

Darunavir Juno

Darunavir (da-ROO-nuh-veer)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Darunavir Juno tablets.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Darunavir Juno against the benefits this medicine is expected to have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet while you are taking Darunavir Juno.

You may need to read it again.

What Darunavir Juno is used for

Darunavir Juno is an antiretroviral medicine. It belongs to a group of medicines called protease (PRO-tee-ase) inhibitors. Darunavir Juno 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.

Darunavir Juno 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, Darunavir Juno must be taken in combination with cobicistat

or with a low dose of ritonavir, and with other anti-HIV medicines.

In children, Darunavir Juno 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 Darunavir Juno.

Ask your doctor if you have any questions about why Darunavir Juno has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take Darunavir Juno

When you must not use it:

Do not take Darunavir Juno:

- if you are allergic (hypersensitive) to darunavir, other ingredients of DARUNAVIR JUNO or to ritonavir or to cobicistat. Symptoms of an allergic reaction may include rash, itching or hives on the skin, shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body.

Do not take Darunavir Juno:

- if the packaging is torn or shows signs of tampering.
- if the expiry date (month and year) printed on the pack has passed. If you take DARUNAVIR JUNO after the expiry date it may not work.

DARUNAVIR JUNO should not be given to children younger than 6 years of age.

DARUNAVIR JUNO should not be given to children and adolescents who have never used antiretroviral medicines before.

Do not take DARUNAVIR JUNO in combination with ritonavir or cobicistat with any of the following medicines:

- amiodarone, bepridil, disopyramide, flecainide, mexiletine, propafenone, lidocaine, lignocaine, quinidine or dronedarone (to treat irregular heartbeats)
- ivabradine or ranolazine (to treat heart disease)
- midazolam or triazolam (to treat trouble with sleeping and/or anxiety)
- ergot alkaloids i.e. dihydroergotamine, ergonovine, ergotamine, methylergonovine (to treat migraine and headaches)
- astemizole or terfenadine (to treat allergy symptoms)
- cisapride (to treat some stomach conditions)
- lurasidone or pimozide (to treat psychiatric conditions)
- alfuzosin (to treat an enlarged prostate)
- sildenafil (to treat pulmonary arterial hypertension)
- colchicine (to treat gout) if you have renal/hepatic impairment
- lovastatin, simvastatin or lomitapide (to lower cholesterol levels)
- apixaban (used to reduce blood clotting)

- rifampicin (to treat some infections such as tuberculosis)
- elbasvir/grazoprevir (to treat hepatitis C)
- products that contain St John's wort (*Hypericum perforatum*)
- naloxegol (to treat opioid induced constipation)
- dapoxetine (to treat premature ejaculation)

Do not take DARUNAVIR JUNO 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.

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 DARUNAVIR JUNO (see Taking other medicines).

Before you start to use it

Take special care with DARUNAVIR JUNO:

DARUNAVIR JUNO is not a cure for HIV infection.

DARUNAVIR JUNO does not reduce the risk of passing HIV to others through sexual contact or blood. Therefore, you must continue to use appropriate precautions to prevent passing HIV on to others.

People taking DARUNAVIR JUNO 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 DARUNAVIR JUNO.

Tell your doctor if you have or have had any medical conditions, especially the following:

- **Problems with your liver, including hepatitis B and C.**
Your doctor may need to evaluate your liver before

deciding if you can take DARUNAVIR JUNO.

- **Diabetes.**
DARUNAVIR JUNO, like some other anti-HIV medicines, might increase sugar levels in the blood.
- **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 DARUNAVIR JUNO, with no obvious symptoms.
- **Changes in body fat.**
Redistribution, accumulation or loss of body fat may occur in patients receiving a combination of antiretroviral medicines.
- **Haemophilia.**
Anti-HIV medicines, such as DARUNAVIR JUNO, might increase the risk of bleeding in patients with this blood clotting disorder.
- **An allergy to sulfa medicines (sulphonamides).**

Tell your doctor immediately if you are pregnant or breastfeeding, or intend to become pregnant or breastfeed.

Do not take DARUNAVIR JUNO with cobicistat if you are pregnant or breastfeeding.

During pregnancy and breastfeeding you must not take DARUNAVIR JUNO 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 your breast milk and because of the unknown effects of the medicine on your baby.

If you have not told your doctor about any of the above, tell them before you start treatment with DARUNAVIR JUNO.

