PREZCOBIX®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using PREZCOBIX?

PREZCOBIX contains two active ingredients, darunavir and cobicistat, which work in combination to treat adults who are infected by HIV (Human Immunodeficiency Virus).

For more information, see Section 1. Why am I using PREZCOBIX? in the full CMI.

2. What should I know before I use PREZCOBIX?

Do not use if you have ever had an allergic reaction to PREZCOBIX or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions or are pregnant or plan to become pregnant or are breastfeeding. Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without prescription, as PREZCOBIX might interact with other medicines.

For more information, see Section 2. What should I know before I use PREZCOBIX? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PREZCOBIX and affect how it works. Do not combine PREZCOBIX with medicines listed in Section 2. What should I know before I use PREZCOBIX?

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use PREZCOBIX?

- Always take this medicine exactly as your doctor has told you. You must check with your doctor if you are not sure.
- The usual dose of PREZCOBIX is one tablet orally, once daily with food and always with food. PREZCOBIX cannot work properly without food. Swallow the tablets with a drink such as water, milk, or any other nutritional drink

More instructions can be found in Section 4. How do I use PREZCOBIX? in the full CMI.

5. What should I know while using PREZCOBIX?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using PREZCOBIX. • Tell your doctor if you notice any symptoms of an infection. • Be sure to keep all your doctor's appointments so your progress can be checked. • If you are undergoing anaesthesia, tell your anaesthetist that you are taking PREZCOBIX.
Things you should not do	• Do not stop using this medicine suddenly without talking to your doctor even if you feel better. • Avoid doing things that can spread HIV infection since PREZCOBIX does not stop you from passing the HIV infection to others.
Driving or using machines	• Do not operate machines or drive if you feel dizzy after taking PREZCOBIX.
Looking after your medicine	• Store below 30°C and in the original packaging to protect from moisture. • Keep it where children cannot reach it.

For more information, see Section 5. What should I know while using PREZCOBIX? in the full CMI.

6. Are there any side effects?

The following common side effects may occur when taking PREZCOBIX; nausea, vomiting, headache, abdominal pain, diarrhea, passing wind, rash, itching or hives on the skin.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

PREZCOBIX®

Active ingredient(s): *Darunavir/cobicistat*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PREZCOBIX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PREZCOBIX.**

Where to find information in this leaflet:

1. Why am I using PREZCOBIX?
2. What should I know before I use PREZCOBIX?
3. What if I am taking other medicines?
4. How do I use PREZCOBIX?
5. What should I know while using PREZCOBIX?
6. Are there any side effects?
7. Product details

1. Why am I using PREZCOBIX?

PREZCOBIX contains the active ingredients darunavir and cobicistat. PREZCOBIX is an antiretroviral medicine that works by reducing the amount of HIV in your body. Darunavir is the HIV medicine, which needs to be combined with another medicine, cobicistat, that increases the amount of HIV medicine in your blood to control your HIV infection.

PREZCOBIX is used to treat adults who are infected with HIV. PREZCOBIX must be taken with other anti-HIV medicines. Your doctor will discuss with you which combination of medicines is best for you.

2. What should I know before I use PREZCOBIX?

Warnings

Do not use PREZCOBIX if:

- you are allergic to darunavir, cobicistat, or any of the other ingredients listed the end of this leaflet.

