

WHO-PQ recommended clinical and preclinical information for the patient

This information reflects the recommendations of current WHO guidelines and the scope of WHO's prequalification programme.

Information for the patient
Darunavir 600 mg film-coated tablet*
Darunavir (ethanolate)

Carers or parents looking after the person who takes this medicine should use this information to give the medicine correctly and take note of the warnings and side effects

1. What Darunavir 600 mg film-coated tablet is and what it is used for

Darunavir 600 mg film-coated tablet contains the active substance darunavir. Darunavir 600 mg film-coated tablet is an antiretroviral medicine used with other HIV medicines in the treatment of human immunodeficiency virus (HIV) infection. It belongs to a group of medicines called protease inhibitors.

Darunavir 600 mg film-coated tablet together with other HIV medicines reduces the amount of virus in your blood and keeps it at a low level. It is not a cure for HIV infection but, if taken correctly, the combination will improve your immune system and reduce the risk of developing illnesses linked to HIV infection. Your health care provider will discuss with you which combination of medicines is best for you.

Darunavir 600 mg film-coated tablet can also be used as part of the treatment to reduce the risk of getting HIV infected if you have been exposed to HIV. This is called post-exposure prophylaxis (PEP).

2. What you need to know before you take Darunavir 600 mg film-coated tablet

Do not take darunavir 600 mg film-coated tablet

- if you are **allergic** to darunavir or any of the other ingredients of this medicine (listed in section 6).
- if you have **severe liver problems**. Ask your health care provider if you are not sure if you have severe liver disease.

Do not combine darunavir 600 mg film-coated tablet with any of the following medicines

If you are taking any of these, ask your health care provider about switching to another medicine.

Medicine	Usual purpose of the medicine
Alfuzosin	to treat prostate problems
Amiodarone, bepridil, dronedarone, ivabradine, quinidine, ranolazine	to treat certain heart disorders e.g. irregular heartbeat
Astemizole, terfenadine	to treat allergy
Avanafil	to treat erectile dysfunction
Colchicine (if you have kidney or liver problems)	to treat gout or familial Mediterranean fever
Dapoxetine	to treat premature ejaculation
Domperidone	to treat nausea and vomiting
Elbasvir/grazoprevir, glecaprevir/pibrentasvir	to treat hepatitis C infection
Ergot medicines like ergotamine, dihydroergotamine, ergometrine and methylergometrine	to treat migraine and certain types of severe headaches
Halofantrine	to treat malaria

* Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

Lopinavir/ritonavir	HIV medicine in the same class as darunavir
Lovastatin and simvastatin, and lomitapide	to lower cholesterol levels
Lurasidone, pimozone, quetiapine or sertindole	to treat psychiatric conditions
Naloxegol	to treat constipation caused by certain painkillers
Neratinib	to treat cancer
Phenobarbital, phenytoin	to prevent seizures
Rifampicin, rifapentine	to treat some infections such as tuberculosis
Sildenafil	to treat high blood pressure in the lungs
St. John's wort	Herbal medicine to treat mood problems such as mild depression
Ticagrelor	to prevent platelets clumping together and blocking blood vessels (e.g. in patients who have had a heart attack)
Triazolam and midazolam	to help you sleep and relieve anxiety
Venetoclax	to treat cancer

Warnings and precautions

Talk to your health care provider before taking Darunavir 600 mg film-coated tablet.

Darunavir 600 mg film-coated tablet is not a cure for HIV infection.

People taking darunavir 600 mg film-coated tablets may still develop infections or other illnesses associated with HIV infection. You must keep in regular contact with your health care provider.

People taking Darunavir 600 mg film-coated tablet may get a skin rash. Rarely, a rash may become severe or life-threatening. Speak with your health care provider if you get a rash.

In people taking darunavir 600 mg film-coated tablets and raltegravir, rashes occur more often than in patients taking either medicine without the other.

If you are aged 65 years or older check with your health care provider that darunavir 600 mg film-coated tablet is right for you. This is because this has been used in very few older people.

Tell your health care provider about your general well-being **before** and **during** your treatment.

Look out for certain illnesses

If your immunity is weak when you start darunavir 600 mg film-coated tablet, you might develop infections or inflammation. Look out for signs of infection such as high temperature, swollen lymph glands and sore throat.

With continuing treatment your immunity will recover. When your immune system has improved enough, you will no longer be at higher risk of infection.

Some people taking medicines for HIV infection develop joint pain, stiffness and bone problems which can be serious.

