

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[HA757 trade name][†]
Darunavir (ethanolate)/ritonavir

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [HA757 trade name] is and what it is used for
2. What you need to know before you take [HA757 trade name]
3. How to take [HA757 trade name]
4. Possible side effects
5. How to store [HA757 trade name]
6. Contents of the pack and other information

1. What [HA757 trade name] is and what it is used for

[HA757 trade name] is an antiretroviral medicine used in the treatment of human immunodeficiency virus (HIV) infection.

[HA757 trade name] contains the active substances:

- darunavir, a medicine belonging to a group of medicines called protease inhibitors;
- ritonavir, a medicine which boosts the effects of darunavir. It works by slowing down the breakdown of darunavir so that darunavir continues to work in the body for longer.

[HA757 trade name] 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.

[HA757 trade name] 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 [HA757 trade name]

Do not take [HA757 trade name]

- if you are **allergic** to darunavir, ritonavir or any of the other ingredients of this medicine (listed in section 6).

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

- 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 [HA757 trade name] 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
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 [HA757 trade name].

[HA757 trade name] is not a cure for HIV infection.

People taking [HA757 trade name] may still develop infections or other illnesses associated with HIV infection. You must keep in regular contact with your health care provider.

People taking [HA757 trade name] 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 [HA757 trade name] 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 [HA757 trade name] 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 [HA757 trade name], 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 [HA757 trade name].
- you have **diabetes**. [HA757 trade name] might increase sugar levels in the blood.
- if you have **haemophilia**. [HA757 trade name] 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 [HA757 trade name]

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 [HA757 trade name]. These are mentioned above under the heading ‘Do not combine [HA757 trade name] with any of the following medicines:’

In most cases, [HA757 trade name] can be combined with HIV medicines belonging to another class. [HA757 trade name] 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 [HA757 trade name] works or [HA757 trade name] 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)	bedaquiline, clarithromycin, delamanid, moxifloxacin, rifabutin
Anticoagulants and antiplatelet medicines (medicines to prevent blood clots and blocked blood vessels)	Apixaban, clopidogrel, dabigatran etexilate, edoxaban, rivaroxaban, warfarin

Type of medicine	Examples of medicines
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, indinavir, maraviroc, saquinavir, 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
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	buspirone, 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 [HA757 trade name].

This medicine contains mannitol and may have a mild laxative effect.

3. How to take [HA757 trade name]

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 [HA757 trade name] 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 [HA757 trade name] every day with food and at around the same time. You should take [HA757 trade name] within 30 minutes of eating a meal or taking a snack. The type of food is not important. Swallow the tablet 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 [HA757 trade name] is 2 tablets once daily.

Children weighing 25 to less than 35 kg

Based on your treatment history the recommended dose is:

2 tablets of [HA757 trade name] once daily

or

1 tablet of [HA757 trade name] twice daily

Your health care provider will tell you which is the right dose for you.

[HA757 trade name] should not be given to children below 3 years of age.

If you take more [HA757 trade name] than you should:

If you accidentally take too many [HA757 trade name], contact your health care provider immediately.

If you forget to take [HA757 trade name]

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 [HA757 trade name], 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 [HA757 trade name].

Stopping [HA757 trade name]

Do not stop taking [HA757 trade name] 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 [HA757 trade name]. 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 [HA757 trade name] 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 gain, 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 [HA757 trade name]

Do not store above 30°C. Avoid excursions above 30°C.

Discard the product 90 days after initial opening. (Applicable to 180's count HDPE bottles)

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the bottle, after 'EXP'. The expiry date refers to the last day of that month.

Do not use this medicine if you notice description of the visible signs of deterioration or that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [HA757 trade name] contains

- The active ingredients are darunavir (as ethanolate) 400 mg and ritonavir 50 mg
- The other ingredient(s) of [HA757 trade name] are:
- *Core tablet*: crospovidone, hypromellose, silicified microcrystalline cellulose, colloidal silicon dioxide, magnesium stearate, copovidone, sorbitan monolaurate, dibasic calcium phosphate, microcrystalline cellulose, corn starch, mannitol, sodium stearyl fumarate
- *Film coat*: hypromellose, titanium dioxide, macrogol/PEG, hydroxypropyl cellulose, iron oxide yellow, talc, colloidal anhydrous silica and polysorbate

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [HA757 trade name] looks like and contents of the pack

[HA757 trade name] is a yellow, capsule-shaped, film-coated tablets. They are biconvex (rounded on top and bottom) with a bevelled edge. The tablets have 'H' debossed (stamped into) one side and 'D46' on the other side.

[HA757 trade name] is provided in a round, opaque white plastic (HDPE) bottle containing 56; 60 or 180 tablets. It also contains a canister of desiccant (drying material) and a piece of purified cotton to keep the tablets in place. The bottle has an aluminium/ plastic foil seal and a white, childproof plastic (polypropylene) screw cap

Supplier and Manufacturer

Supplier

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For any information about this medicine, contact the local representative of the supplier.

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Detailed information on this medicine is available on the World Health Organization (WHO) website:
<https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>