  Always check the ingredients to make sure you can use this medicine.
- Do not use PREZCOBIX if you are taking any of the following medicines:
  - alfuzosin (to treat an enlarged prostate)
  - astemizole or terfenadine (to treat allergy symptoms)
  - cisapride (to treat some stomach conditions)
  - colchicine (to treat gout) if you have renal/hepatic impairment
  - amiodarone, bepridil, disopyramide, flecainide, systemic lidocaine, mexiletine, propafenone, quinidine or dronedarone (to treat irregular heartbeats)
  - dronedarone, ivabradine or ranolazine (to treat heart disease)
  - lomitapide, lovastatin or simvastatin (to lower cholesterol levels)
  - midazolam or triazolam (to treat trouble with sleeping and/or anxiety)
  - lurasidone or pimozide (to treat psychiatric conditions)
  - apixaban (used to reduce blood clotting)
  - carbamazepine, phenobarbital, phenytoin (medicines to prevent seizures or to treat trigeminal neuralgia)
  - ergot alkaloids i.e. dihydroergotamine, ergonovine, ergotamine, methylergonovine (to treat migraine and headaches)
  - sildenafil (to treat pulmonary arterial hypertension)
  - rifampin (to treat some infections such as tuberculosis)
  - elbasvir/grazoprevir (to treat hepatitis C)
  - products that contain St John's wort (Hypericum perforatum)
  - naloxegol (to treat opioid induced constipation)
  - dapoxetine (to treat premature ejaculation)

  If you are taking any of these, ask your doctor about switching to another medicine. This is **not** a complete list of medicines. Therefore, tell your doctor about **all** medicines you take.

  There are other medicines that you need to be careful of when taking PREZCOBIX (see Section 3. What if I am taking other medicines?)

Check with your doctor if you:

- have or have had any other medical conditions, especially the following:
  - Kidney problems or are undergoing kidney dialysis treatment.
  - Problems with your liver, including hepatitis B and hepatitis C. Your doctor may need to evaluate your liver before deciding if you can take PREZCOBIX.
  - Diabetes. PREZCOBIX, like some other anti-HIV medicines, might increase sugar levels in the blood.
  - Haemophilia. Anti-HIV medicines, such as PREZCOBIX, might increase the risk of bleeding in patients with this blood clotting disorder.
  - allergy to sulfa medicines (sulphonamides) or any other medicines.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not take PREZCOBIX if you are pregnant or breastfeeding.

It is recommended that HIV infected women should not breastfeed because of the possibility of the baby becoming infected with HIV through breast milk and because of the unknown effects of the medicine on the baby.

Use in children and adolescents

PREZCOBIX should not be given to children younger than 18 years of age.

Take special care with PREZCOBIX

PREZCOBIX is not a cure for HIV infection.

Talk to your doctor about appropriate precautions to lower the chance of spreading HIV to others.

People taking PREZCOBIX can still develop infections or other illnesses associated with HIV. You should continue to keep in regular contact with your doctor and to monitor your health while taking PREZCOBIX.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

There are some medicines that you must not combine with PREZCOBIX. These are mentioned above under the subsection 'Do not use PREZCOBIX if'.

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

The effects of PREZCOBIX might be reduced if you take any of the following medicines. Tell your doctor if you take any of the following:

- medicines to treat hepatitis C (telaprevir, boceprevir, glecaprevir/pibrentasvir)
- medicines to prevent seizures (oxcarbazepine)
- corticosteroids (dexamethasone)
- medicines to treat excessive sleepiness (armodafinil, modafinil)
- medicines to treat some infections such as tuberculosis (rifabutin, rifapentine)

The effects of other medicines might be influenced if you take PREZCOBIX and your doctor might want to do some additional blood tests. Tell your doctor if you take:

- medicines for heart disease (amlodipine, diltiazem, felodipine, nifedipine, nicardipine, tadalafil, verapamil)
- medicines used to reduce clotting of the blood (dabigatran etexcilate, edoxaban, rivaroxaban, warfarin) or to prevent blood clots (ticagrelor, clopidogrel)
- oestrogen-based hormonal contraceptives. PREZCOBIX might reduce the effectiveness of hormonal contraceptives. Therefore, additional or alternative (non-hormonal) methods of contraception are recommended. If you take a contraceptive containing drospirenone your potassium levels might become elevated.
- medicines to lower cholesterol levels (pravastatin, atorvastatin, rosuvastatin, pitavastatin). The risk of muscle tissue disorder might be increased. Atorvastatin, rosuvastatin, or pravastatin, at a reduced starting dose, could be used as an alternative.
- medicines for your immune system (cyclosporine, tacrolimus, sirolimus, everolimus, rapamycin). Your doctor might want to do some additional tests.
- corticosteroids (betamethasone, budesonide, fluticasone, mometasone, prednisone, triamcinolone)
- medicines to treat asthma (salmeterol)
- medicines to treat gout (colchicine). If you have renal/hepatic impairment, do not take colchicine with PREZCOBIX.
- medicines to treat malaria (artemether/lumefantrine)
- medicines to treat cancer (dasatinib, everolimus, irinotecan, nilotinib, vinblastine, vincristine)
- medicines to prevent seizures (clonazepam)
- medicines to treat psychiatric conditions (risperidone, thioridazine, quetiapine, perphenazine)
- medicines against bacterial infections (erythromycin and telithromycin)
- medicines to treat pain (fentanyl, oxycodone, tramadol)
- medicines to treat urinary disorders (fesoterodine, solifenacin)
- medicines to treat nausea and vomiting (domperidone).

