

[Home](#) → [Drugs, Herbs and Supplements](#) → Darunavir

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## Darunavir

pronounced as (da roon' a veer)

### Why is this medication prescribed?

Darunavir is used with a pharmacokinetic booster (a medication that increases the amount of other medications in the body) such as ritonavir (Norvir) or cobicistat (Tybost), and other medications to treat human immunodeficiency virus (HIV) infection in adults and children 3 years of age and older. Darunavir is in a class of medications called protease inhibitors. It works by decreasing the amount of HIV in the blood. Although darunavir does not cure HIV, it may decrease your chance of developing acquired immunodeficiency syndrome (AIDS) and HIV-related illnesses such as serious infections or cancer. Taking these medications along with practicing safer sex and making other life-style changes may decrease the risk of transmitting the HIV virus to other people.

### How should this medicine be used?

Darunavir comes as a tablet and oral suspension (liquid) to take by mouth. It is usually taken with food and with ritonavir once or twice a day or with food and with cobicistat once a day. Take darunavir at around the same time(s) every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take darunavir exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Do not take darunavir without ritonavir or cobicistat.

Swallow the tablets/capsules whole; do not split, chew, or crush them.

Shake the suspension well right before each use to mix the medication evenly. Use the oral dosing syringe that came with the medication to withdraw the right amount of suspension from the bottle. You can swallow the suspension straight from the syringe. Wash the syringe with water and allow it to dry thoroughly after use.

Darunavir controls HIV but does not cure it. Darunavir also does not treat HIV infection alone and must always be given with a complete regimen. It is important that all of the medications prescribed by your doctor to treat HIV infection are taken together so that the medications will continue to work to control the infection. Continue to take darunavir even if you feel well. Do not stop taking darunavir without talking to your doctor. If you stop taking darunavir or skip doses, your condition may become more difficult to treat. When your supply of darunavir starts to run low, get more from your doctor or pharmacist.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

## Other uses for this medicine

Darunavir is also sometimes used to prevent infection in healthcare workers or other people who were accidentally exposed to HIV. Talk to your doctor about the risks of using this medication for your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking darunavir,

- tell your doctor and pharmacist if you are allergic to darunavir, sulfa medications, any other medications, or any of the ingredients in darunavir tablets or suspension. Ask your pharmacist for a list of the ingredients or if you are unsure if a medication you are allergic to is a sulfa medication.
- tell your doctor if you are taking any of the following medications: alfuzosin (Uroxatral); cisapride (Propulsid) (not available in the U.S.); dronedarone (Multaq); elbasvir/grazoprevir (Zepatier); ergot-type medications such as dihydroergotamine (D.H.E. 45, Migranal), ergotamine (Ergomar, in Cafergot, in Migergot), and methylergonovine (Methergine); lomitapide (Juxtapid); lovastatin (Mevacor, in Advicor); lurasidone (Latuda), midazolam (given by mouth); pimozone (Orap); ranolazine (Ranexa); rifampin (Rifadin, Rimactane, in Rifamate, in Rifater); sildenafil (only Revatio brand used for lung disease); simvastatin (Zocor, in Vytorin); St. John's wort; or triazolam (Halcion). Your doctor will probably tell you not to take darunavir. Also, if you have kidney or liver disease and are taking colchicine (Colcrys, Mitigare, in Col-Probenecid), your doctor will probably tell you not to take darunavir.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: anticoagulants ('blood thinners') such as apixaban (Eliquis), rivaroxaban (Xarelto), and warfarin (Coumadin, Jantoven); antifungals such as itraconazole (Onmel, Sporanox), ketoconazole (Nizoral), posaconazole (Noxafil), and voriconazole (Vfend); artemether/lumefantrine (Coartem); beta blockers such as carvedilol (Coreg), metoprolol (Lopressor, Toprol XL, in Dutoprol, in Lopressor HCT), and timolol (Betimol, Istalol, in Combigan, in Cosopt, others); betamethasone; boceprevir (no longer available in the U.S.; Victrelis); bosentan (Tracleer); budesonide (Entocort, Pulmicort, Uceris, others); buprenorphine (Belbuca, Buprenex, Butrans, in Suboxone, others); buprenorphine/naloxone (Bunavail, Suboxone, Zubsolv); buspirone; calcium-channel blockers such as amlodipine (Norvasc, in Caduet), diltiazem (Cardizem CD, Cartia, XT, Diltzac, others), felodipine (Plendil), nicardipine (Cardene), nifedipine (Adalat CC, Afebitab CR, Procardia), and verapamil (Calan, Covera, Verelan, in Tarka); certain chemotherapy medications such as dasatinib (Sprycel), nilotinib (Tasigna), vinblastine, and vincristine (Marqibo Kit); cholesterol-lowering medications (statins) such as atorvastatin (Lipitor, in Caduet), pravastatin (Pravachol), and rosuvastatin (Crestor); ciclesonide (Alvesco); clarithromycin (Biaxin, in Prevpac); certain medications for depression such as amitriptyline, desipramine (Norpramin), imipramine, nortriptyline, paroxetine (Brisdelle, Paxil, Pexeva), sertraline (Zoloft), and trazodone; dexamethasone; diazepam (Diastat, Valium); estazolam; fentanyl (Abstral, Duragesic, Subsys); fluticasone (Flonase, Flovent, in Advair); certain medications for hepatitis C virus (HCV) such as glecaprevir/pibrentasvir (Mavyret) and simeprevir (no longer available in U.S.; Olysio); other medications for HIV including indinavir (Crixivan), lopinavir/ritonavir (Kaletra), maraviroc (Selzentry), and saquinavir (Invirase); hormonal (estrogen) contraceptives (birth control pills, patches, rings, implants, or injections); medications for irregular heartbeat including amiodarone (Nexterone, Pacerone), bepridil (no longer available in U.S.), digoxin (Lanoxin), disopyramide (Norpace), flecainide, lidocaine (Xylocaine), mexiletine, propafenone (Rythmol), and quinidine (in Nuedexta);

