

PREZISTA® FILM COATED TABLET

Darunavir (600mg)

What is in this leaflet

1. What PREZISTA® is used for
2. How PREZISTA® works
3. Before you use PREZISTA®
4. How to use PREZISTA®
5. While you are using it
6. Side effects
7. Storage and Disposal of PREZISTA®
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What PREZISTA® is used for

PREZISTA is an antiretroviral medicine. It belongs to a group called protease inhibitors.

PREZISTA is used to treat adults who are infected with HIV.

PREZISTA must be taken in combination with a low dose of ritonavir and other anti-HIV medicines.

Your doctor will discuss with you which combination of medicines is best for you.

How PREZISTA® works

PREZISTA works by reducing the amount of Human Immunodeficiency Virus (HIV) in your body. This will improve your immune system and reduces the risk of developing illnesses linked to HIV infection.

Before you use PREZISTA®

- When you must not use it
Do not take PREZISTA:
 - if you are **allergic** (hypersensitive) to darunavir, other ingredients of PREZISTA or to ritonavir.

Tell your doctor about **all** medicines you take.

Do not combine PREZISTA with any of the following medicines:

- *astemizole* or *fenfenadine* (to treat allergy symptoms)

- *midazolam* or *triazolam* (to treat trouble with sleeping and/or anxiety)
- *cisapride* (to treat some stomach conditions)
- *lurasidone* or *pimozide* (to treat psychiatric conditions)
- *ergot alkaloids* (to treat migraine and headaches)
- *alfuzosin* (to treat enlarged prostate gland)
- *sildenafil* (to treat pulmonary arterial hypertension)
- *colchicine* (to treat gout or familial Mediterranean fever), if you have renal/hepatic impairment
- *lovastatin*, *simvastatin*, or *lomitapide* (to lower cholesterol levels)
- *dronedarone*, *ivabradine*, *ranolazine* (to treat chest pain)
- *rifampin* (to treat some infections such as tuberculosis)
- *elbasvir/grazoprevir* (to treat hepatitis C infection)
- *St. John's wort* (*Hypericum perforatum*) (a herbal product used in products for depression)
- *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.

Pregnancy and Breastfeeding

Tell your doctor immediately if you are pregnant, planning to become pregnant or if you are breast-feeding. During pregnancy and breast-feeding, do not take PREZISTA with ritonavir, unless it is specifically approved by your doctor. It is recommended that HIV infected women should not breast-feed their infants because of the possibility of your baby becoming infected with HIV through your

breast milk and because of the unknown effects of the medicine on your baby.

- Before you start to use it
Take special care with PREZISTA
PREZISTA is not a cure for HIV infection. PREZISTA does not reduce the risk of passing HIV to others through sexual contact or blood contaminations. Therefore, you must continue to use appropriate precautions.

People taking PREZISTA may still develop infections or other illnesses associated with HIV infection. You must keep in regular contact with your doctor.

Tell your doctor about your situation

Make sure that you check the following points and tell your doctor if any of these apply to you.

- Tell your doctor if you have had **problems with your liver** before, including hepatitis B or C infection. Your doctor may evaluate how severe your liver disease is before deciding if you can take PREZISTA.
- Tell your doctor if you have **diabetes**. In general, anti-HIV medicines such as PREZISTA might increase sugar levels in the blood.
- Tell your doctor immediately if you notice any **symptoms of infection or inflammation**. In some patients with advanced HIV infection, signs and symptoms of infection or inflammation may occur after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response.
- Tell your doctor if you have **hemophilia**. Anti-HIV medicines, such as PREZISTA, might increase the risk of bleeding.
- Tell your doctor if you are **allergic to sulfa medicines**.

PREZISTA® FILM COATED TABLET

Darunavir (600mg)

- Taking other medicines

Tell your doctor about your medicines

PREZISTA might interact with other medicines. Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

There are some medicines that **you must not combine** with PREZISTA. These are mentioned above under the heading 'Do not combine PREZISTA with any of the following:'.

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 infection (*glecaprevir/pibrentasvir*, *boceprevir*).
- medicines to prevent seizures (*phenobarbital*, *phenytoin*).
- corticosteroids (*dexamethasone*).
- medicines to treat some infections such as tuberculosis (*rifapentine*).

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 (*amiodarone*, *amlodipine*, *bepidil*, *bosentan*, *carvedilol*, *diltiazem*, *felodipine*, *flecainide*, *disopyramide*, *lidocaine*, *metoprolol*, *mexiletine*, *nifedipine*, *nicardipine*, *propafenone*, *tadalafil*, *timolol*, *quinidine*, *verapamil*).
- medicines used to reduce clotting of the blood (e.g. *apixaban*, *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 methods (non-hormonal) contraception are recommended. If you take a contraceptive containing *drospirinone*, your potassium levels might become elevated
- medicines to lower cholesterol levels (e.g. *atorvastatin*, *pravastatin*, *rosuvastatin*). The risk of muscle tissue disorder might be increased. *Atorvastatin*, *pravastatin* or *rosuvastatin*, at a reduced starting dose, could be used.
- medicines for your immune system (*everolimus*, *cyclosporin*, *tacrolimus*, *sirolimus*). 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 or familial Mediterranean fever (*colchicine*).
- combination medicine to treat malaria (*artemether/lumefantrine*).
- medicines to treat cancer (*dasatinib*, *everolimus*, *irinotecan*, *nilotinib*, *vinblastine*, *vincristine*).
- medicine to prevent seizures (*clonazepam*)
- medicines to treat depression and anxiety (*amitriptyline*, *desipramine*, *imipramine*, *nortriptyline*, *trazodone*).
- medicines to treat fungal infections (*clotrimazole*, *fluconazole*, *isavuconazole*, *posaconazole*).
- sedatives/hypnotics (*bupirone*, *clorazepate*, *diazepam*, *estazolam*, *flurazepam*, *zolpidem*).