The dosage of other medicines might need to be changed and your doctor might do some additional blood tests. Tell your doctor if you take:

- medicines to treat certain heart disorders (digoxin, carvedilol, metoprolol, timolol, bosentan)
- medicines to treat fungal infections (clotrimazole, fluconazole, isavuconazole, itraconazole, ketoconazole, posaconazole, voriconazole)
- medicines for erectile dysfunction (avanafil, vardenafil, tadalafil, sildenafil)
- medicines against bacterial infections (clarithromycin)
- medicines to treat depression and anxiety (paroxetine, sertraline, amitriptyline, desipramine, imipramine, nortriptyline, and trazodone)
- medicines to treat narcotic dependence (buprenorphine/ naloxone, methadone)
- medicines to treat trouble sleeping and/or anxiety (buspirone, clorazepate, diazepam, estazolam, flurazepam, zolpidem).

This is **not** a complete list of medicines. Tell your healthcare provider about **all** medicines that you are taking.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PREZCOBIX.

4. How do I use PREZCOBIX?

How much to take

- The usual dose of PREZCOBIX is one tablet orally, once daily with food.
- Follow the instructions provided and use PREZCOBIX until your doctor tells you to stop.
- Always use PREZCOBIX exactly as your doctor has told you. You must check with your doctor if you are not sure.
- Make sure that you always have enough PREZCOBIX available so that you don't run out. For example, in case you cannot return home, need to travel or stay in a hospital.

When to take PREZCOBIX

- **You must take PREZCOBIX every day and always with food.** PREZCOBIX cannot work properly without food.
- **You must eat a meal or a snack within 30 minutes prior to taking your PREZCOBIX.** The type of food is not important.
- Even if you feel better, do not stop taking PREZCOBIX without talking to your doctor.

How to take PREZCOBIX

- Take PREZCOBIX with food.
- Swallow the tablets with a drink such as water, milk, or any other nutritional drink.
- Do not crush or chew the tablet.
- Take your other HIV medicines used in combination with PREZCOBIX as recommended by your doctor.

Removing the child resistant cap

The plastic bottle comes with a child resistant cap and should be opened as follows:

- Push the plastic screw cap down while turning it counter clockwise.
- Remove the unscrewed cap.

If you forget to use PREZCOBIX

- PREZCOBIX should be used regularly at the same time each day.
- If you notice within 12 hours, you must take the tablets immediately. Always take with food.
- If you notice after 12 hours, then skip the intake and take the next doses as usual.

Do not take a double dose to make up for the dose you missed.

- Please refer to your doctor for instructions on missed doses of other HIV medicines used in combination with PREZCOBIX.

If you use too much PREZCOBIX

If you think that you have used too much PREZCOBIX, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using PREZCOBIX?

Things you should do

Call your doctor straight away if you:

- **Notice any symptoms of infection**. In some patients with advanced HIV infection and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response. This improvement enables the body to fight infections that may have been present prior to taking PREZCOBIX, with no obvious symptoms.
- **Be sure to keep all your doctor's appointments so your progress can be checked**. Your doctor will want to do some blood, urine and other tests from time to time to check on your progress.
- If you are undergoing anaesthesia, tell your anaesthetist that you are taking PREZCOBIX.