Taking other medicines

Some medicines may affect the levels of DARUNAVIR JUNO or DARUNAVIR JUNO may affect the level of other medicines in the body when they are taken at the same time as DARUNAVIR JUNO. Your doctor might want to do some additional blood tests.

For this reason, tell your doctor if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

Know the medicines you take. Keep a list of medicines and show it to your doctor and pharmacist when you get a new medicine. Your doctor and your pharmacist can tell you if you can take these medicines with DARUNAVIR JUNO.

- Tell your doctor if you are taking any of the following medicines. You must not take these medicines while taking DARUNAVIR JUNO in combination with ritonavir or cobicistat: alfuzosin, amiodarone, apixaban, astemizole, bepridil, cisapride, colchicine, dapoxetine, disopyramide, dronedarone, elbasvir/grazoprevir, ergot alkaloids (dihydroergotamine, ergonovine, ergotamine, methylergonovine), flecainide, ivabradine, lidocaine (lignocaine), lomitapide, lovastatin, lurasidone, mexiletine, midazolam, naloxegol, pimozone, propafenone, quinidine, ranolazine, rifampicin, sildenafil, simvastatin, products that contain St John's wort (*Hypericum perforatum*), terfenadine or triazolam.

- **Tell your doctor if you are taking the following medicines to treat epilepsy and prevent seizures. You must not take these medicines while you are taking DARUNAVIR JUNO in combination with cobicistat: carbamazepine, phenobarbital or phenytoin.**
- **Tell your doctor if you take other anti-HIV medicines. DARUNAVIR JUNO can be combined with some other anti-HIV medicines while other combinations are not recommended.**
- **If you take DARUNAVIR JUNO with some other medicines, the effects of DARUNAVIR JUNO or other medicines might be influenced. The dosage of some medicines may need to be changed. Some combinations are not recommended. Tell your doctor if you take any of the following:**
 - contraceptives. DARUNAVIR JUNO 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 for heart disease (amlodipine, diltiazem, felodipine, nifedipine, nicardipine, tadalafil, verapamil).
 - medicines to treat certain heart disorders (digoxin, carvedilol, metoprolol, timolol, bosentan).
 - medicines used to prevent clotting of the blood (clopidogrel, dabigatran, edoxaban, rivaroxaban, ticagrelor, warfarin).
 - medicines to lower cholesterol levels (atorvastatin, pitavastatin, pravastatin, rosuvastatin). The risk of muscle tissue disorder might be increased.

Atorvastatin, pitavastatin, pravastatin or rosuvastatin at a reduced starting dose, could be used as an alternative.

- medicines for your immune system (ciclosporin, everolimus, tacrolimus, sirolimus). Your doctor might want to do some additional tests.
- medicine to treat asthma (salmeterol).
- corticosteroids (betamethasone, budesonide, dexamethasone, fluticasone propionate, mometasone, prednisone, triamcinolone).
- medicines to treat cancer (dasatinib, everolimus, irinotecan, nilotinib, vinblastine, vincristine)
- medicines used to treat narcotic dependence (buprenorphine, naloxone, methadone).
- medicines to treat malaria (artemether/lumefantrine)
- medicines to treat hepatitis C (glecaprevir/pibrentasvir).
- medicines to treat urinary disorders (fesoterodine, solifenacin).
- medicines to treat nausea and vomiting (domperidone).
- medicines to treat fungal infections (clotrimazole, fluconazole, isavuconazole, itraconazole, ketoconazole, posaconazole voriconazole).
- medicines to treat infections such as tuberculosis (rifampentine, rifabutin) or other bacterial infections (clarithromycin).
- medicines to treat gout (colchicine). If you have renal/hepatic impairment, do not take colchicine with DARUNAVIR JUNO.
- medicines for erectile dysfunction (avanafil, sildenafil, vardenafil, tadalafil).
- medicines to treat depression and anxiety (paroxetine, sertraline, amitriptyline, desipramine, imipramine, nortriptyline, and trazodone).
- sedatives (buspirone,

clorazepate, diazepam, estazolam, flurazepam, zolpidem).

- medicines to treat excessive sleepiness (armodafinil, modafinil).
- medicines to treat psychiatric conditions (perphenazine, quetiapine, risperidone, thioridazine).
- medicines to treat epilepsy, prevent seizures or to treat trigeminal neuralgia
- (carbamazepine, clonazepam, oxcarbazepine, phenobarbital, phenytoin).
- 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 DARUNAVIR JUNO. There is an increased risk of serious breathing difficulties with use or abuse of these pain medicines while on treatment with DARUNAVIR JUNO.