Contact your health care provider at once if you get these conditions.

Tell your health care provider if:

- you have ever had **problems with your liver**, including hepatitis B or C. Your health care provider may check how well your liver is working to decide if you can take darunavir 600 mg film-coated tablet.
- you have **diabetes**. Darunavir 600 mg film-coated tablet might increase sugar levels in the blood.
- if you have **haemophilia**. Darunavir 600 mg film-coated tablet might increase the risk of bleeding.

- Tell your health care provider if you are **allergic to sulfonamides** (medicines used to treat certain infections).

Other medicines and darunavir 600 mg film-coated tablet

Tell your health care provider if you are taking or have recently taken any other medicines.

There are some medicines that **you must not combine** with darunavir 600 mg film-coated tablets. These are mentioned above under the heading ‘Do not combine darunavir 600 mg film-coated tablets with any of the following medicines:’

In most cases, darunavir 600 mg film-coated tablets can be combined with HIV medicines belonging to another class. Darunavir 600 mg film-coated tablets must not be used with certain protease inhibitors (PIs), which are a class of HIV medicines. In some cases, dosage of other medicines might need to be changed. Therefore, always tell your health care provider if you take other HIV medicines and follow your health care provider’s instruction carefully on which medicines can be combined.

Tell your health care provider of **all** the medicines you take. The following is a list of some of the medicines that can either have an effect on how darunavir 600 mg film-coated tablet works or Darunavir 600 mg film-coated tablets may have an effect on how the medicines work. Taking these medicines together may increase side effects or the medicines may not work well enough, so your health care provider may need to adjust your treatment.

Type of medicine	Examples of medicines
Anaesthetics	ketamine
Antibiotics (including medicines for tuberculosis)	bedaquilline, clarithromycin, delamanid, moxifloxacin, rifabutin
Anticoagulants and antiplatelet medicines (medicines to prevent blood clots and blocked blood vessels)	Apixaban, clopidogrel, dabigatran etexilate, edoxaban, rivaroxaban, warfarin
Antidepressants	amitriptyline, desipramine, imipramine, nortriptyline, paroxetine, sertraline, trazodone
Antifungal medicines	clotrimazole, fluconazole, isavuconazole, itraconazole, ketoconazole, posaconazole, voriconazole
Asthma medicine	salmeterol
Cancer medicines	cisplatin, cyclophosphamide, dacarbazine, dasatinib, docetaxel, everolimus, ifosfamide, imatinib, irinotecan, nilotinib, paclitaxel, tamoxifen, vinblastine, vincristine, vinorelbine,
Contraceptive medicines containing an oestrogen and progestogen	ethinylestradiol/drospirenone, ethinylestradiol/norethindrone, medroxyprogesterone
Hormone replacement therapy	etonogestrel (vaginal ring) dydrogesterone, norethisterone
Corticosteroids, usually used for inflammatory condition	betamethasone, budesonide, dexamethasone, fluticasone, mometasone, prednisone, triamcinolone
HIV medicines	efavirenz, maraviroc, tenofovir disoproxil
Medicines for worm infections	albendazole
Medicines for malaria	artemether/lumefantrine, artemisinin, mefloquine, atovaquone/proguanil, quinine
Medicines for epilepsy or fits and nerve pain	carbamazepine, clonazepam, lamotrigine, oxcarbazepine, valproate
Medicines for Parkinson’s disease	levodopa/carbidopa

Type of medicine	Examples of medicines
Medicines for diabetes	glibenclamide, gliclazide
Medicines for heart problems and high blood pressure	amlodipine, digoxin, diltiazem, disopyramide, carvedilol, felodipine, flecainide, lidocaine, metoprolol, mexiletine, nicardipine, nifedipine, propafenone, timolol, verapamil
Medicines for digestive problems	loperamide
Medicines for gout	colchicine
Medicines for psychiatric disorders such as schizophrenia	clozapine, perphenazine, risperidone, thioridazine
Medicines for urinary disorders	fesoterodine, solifenacin
Medicines to control the immune system (e.g. to prevent rejection after transplantation)	ciclosporin, everolimus, sirolimus, tacrolimus
Medicines to increase blood flow (to treat high blood pressure in the lungs and also erectile disorders)	bosentan, sildenafil, tadalafil, vardenafil
Medicines to lower cholesterol in the blood	atorvastatin, pravastatin, rosuvastatin
Medicines to reduce anxiety and to help sleep	bupirone, clorazepate, diazepam, estazolam, flurazepam, midazolam injection, zolpidem
Opioid medicines (for treating pain or opioid addiction)	alfentanil, buprenorphine/naloxone, fentanyl, methadone, morphine, oxycodone, tramadol

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

Pregnancy and breast-feeding

If you become pregnant, or are planning to become pregnant, contact your health care provider to discuss the potential benefits and risks of your antiretroviral therapy to you and your child.

