and symptoms of liver problems.

- Dark “tea-colored” urine
- Your skin or the white part of your eyes turns yellow
- Light colored stools (bowel movements)
- Nausea and/or vomiting
- Pain or tenderness on your right side below your ribs
- Loss of appetite

**Severe or life-threatening skin reactions or rash.** Sometimes these skin reactions and skin rashes can become severe and require treatment in a hospital. Call your healthcare provider right away if you develop a rash. Stop taking Prezcobix and call your healthcare provider right away if you develop any skin changes with symptoms below:

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

**Kidney problems.** Prezcobix, when taken with certain other medicines, can cause new or worse kidney problems, including kidney failure. Your healthcare provider should check your kidneys before you start and while you are taking Prezcobix.

**Diabetes and high blood sugar (hyperglycemia).** Some people who take protease inhibitors including Prezcobix can get high blood sugar, develop diabetes, or their diabetes can get worse. Some people have had to start taking medicine to treat diabetes or have changes to their dose of diabetes medicine. Tell your healthcare provider if you notice an increase in thirst or if you start urinating more often while taking Prezcobix.

**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 Prezcobix.

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

These are not all the possible side effects of Prezcobix. 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 PREZCOBIX 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 Prezcobix with other medicines.

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

### ***MORE INFORMATION***

Visit the [Prezcobix website](#).

Visit the [Prezcobix healthcare professional website](#).

Download the full [Prescribing Information](#).

Read the [Important Safety Information](#).

Visit the [Janssen CarePath website](#) for Prezcobix.

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