

ข้อมูลยาภาษาอังกฤษสำหรับผู้ป่วย
PATIENT INFORMATION
PREZCOBIX® (prez-koe-bix)
 (INN: darunavir 800 mg and cobicistat 150 mg)
 tablets

What is the most important information I should know about PREZCOBIX?

- **PREZCOBIX may cause 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 hepatitis B or C 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
 - vomiting
 - yellowing of your skin or whites of your eyes
 - pain or tenderness on your right side below your ribs
 - pale colored stools (bowel movements)
 - loss of appetite
 - nausea
- **PREZCOBIX may cause 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
 - blisters or skin lesions
 - tiredness
 - mouth sores or ulcers
 - muscle or joint pain
 - red or inflamed eyes, like "pink eye" (conjunctivitis)
- **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.

See "**What are the possible side effects of PREZCOBIX?**" for more information about side effects.

What is PREZCOBIX?

PREZCOBIX is a prescription medicine that is used with other HIV-1 medicines to treat HIV-1 infection in adults and in children who weigh at least 88 pounds (40 kg).

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

PREZCOBIX contains the prescription medicines darunavir and cobicistat.

It is not known if PREZCOBIX is safe and effective in children weighing less than 88 pounds (40 kg).

Do not take PREZCOBIX with any medicine that contains:

- alfuzosin
- carbamazepine
- cisapride
- colchicine, if you have liver or kidney problems
- dronedarone
- elbasvir and grazoprevir
- ergot-containing medicines:
 - dihydroergotamine
 - ergotamine tartrate
 - methylergonovine
- ivabradine
- lomitapide
- lovastatin
- lurasidone
- midazolam, when taken by mouth
- naloxegol
- phenobarbital
- phenytoin
- pimozide
- ranolazine
- rifampin
- sildenafil, when used for the treatment of pulmonary arterial hypertension (PAH)
- simvastatin
- St. John's wort (*Hypericum perforatum*)
- triazolam

Serious problems can happen if you take any of these medicines with PREZCOBIX. This is not a complete list of medicines. Therefore, tell your healthcare provider about all medicines you take.

Before taking PREZCOBIX, tell your healthcare provider about all your medical conditions, including if you:

- have liver problems, including hepatitis B or hepatitis C
- have kidney problems
- are allergic to sulfa (sulfonamide)
- have diabetes
- have hemophilia
- are pregnant or plan to become pregnant.
 - It is not known if PREZCOBIX will harm your unborn baby.
 - PREZCOBIX should not be used during pregnancy because the PREZCOBIX levels in your blood may be lower during pregnancy and may not control your HIV-1.
 - Tell your healthcare provider right away if you become pregnant during treatment with PREZCOBIX.
 - Your healthcare provider will prescribe different medicines if you become pregnant during treatment with PREZCOBIX.
 - **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 PREZCOBIX.** Talk to your healthcare provider about forms of birth control that may be used during treatment with PREZCOBIX.
 - **Pregnancy Exposure Registry:** There is a pregnancy exposure registry for people who take HIV-1 medicines during pregnancy. The purpose of the registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. Do not breastfeed if you take PREZCOBIX.
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - It is not known if PREZCOBIX can pass into your breast milk.
 - Talk to your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, topical creams, vitamins, and herbal supplements. Some medicines interact with PREZCOBIX. **Keep a list of your medicines to show your healthcare provider and pharmacist.**

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with PREZCOBIX.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take PREZCOBIX with other medicines.

How should I take PREZCOBIX?

- Take PREZCOBIX exactly as your healthcare provider tells you.
- Do not change your dose or stop taking PREZCOBIX without talking to your healthcare provider.
- Take PREZCOBIX 1 time a day with food.
- Do not miss a dose of PREZCOBIX.
- If you take too much PREZCOBIX, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of PREZCOBIX?

PREZCOBIX may cause serious side effects, including:

- See "**What is the most important information I should know about PREZCOBIX?**"
- **Diabetes and high blood sugar (hyperglycemia).** Some people who take protease inhibitors including PREZCOBIX can get high blood sugar, develop diabetes, or your diabetes can get worse. Tell your healthcare provider if you notice an increase in thirst or urinate often while taking PREZCOBIX.
- **Changes in body fat** can happen in people who take HIV-1 medications. The changes may include an increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these conditions are not known.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having new symptoms after starting your HIV-1 medicine.
- **Increased bleeding for hemophiliacs.** Some people with hemophilia have increased bleeding with protease inhibitors including PREZCOBIX.

The most common side effects of darunavir, one of the medicines in PREZCOBIX, include:

- | | |
|------------|---------------------------------|
| ○ diarrhea | ○ headache |
| ○ nausea | ○ stomach-area (abdominal) pain |
| ○ rash | ○ vomiting |

These are not all of the possible side effects of PREZCOBIX. Call your doctor for medical advice about side effects.

How should I store PREZCOBIX?

- Do not store above 30°C

Keep PREZCOBIX and all medicines out of reach of children.

Shelf life: See expiry date on the outer pack.

General information about the safe and effective use of PREZCOBIX.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use PREZCOBIX for a condition for which it was not prescribed. Do not give PREZCOBIX to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about PREZCOBIX that is written for health professionals.

What are the ingredients in PREZCOBIX?

Active ingredients: darunavir and cobicistat

Inactive ingredients: colloidal silicon dioxide, crospovidone, hypromellose, magnesium stearate, and silicified microcrystalline cellulose. The tablets are film-coated with a coating material containing iron oxide black, iron oxide red, polyethylene glycol, polyvinyl alcohol (partially hydrolyzed), talc, and titanium dioxide.

MANUFACTURED BY	MARKETING AUTHORIZATION NUMBER	DATE OF AUTHORIZATION
Janssen Ortho LLC Gurabo, Puerto Rico Packaged and released by Janssen Cilag S.p.A. Latina, Italy	2C 15119/64 (NC)	14-Dec-2021

NATURE AND CONTENT OF CONTAINER

30 tablets per bottle.

DATE OF REVISION OF THE TEXT

28-Apr-2023 (USPIL version Apr-2022)

Imported by

Janssen-Cilag Ltd., Bangkok, Thailand

To report Suspected Adverse Reactions, please contact us at aepqcjacth@its.jnj.com

For any product information, please contact us at medinfosea@its.jnj.com

Please see full prescribing information at <https://ndi.fda.moph.go.th/>.

<http://www.fda.moph.go.th/sites/oss/Pages/Main.aspx>