- certain medicines to treat moderate or severe 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 used to reduce clotting of the blood (*dabigatran etexilate*, *edoxaban*, *warfarin*)
- medicines to treat certain heart disorders (*digoxin*)
- medicines against fungal infections (*itraconazole*, *ketoconazole*, *voriconazole*)
- medicines against bacterial infections (*rifabutin*)
- medicines for erectile dysfunction (*avanafil*, *sildenafil*, *varденаfil*, *tadalafil*)
- antibiotics (*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*)
- medicines used as sedatives (*parenteral midazolam*)

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

Taking PREZISTA with food and drink

See 'How to use PREZISTA' with food and drink.

How to use PREZISTA®

PREZISTA® FILM COATED TABLET

Darunavir (600mg)

- How much to use

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 available so that you don't run out. For example, in case you cannot return home, need to travel or stay in a hospital.

Adults who have taken anti-HIV medicines before (your doctor will determine this)

The dose is 600 mg (1 tablet containing 600 mg of PREZISTA) together with 100 mg ritonavir twice daily.

Instructions

You must take PREZISTA every day and always in combination with 100 mg of ritonavir and with food. PREZISTA cannot work properly without ritonavir and food. You must eat a meal or a snack within 30 minutes prior to taking your PREZISTA and ritonavir. The type of food is not important.

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

When the dose of PREZISTA is 600 mg with 100 mg ritonavir twice daily

- Take one 600 mg tablet in the morning and one 600 mg tablet in the evening.
- Take PREZISTA always together with 100 mg of ritonavir.
- Take PREZISTA with food.
- Swallow the tablet(s) 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.

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.

- When to use it

Always use PREZISTA exactly as your doctor has told you. You must check with your doctor if you are not sure.

- How long to use it

Continue taking PREZISTA for as long as your doctor recommends.

- If you forget to use it

If your dosing regimen is PREZISTA with ritonavir twice a day:

If you notice within 6 hours, you must take the tablets immediately. Always take with ritonavir and food. If you notice after 6 hours, then skip the intake and take the next doses as usual. Do not take a double dose to make up for a forgotten dose.

Please refer to your doctor for instructions on missed doses of other HIV medicines used in combination with PREZISTA and ritonavir.

- If you use too much (overdose)

Contact your doctor or pharmacist immediately.

While you are using it

- Things you must do

If you have any further questions on the use of this product, ask your doctor.

- Things you must not do

Do not stop using 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.

- Things to be careful of

Driving and using machines

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

Side effects

Like all medicines, PREZISTA can cause side effects, although not everybody gets them.

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.

The following is not a complete list of side effects reported with PREZISTA.

Liver problems that may occasionally be severe have been reported. Your doctor should do blood tests prior to initiating PREZISTA. 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. Talk to your doctor about the signs and symptoms of liver problems. These may include yellowing of your skin or whites of your eyes, dark (tea colored) urine, pale colored stools (bowel movements), nausea, vomiting, loss of appetite, or pain, aching, or sensitivity on your right side below your ribs.

Skin rash has been reported in 10.3% of 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.

PREZISTA[®] FILM COATED TABLET

Darunavir (600mg)

Your doctor will advise you how to deal with your symptoms or whether PREZISTA must be stopped.

Other clinically relevant severe side effects, reported at an uncommon or rare frequency were inflammation of the pancreas, increased blood fat levels, diabetes, and symptoms of infection. Darunavir crystals in the kidney causing kidney disease have been reported at a very rare frequency.

The most commonly reported side effects include abdominal pain, diarrhea, headache, nausea, rash and vomiting.

Some side effects are typical for anti-HIV medicines. These are:

- raised blood sugar and worsening of diabetes.
- immune reconstitution inflammatory 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 healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment.
- increased bleeding in patients with hemophilia.
- muscle pain, tenderness or weakness. On rare occasions, these muscle disorders have been serious.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the

National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [(Consumers → Reporting Side Effects or Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of PREZISTA[®]

- Storage

Do not store above 30°C

Keep out of the reach and sight of children.

PREZISTA tablets do not require any special storage conditions.

Do not use PREZISTA after the expiry date, which is stated on the box and on the bottle after the letters EXP. The expiry date refers to the last day of that month.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Film-coated, orange, oval-shaped tablet, mentioning TMC on one side, 600MG on the other side. 60 tablets in a plastic bottle.

- Ingredients

Active ingredients

The active substance is darunavir. Each 600 mg tablet contains 650.46 mg of darunavir ethanolate, corresponding to 600 mg of darunavir.

Inactive ingredients

The other ingredients of the orange tablet are microcrystalline cellulose, colloidal anhydrous silica, crospovidone, magnesium stearate. The film-coating contains polyvinyl alcohol - partially hydrolyzed, macrogol 3350, titanium dioxide

(E171), talc.

- MAL number
MAL19046001ARZ

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Product Registration Holder

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