Remind any doctor, dentist or pharmacist you visit that you are using PREZCOBIX.

Things you should not do

- Do not stop taking PREZCOBIX without talking to your doctor first. HIV therapy may increase your sense of well being. Even when you feel better, do not stop taking PREZCOBIX. Talk to your doctor first.
- Avoid doing things that can spread HIV infection since PREZCOBIX does not stop you from passing the HIV infection to others:
    - Do not share needles or other injection equipment.

- Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades.
- Do not have any kind of sex without protection. Always practise safer sex by using a latex or polyurethane condom or other barrier to reduce the chance of passing the infection through semen, vaginal secretions, or blood.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PREZCOBIX affects you.

Do not operate machines or drive if you feel dizzy after taking PREZCOBIX.

Looking after your medicine

- Store below 30°C and in the original packaging to protect from moisture.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

When treating HIV infection, it is not always easy to identify what side effects are caused by PREZCOBIX, which are caused by other medicines you are taking, or which are caused by the HIV infection itself.

PREZCOBIX may change some values of your blood chemistry. These can be seen in the results of blood tests. Your doctor will explain these to you.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Infection related: • symptoms such as a fever or rashes. **Stomach or gut related:** • abdominal pain, diarrhoea • passing wind	**Speak to your doctor if you have any of these less serious side effects and they worry you.**
• loss of appetite **Muscle related:** • muscle pain, tenderness or weakness. On rare occasions, these muscle disorders have been serious. **Blood related:** • increased blood fat levels • raised blood sugar and worsening of diabetes. **Liver related:** • Liver problems that may occasionally be severe have been reported. Your doctor should do blood tests prior to initiating PREZCOBIX. If you have chronic hepatitis B or C infection, your doctor should check your blood tests more often because you have an increased chance of developing liver problems. Signs and symptoms of liver problems may include: yellowing of your skin or whites of your eyes, dark (tea coloured) urine, pale coloured stools (bowel movements), nausea, vomiting, loss of appetite, or pain, aching, or sensitivity on your right side below your ribs. **Immune related:** • Immune reactivation syndrome. In some patients with advanced HIV infection (AIDS) and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started, including PREZCOBIX. In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. • **Other:** • nausea, vomiting • headache	
Skin related:	**It is important to consult your**

Less serious side effects	What to do
• Skin rash has been reported in patients receiving PREZCOBIX. Occasionally a rash can be severe or potentially life threatening. In patients taking PREZCOBIX and raltegravir, rashes (generally mild or moderate) may occur more frequently than in patients taking either drug separately	**doctor if you develop a rash. Your doctor will advise you how to deal with your symptoms or whether PREZCOBIX must be stopped.**

Serious side effects

Serious side effects	What to do
Allergy related • rash, itching or hives on the skin • shortness of breath, wheezing or difficulty breathing • swelling of the face, lips, tongue or other parts of the body. **Bleeding related:** • increased bleeding in patients with haemophilia.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What PREZCOBIX contains

Active ingredient (main ingredient)	• darunavir 800 mg (as darunavir ethanolate) • cobicistat 150 mg
Other ingredients (inactive ingredients)	• hypromellose • silicon dioxide • microcrystalline cellulose • crospovidone • magnesium stearate • Opadry II complete film coating system 85F140053 Pink (ARTG PI No. 109886) (Film Coating)

Do not take this medicine if you are allergic to any of these ingredients.

What PREZCOBIX looks like

PREZCOBIX 800/150 mg film-coated tablet: Pink oval-shaped tablet, debossed with “800” on one side and “TG” on the opposite side. Each plastic bottle contains 30 tablets. (AUST R 231198).

Who distributes PREZCOBIX

Janssen-Cilag Pty Ltd

17 Khartoum Rd

Macquarie Park, NSW 2113, Australia

Telephone: 1800 226 334

NZ office: Auckland New Zealand

This leaflet was prepared in February 2026.