It is not known whether darunavir and ritonavir pass into milk. If you want to breast-feed your baby, you should ask your health care provider for advice on the risks and benefits.

Driving and using machines

Do not operate machines or drive if you feel dizzy after taking darunavir 600 mg film-coated tablets.

3. How to take Darunavir 600 mg film-coated tablet

Always take this medicine exactly as your health care provider has told you. Check with your health care provider if you are not sure.

Even if you feel better, do not stop taking darunavir 600 mg film-coated tablets without talking to your health care provider.

You must not change the dose, change your HIV medicines or stop treatment without checking with your health care provider.

You must take darunavir 600 mg film-coated tablets every day around the same time and always in combination with ritonavir and with food. Darunavir 600 mg film-coated tablet cannot work properly without ritonavir. You should take darunavir 600 mg film-coated tablet within 30 minutes of eating a meal or taking a snack. The type of food is not important. Swallow the tablets with a drink such as water or milk.

Dose

Adults, children from 10 years and teenagers weighing at least 35 kg

The recommended dose of darunavir 600 mg film-coated tablet is:

1 tablet of darunavir 600 mg film-coated tablet in combination with 100 mg ritonavir twice daily.

Children from 3 years weighing 14 to 34 kg

The recommended dose of darunavir 600 mg film-coated tablet is:

1 tablet of darunavir 600 mg film-coated tablet in combination with 100 mg ritonavir once daily.

Children below 3 years of age and weighing less than 14 kg darunavir 600 mg film-coated tablet should not be given.

If you take more darunavir 600 mg film-coated tablets than you should:

If you accidentally take too many darunavir 600 mg film-coated tablets, contact your health care provider immediately.

If you forget to take darunavir 600 mg film-coated tablets

It is important not to miss a dose.

If you take your medicine **once daily** and miss a dose **within 12 hours of when you usually take it**, take it as soon as you can, and then take your next dose at its regular time.

If you miss a dose and **it is less than 12 hours before you usually take a dose**, do not take the missed dose. Wait and take the next dose at the usual time. Do not take a double dose to make up for a forgotten tablet.

If you take your medicine **twice daily** and miss a dose **within 6 hours of when you usually take it**, take it as soon as you can, and then take your next dose at its regular time.

If you miss a dose and **it is less than 6 hours before you usually take a dose**, do not take the missed dose. Wait and take the next dose at the usual time. Do not take a double dose to make up for a forgotten tablet.

If you vomit (are sick) within 4 hours of taking darunavir 600 mg film-coated tablets, take another tablet straightaway with some food. Do not wait until your next dose is due. You do not need to take another tablet if you vomited more than 4 hours after taking darunavir 600 mg film-coated tablets.

Stopping darunavir 600 mg film-coated tablets

Do not stop taking darunavir 600 mg film-coated tablets without talking to your health care provider first. HIV treatment may increase your sense of well-being. Even when you feel better, do not stop taking darunavir 600 mg film-coated tablet. Talk to your health care provider first if you are thinking of stopping your medicine.

If you have any questions about this medicine, ask your health care provider.

4. Possible side effects

During HIV therapy you may put on weight and levels of blood lipids (fats in the blood) and glucose (blood sugar) may rise. This is partly linked to restored health and lifestyle, and in the case of blood lipids sometimes to the HIV medicines.

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

Tell your health care provider if you have:

- yellowing of your skin or whites of your eyes, dark (tea-coloured) urine, pale stools (bowel movements), nausea, vomiting, loss of appetite, or pain, aching, or discomfort on your right side below your ribs. These are symptoms of liver problems that may occasionally be severe.
- skin rash (more often when used in combination with raltegravir), itching. The rash is usually mild to moderate. A skin rash might also be a symptom of a rare severe condition. It is therefore important to contact your health care provider if you develop a rash. Your health care provider will say how to deal with your symptoms or whether darunavir 600 mg film-coated tablets must be stopped.