certain medications for seizures such as carbamazepine (Carbatrol, Equetro, Tegretol, others), clonazepam (Klonopin), phenobarbital, and phenytoin (Dilantin, Phenytek); certain medications that suppress the immune system such as cyclosporine (Gengraf, Neoral, Sandimmune), everolimus (Afinitor, Zortress), sirolimus (Rapamune), and tacrolimus (Astagraf XL, Prograf); methadone (Dolophine, Methadose); methylprednisolone; mometasone (Asmanex); omeprazole (Prilosec); oxycodone (Xtampza); certain phosphodiesterase inhibitors (PDE-5 inhibitors) used for erectile dysfunction such as avanafil (Stendra), sildenafil (Viagra), tadalafil (Cialis), and vardenafil (Levitra, Staxyn); perphenazine; prednisone (Rayos); quetiapine (Seroquel); rifabutin (Mycobutin); rifapentine (Priftin); risperidone (Risperdal); salmeterol (Serevent, in Advair); tadalafil (Adcirca); thioridazine; ticagrelor (Brilinta); tramadol (Conzip); triamcinolone (Nasacort); and zolpidem (Ambien, Edluar, Intermezzo). Many other medications may also interact with darunavir, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

- if you are taking didanosine (Videx), take it 1 hour before or 2 hours after you take darunavir.
- tell your doctor if you have or have ever had diabetes or high blood sugar; hemophilia (bleeding disorder in which the blood does not clot properly); hepatitis (swelling of the liver caused by a virus), cirrhosis (a disease which causes scarring of liver tissue), or any other liver disease; or an infection that does not go away or that comes and goes such as cytomegalovirus (CMV; a viral infection that may cause symptoms in patients with weak immune systems), mycobacterium avium complex disease (MAC; a bacterial infection that may cause serious symptoms in people with AIDS), pneumonia, or tuberculosis (TB; a type of lung infection).
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking darunavir, call your doctor. Do not breast-feed if you are infected with HIV or are taking darunavir.
- you should know that darunavir may decrease the effectiveness of hormonal contraceptives (birth control pills, patches, rings, injections, or implants). Talk to your doctor about a non-hormonal birth control such as a barrier method (device that blocks sperm from entering the uterus such as a condom or a diaphragm) to prevent pregnancy while you are taking this medication. Ask your doctor to help you choose a method of birth control that will work for you.
- you should know that your body fat may increase or move to different areas of your body such as your breasts, upper back, neck, chest, and stomach area. Loss of fat from the legs, arms, and face can also happen.
- you should know that you may experience hyperglycemia (increases in your blood sugar) while you are taking this medication, even if you do not already have diabetes. Tell your doctor immediately if you have any of the following symptoms while you are taking darunavir: extreme thirst, frequent urination, extreme hunger, blurred vision, or weakness. It is very important to call your doctor as soon as you have any of these symptoms, because high blood sugar that is not treated can cause a serious condition called ketoacidosis. Ketoacidosis may become life-threatening if it is not treated at an early stage. Symptoms of ketoacidosis include: dry mouth, nausea and vomiting, shortness of breath, breath that smells fruity, and decreased consciousness.
- you should know that while you are taking medications to treat HIV infection, your immune system may get stronger and begin to fight other infections that were already in your body. This may cause you to develop symptoms of those infections. If you have new or worsening symptoms at anytime during your treatment with darunavir, be sure to tell your doctor.

## What special dietary instructions should I follow?

Talk to your doctor about eating grapefruit and drinking grapefruit juice while taking this medicine.

## What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

It is important that you take cobicistat, and all other medications prescribed by your doctor to treat HIV medication, every day and on a regular schedule. Missed doses may cause the medications to not work as well at treating the infection. Do not stop any of these medications without talking to your doctor.

## What side effects can this medication cause?

**Darunavir may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- headache
- diarrhea
- vomiting
- stomach pain
- constipation

**Some side effects can be serious. If you experience any of these symptoms, stop taking darunavir and call your doctor immediately or get emergency medical treatment:**

- rash
- peeling or blistering skin
- mouth sores
- red, swollen, itchy, or teary eyes
- muscle or joint aches
- fever
- swelling, tenderness, redness, or other signs of infection
- nausea
- extreme tiredness
- loss of appetite
- pain in the upper right part of the stomach
- yellowing of the skin or eyes
- pale or dark stools

Darunavir may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>] ) for more information if you do not have access to a take-back program.

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests to be sure it is safe for you to take darunavir and to check your body's response to darunavir.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Prezista<sup>®</sup>

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