

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 PREZISTA?

PREZISTA contains the active ingredient darunavir. PREZISTA is used to treat adults, and children 6 years of age or above weighing more than 20 kg, who are infected by HIV (Human Immunodeficiency Virus).

For more information, see Section [1. Why am I using PREZISTA?](#) in the full CMI.

2. What should I know before I use PREZISTA?

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

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use PREZISTA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PREZISTA and affect how it works. **Do not combine PREZISTA with medicines listed in [Section 2. What should I know before I use PREZISTA?](#)**

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 PREZISTA?

- Always take PREZISTA exactly as your doctor has told you. You must check with your doctor if you are not sure.
- Adults: The usual dose of PREZISTA is 800 mg once daily or 600 mg twice daily taken together with 100 mg ritonavir or 150 mg cobicistat, and always with food.
- Children 6 years of age and older: The doctor will work out the right dose based on the weight of the child. The doctor will inform you exactly how many PREZISTA tablets and how much ritonavir (capsules or solution) your child should take.

PREZISTA 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 PREZISTA?](#) in the full CMI.

5. What should I know while using PREZISTA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking PREZISTA. • 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 PREZISTA.
Things you should not do	• Do not stop taking PREZISTA suddenly without talking to your doctor even if you feel better. • Avoid doing things that can spread HIV infection since PREZISTA 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 PREZISTA.
Looking after your medicine	• Store below 30°C. • Keep it where children cannot reach it.

For more information, see Section [5. What should I know while using PREZISTA?](#) in the full CMI.

6. Are there any side effects?

The most common side effects are nausea, vomiting, headache, abdominal pain, diarrhoea, indigestion, passing wind, rash, itching or hives on the skin, weakness or lack of energy, and feeling tired.

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.

PREZISTA®

Active ingredient(s): darunavir (da-ROO-nuh-veer)

Consumer Medicine Information (CMI)

This leaflet provides important information about using PREZISTA. **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 PREZISTA.**

Where to find information in this leaflet:

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

1. Why am I using PREZISTA?

PREZISTA contains the active ingredient darunavir.

PREZISTA is an antiretroviral medicine that works by reducing the amount of HIV in your body. It belongs to a group of medicines called protease (PRO-tee-ase) inhibitors.

Darunavir is the HIV medicine, which needs to be combined with another medicine, cobicistat or ritonavir, that increases the amount of HIV medicine in your blood to control your HIV infection. PREZISTA works by reducing the amount of HIV in your body. Reducing the amount of HIV in your blood improves your immune system, and reduces the risk of developing illnesses as a result of HIV infection.

PREZISTA is used to treat adults, and children 6 years of age or above weighing more than 20 kg, who are infected by HIV (Human Immunodeficiency Virus). In adults, PREZISTA must be taken in combination with cobicistat or with a low dose of ritonavir, and with other anti-HIV medicines. In children, PREZISTA must be taken in combination with a low dose of ritonavir, and with other anti-HIV medicines. Your doctor will discuss with you which combination of medicines will work best with PREZISTA.

2. What should I know before I use PREZISTA?

Warnings

Do not use PREZISTA if:

- You are allergic to darunavir, cobicistat, ritonavir or any of the other ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Do not use PREZISTA if you are taking any of the following medicines:

- o amiodarone, bepridil, disopyramide, flecainide, mexiletine, propafenone, lidocaine, quinidine or dronedarone (to treat irregular heartbeats)
- o ivabradine or ranolazine (to treat heart disease)
- o midazolam or triazolam (to treat trouble with sleeping and/or anxiety)
- o ergot alkaloids i.e. dihydroergotamine, ergonovine, ergotamine, methylergonovine (to treat migraine and headaches)
- o astemizole or terfenadine (to treat allergy symptoms)
- o cisapride (to treat some stomach conditions)
- o lurasidone or pimozide (to treat psychiatric conditions)
- o alfuzosin (to treat an enlarged prostate)
- o sildenafil (to treat pulmonary arterial hypertension)
- o colchicine (to treat gout) if you have renal/hepatic impairment
- o lovastatin, simvastatin or lomitapide (to lower cholesterol levels)
- o apixaban (used to reduce blood clotting)
- o carbamazepine, phenobarbital, phenytoin (medicines to prevent seizures or to treat trigeminal neuralgia)
- o rifampicin (to treat some infections such as tuberculosis)
- o elbasvir/grazoprevir (to treat hepatitis C)
- o products that contain St John's wort (*Hypericum perforatum*)
- o naloxegol (to treat opioid induced constipation)
- o 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 PREZISTA (see Section [3. What if I am taking other medicines?](#))

Do not take PREZISTA in combination with cobicistat with:

- certain medicines to treat epilepsy and prevent seizures (carbamazepine, phenobarbital or phenytoin). If you are taking any of these, ask your doctor about switching to another medicine.

Check with your doctor if you:

- have or have had any other medical conditions, especially the following:
 - o **Problems with your liver, including hepatitis B and hepatitis C.** Your doctor may need to evaluate your liver before deciding if you can take PREZISTA.