Other important severe side effects are:

- diabetes (common)
- inflammation of the pancreas (uncommon), which can cause severe pain in your belly and back, feeling sick (nausea), being sick (vomiting) and loss of appetite.

Very common side effects (that may affect more than 1 in 10 people):

- diarrhoea.

Common side effects (may affect up to 1 in 10 people)

- vomiting, nausea, abdominal (belly) pain or distension (swelling), indigestion, flatulence (gas)
- headache, tiredness, dizziness, numbness, tingling or pain in hands or feet, loss of strength, difficulty falling asleep
- rash, itchiness
- blood tests showing changes in certain enzymes (indicating stress on the liver and pancreas), raised cholesterol, triglycerides, blood lipids and glucose (blood sugar).

Uncommon side effects (may affect up to 1 in 100 people)

- pain because of blockage in blood supply to a part of the heart, changes in electrocardiogram (test of the heart's electrical activity), rapid heartbeat
- decreased or abnormal sensation to touch, pain and temperature, pins and needles, attention disturbance, loss of memory, lack of energy, sleepiness, taste disturbance
- difficulty breathing, cough, nosebleed, throat irritation
- inflammation of the stomach or mouth, abnormal sensation in the mouth, heartburn, retching, dry mouth, discomfort of the abdomen, constipation, belching
- inflammation of the liver, fat build-up in the liver, blood tests indicating liver damage
- kidney failure, kidney stones, pain and discomfort on passing urine, passing urine frequently sometimes at night; tests showing protein and bilirubin in the urine
- itchy rash, widespread rash, swelling of the skin and other tissues (most often the lips or the eyes), skin reddening, eczema, excessive sweating, night sweats, hair loss, acne, dry skin, discoloration of nails
- muscle pain, muscle cramps or weakness, pain in arms and legs, osteoporosis (bones become fragile), osteonecrosis (permanent bone damage); blood test showing markers for bone damage
- gout, weight loss, decreased appetite and weight loss, increased appetite and weight gain, excessive thirst
- thyroid gland working less well. This can be seen in a blood test.
- high blood pressure, flushing
- red eyes, dry eyes
- fever, swelling of ankles due to build-up of fluids, feeling generally unwell, feeling hot, irritability, pain, spinning sensation
- immune reconstitution inflammatory syndrome (body fighting off infections as immunity recovers), allergy
- herpes simplex (cold sores or genital herpes)
- erectile dysfunction, enlargement of breasts
- blood tests showing reduced white cells and platelets (components that help the blood to clot), anaemia
- sleeping problems, depression, disorientation, anxiety, abnormal dreams, decrease in sexual drive

Rare side effects (may affect up to 1 in 1,000 people)

- a reaction called DRESS (a severe reaction affecting the skin, blood and internal organs), Stevens-Johnson syndrome (serious reaction with flu-like symptoms and painful rash affecting the skin, mouth, eyes and genitals)
- heart attack, slow heartbeat, palpitations
- visual disturbance
- chills, feeling abnormal
- confusion, altered mood, restlessness
- fainting, convulsions (fits), loss of taste
- mouth sores, vomiting blood, inflammation of the lips, dry lips, coated tongue
- runny nose
- skin lesions (damage or abnormalities), seborrheic dermatitis (red skin and scaly patches on the scalp and dandruff)
- stiffness of muscles or joints, joint pain and inflammation
- blood tests showing increase in eosinophils (a type of white blood cells)
- darunavir crystals in the kidney causing kidney disease

Side effects for which there is not enough information to work out how many people are affected:

- toxic epidermal necrolysis (life-threatening reaction with flu-like effects and blistering in the skin, mouth eyes and genitals), acute generalised exanthematous pustulosis (pus-filled pimples with red surrounding skin)

Some side effects are typical for HIV medicines in the same family as darunavir. These are:

- muscle pain, tenderness or weakness. On rare occasions, these muscle disorders have been serious.

If you get any side effects talk to your health care provider. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store Darunavir 600 mg film-coated tablets

Product specific information on the storage conditions is shown in the product information as approved by the reference authority, stated in WHOPAR part 1.

6. Contents of the pack and other information

What Darunavir 600 mg film-coated tablet contains

What Darunavir 600 mg film-coated tablet looks like and contents of the pack

Supplier and Manufacturer

This leaflet was last revised in May 2026

Product specific information on the composition, visual appearance of the formulation, appearance and size of packs as well as on the supplier, is shown in the product information as approved by the reference authority, stated in WHOPAR part 1.