- o **Diabetes.** PREZISTA, like some other anti-HIV medicines, might increase sugar levels in the blood.
- o **Haemophilia.** Anti-HIV medicines, such as PREZISTA, might increase the risk of bleeding in patients with this blood clotting disorder.
- o 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 PREZISTA with cobicistat if you are pregnant or breastfeeding.

During pregnancy and breastfeeding you must not take PREZISTA with ritonavir, unless it is specifically approved by your doctor. It is recommended that HIV infected women should not breastfeed their infants because of the possibility of your 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

- PREZISTA should not be given to children younger than 6 years of age.
- PREZISTA should not be given to children and adolescents who have never used antiretroviral medicines before.

Take special care with PREZISTA:

- PREZISTA 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 PREZISTA 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 PREZISTA.

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 PREZISTA. These are mentioned above under the subsection '[Do not use PREZISTA if](#)'.

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.

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

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

The effects of other medicines might be influenced if you take PREZISTA 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 (e.g. dabigatran etexilate, edoxaban, rivaroxaban, warfarin) or to prevent blood clots (e.g. ticagrelor, clopidogrel)
- contraceptives. PREZISTA 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 (atorvastatin, pitavastatin, pravastatin, rosuvastatin). The risk of muscle tissue disorder might be increased.
- medicines for your immune system (cyclosporin, everolimus, tacrolimus, sirolimus). Your doctor might want to do some additional tests.
- corticosteroids (betamethasone, budesonide, fluticasone, mometasone, prednisone, triamcinolone)
- medicine to treat asthma (salmeterol)
- medicines to treat gout (colchicine). If you have renal/hepatic impairment, do not take colchicine with PREZISTA.
- medicines to treat malaria (artemether/lumefantrine)
- medicines to treat cancer (dasatinib, everolimus, irinotecan, nilotinib, vinblastine, vincristine)
- medicines to prevent seizures (clonazepam)
- medicines to treat depression and anxiety (amitriptyline, desipramine, imipramine, nortriptyline, and trazodone)
- medicines to treat fungal infections (clotrimazole, fluconazole, isavuconazole, posaconazole)
- sedatives (buspirone, clorazepate, diazepam, estazolam, flurazepam, zolpidem)
- certain medicines to treat moderate or severe pain (fentanyl, oxycodone, tramadol). The amount of the pain medicine in the body might increase if it is used with PREZISTA. There is an increased risk of serious breathing difficulties with use or abuse of these pain medicines while on treatment with PREZISTA.
- 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 used to reduce clotting of the blood (e.g. dabigatran etexilate, edoxaban, warfarin)
- medicines to treat certain heart disorders (digoxin, carvedilol, metoprolol, timolol, bosentan)
- medicines to treat fungal infections itraconazole, ketoconazole, voriconazole)
- medicines to treat some infections (rifabutin)
- medicines for erectile dysfunction (avanafil, sildenafil, vardenafil, tadalafil)
- medicines against bacterial infections (clarithromycin).
- medicines to treat depression and anxiety (paroxetine, sertraline)
- medicines to prevent seizures or to treat trigeminal neuralgia (carbamazepine)
- medicines to treat narcotic dependence (buprenorphine/ naloxone, methadone)
- medicines to treat psychiatric conditions (perphenazine, quetiapine, risperidone, thioridazine)

This is **not** a complete list of medicines. Therefore, tell your doctor about **all** medicines you take.

Please refer to the ritonavir or cobicistat Consumer Medicine Information for information on ritonavir or cobicistat.

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

4. How do I use PREZISTA?

Adults

How much to take

- The usual dose of PREZISTA is 800 mg once daily or 600 mg twice daily taken together with 100 mg ritonavir or 150 mg cobicistat, and always with food. Your doctor will decide which dose is right for you.
- Follow the instructions provided and use PREZISTA until your doctor tells you to stop.
- Always use PREZISTA 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 PREZISTA and ritonavir or cobicistat available so that you don't run out. For example, in case you cannot return home, need to travel or stay in a hospital.
- If your child feels better, do not stop administering PREZISTA without talking to the child's doctor.

When to take PREZISTA

- **You must take PREZISTA every day and always in combination with ritonavir (or cobicistat, in adults only), and with food.** PREZISTA cannot work properly without ritonavir (or cobicistat, and food).
- **You must eat a meal or a snack within 30 minutes prior to taking your PREZISTA and ritonavir or cobicistat.** The type of food is not important.

- Even if you feel better, do not stop taking PREZISTA without talking to your doctor.

How to take PREZISTA

- Take PREZISTA always together with 100 milligrams of ritonavir or 150 milligrams of cobicistat.
- Take PREZISTA with food.
- Swallow the tablets with a drink such as water, milk, or any other nutritional drink.
- Take your other HIV medicines used in combination with PREZISTA and ritonavir or cobicistat as recommended by your doctor.

Children 6 years of age and older, weighing at least 20 kg, who have taken any anti-HIV medicines before (your child's doctor will determine this)

- The doctor will work out the right dose based on the weight of the child. The doctor will inform you exactly on how many PREZISTA tablets and how much ritonavir (capsules or solution) your child should take.
- If your child feels better, do not stop administering PREZISTA without talking to the child's doctor.
- Take PREZISTA always together with ritonavir.
- Take PREZISTA with food.
- Swallow the tablets with a drink such as water, milk, or any other nutritional drink.
- Take your other HIV medicines used in combination with PREZISTA and ritonavir as recommended by your doctor.
- If your child cannot tolerate ritonavir oral solution, consult 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 take PREZISTA

- PREZISTA should be used regularly at the same time each day.
- **If you forget to take PREZISTA and your dosing regimen is PREZISTA with ritonavir or cobicistat once a day:** If you notice within 12 hours, you must take the tablets immediately. Always take with ritonavir or cobicistat and food. If you notice after 12 hours, then skip the intake and take the next doses as usual.

- **If you forget to take PREZISTA and your dosing regimen is PREZISTA with ritonavir twice a day:** If you notice within 6 hours, you must take the tablet/s immediately. Always take with ritonavir and food. If you notice after 6 hours, then skip the dose and take the next doses as usual.
- Please refer to your doctor for instructions on missed doses of other HIV medicines used in combination with PREZISTA and ritonavir or cobicistat.

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

If you use too much PREZISTA

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

You should immediately:

- phone the Poisons Information Centre (in Australia telephone **13 11 26**. In New Zealand telephone **0800 POISON** or **0800 764 766**), 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 PREZISTA?

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 PREZISTA, 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.
- **Be sure to follow up your doctor's instructions about other medicines you should take, and other things you should do.**
- **If you are undergoing anaesthesia, tell your anaesthetist that you are taking PREZISTA.**

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

Things you should not do

- **Do not stop taking PREZISTA without talking to your doctor first.** HIV therapy may increase your sense of well being. Even when you feel better, do not stop taking PREZISTA. Talk to your doctor first.

- **Avoid doing things that can spread HIV infection** since PREZISTA does not stop you from passing the HIV infection to others:
 - o Do not share needles or other injection equipment.
 - o Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades.
 - o 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 PREZISTA affects you.

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

Looking after your medicine

- Store below 30°C.
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:
 - o in the bathroom or near a sink, or
 - o 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 PREZISTA, which are caused by other medicines you are taking, or which are caused by the HIV infection itself.

PREZISTA 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 of infection such as fever or rashes. Some people with HIV who have had	Speak to your doctor if you have any of these less

Less serious side effects	What to do
infections in the past may experience a return of symptoms soon after taking anti-HIV medicines. Stomach or gut-related: - abdominal pain, diarrhoea - upper abdominal pain that radiates into the back which may be due to inflammation of the pancreas 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. - PREZISTA 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. Liver-related: - Liver problems that may occasionally be severe have been reported. 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 PREZISTA. In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks health body tissue) may also occur after you start taking medicines for treatment of your HIV infection. Autoimmune disorders may	serious side effects and they worry you.

Less serious side effects	What to do
occur many months after the start of treatment. Others: - nausea, vomiting - headache - indigestion - passing wind - rash, (see information below) itching or hives on the skin - weakness or lack of energy	
Skin-related: Skin rash has been reported in patients receiving PREZISTA. Occasionally a rash can be severe or potentially life threatening. In patients taking PREZISTA and raltegravir, rashes (generally mild or moderate) may occur more frequently than in patients taking either drug separately.	It is important to consult your doctor if you develop a rash. Your doctor will advise you how to deal with your symptoms or whether PREZISTA must be stopped

Serious side effects

Serious side effects	What to do
Signs and symptoms of an allergic reaction: - rash, itching or hives on the skin - shortness of breath, wheezing or trouble 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.

Please refer to the ritonavir or cobicistat Consumer Medicine Information for information on ritonavir or cobicistat.

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 PREZISTA contains

Active ingredient (main ingredient)	darunavir 600 mg or 800 mg (as darunavir ethanolate)
Other ingredients (inactive ingredients)	• microcrystalline cellulose • colloidal anhydrous silica • crospovidone • magnesium stearate • polyvinyl alcohol • macrogol 3350 • titanium dioxide (E171) • purified talc • [600 mg tablets] sunset yellow FCF aluminium lake • [800 mg tablets] hypromellose and iron oxide red (E172).

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

What PREZISTA looks like

PREZISTA 600 mg film-coated tablets are orange, oval shaped tablets, with TMC on one side, 600MG on the other side. Each plastic bottle contains 60 tablets. (AUST R 153628).

PREZISTA 800 mg film-coated tablets are dark red, oval shaped tablets, with 800 on one side and T on the other side. Each plastic bottle contains 30 tablets (AUST 199320).

Who distributes PREZISTA

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Macquarie Park NSW 2113 Australia
Telephone: 1800 226 334
NZ Office: Auckland, New Zealand
Telephone: 0800 800 806

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