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.

Taking Darunavir Juno

Adults

Always use DARUNAVIR JUNO 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 DARUNAVIR JUNO 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.

How much Darunavir Juno to take

Take DARUNAVIR JUNO exactly as directed by your doctor. Your doctor will decide which dose is right for you.

You must take DARUNAVIR JUNO every day and always in combination with 100 milligrams of ritonavir or 150 milligrams of cobicistat, and with food. DARUNAVIR JUNO cannot work properly without ritonavir or cobicistat, and food. You must eat a meal or a snack within 30 minutes prior to taking your DARUNAVIR JUNO and ritonavir or cobicistat. The type of food is not important.

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

Instructions:

- Take DARUNAVIR JUNO always together with 100 milligrams of ritonavir or 150 milligrams of cobicistat.
- Take DARUNAVIR JUNO 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 DARUNAVIR JUNO 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 DARUNAVIR JUNO tablets and how much ritonavir (capsules or solution) your child should take.

If your child feels better, do not stop administering DARUNAVIR JUNO without talking to the child's doctor.

Instructions:

- Take DARUNAVIR JUNO always together with ritonavir.
- Take DARUNAVIR JUNO 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 DARUNAVIR JUNO 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 counterclockwise.
- Remove the unscrewed cap.



What do I do if I forget to take Darunavir Juno?

If you forget to take DARUNAVIR JUNO and your dosing regimen is DARUNAVIR JUNO 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. Do not take a double dose to make up for a forgotten dose.

If you forget to take DARUNAVIR JUNO and your

dosing regimen is DARUNAVIR JUNO 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. 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 DARUNAVIR JUNO and ritonavir or cobicistat.

What do I do if I take too much (overdose)?

If you think you or anybody else has taken too much DARUNAVIR JUNO, contact your doctor, pharmacist or the Poisons Information Centre who will advise you what to do.

You can contact the Poisons Information Centre by dialling:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766.

While you are taking Darunavir Juno

Things you must do:

Do not stop taking DARUNAVIR JUNO without talking to your doctor first.

HIV therapy may increase your sense of wellbeing. Even when you feel better, do not stop taking DARUNAVIR JUNO. Talk to your doctor first.

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.

Ask your doctor or pharmacist if you have any questions.

Tell any other doctors and pharmacists who are treating you that you are taking DARUNAVIR JUNO. If you are undergoing anaesthesia, tell your anaesthetist that you are taking DARUNAVIR JUNO.

If you are about to be started on any new medicines, tell your doctor or pharmacist that you are taking DARUNAVIR JUNO.

If you become pregnant while taking DARUNAVIR JUNO, tell your doctor immediately. You must not take DARUNAVIR JUNO with cobicistat if you are pregnant or breastfeeding.

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

Things to be careful of

Driving and using machines

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

Side Effects

Like all medicines, DARUNAVIR JUNO can have side effects. Some of these effects may be serious.

Tell your doctor or pharmacist if you do not feel well while you are being treated with DARUNAVIR JUNO.

When treating HIV infection, it is not always easy to identify what side effects are caused by DARUNAVIR JUNO, which are caused by other medicines you are taking, or which are caused by the HIV infection itself.

The most common side effects are:

- nausea, vomiting
- headache
- abdominal pain, diarrhoea,
- rash (see information below)

- changes in body fat (see information below)
- weakness or lack of energy
- feeling tired.

DARUNAVIR JUNO 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 problems that may occasionally be severe have been reported. Your doctor should do blood tests prior to initiating DARUNAVIR JUNO. 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 coloured) urine, pale coloured 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% of patients receiving DARUNAVIR JUNO. Occasionally a rash can be severe or potentially life threatening. In patients taking DARUNAVIR JUNO 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 DARUNAVIR JUNO must be stopped.

Tell your doctor if you experience the following side effects:

- inflammation of the pancreas
- increased blood fat levels
- diabetes
- symptoms of infection
- changes in body fat

- kidney stones, difficult or painful urination, blood in the urine.

Some side effects are typical for anti-HIV medicines in the same family as DARUNAVIR JUNO. These are:

- raised blood sugar and worsening of diabetes.
- 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 DARUNAVIR JUNO. 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 occur many months after the start of treatment.
- increased bleeding in patients with haemophilia.
- muscle pain, tenderness or weakness. On rare occasions, these muscle disorders have been serious.

If you experience any of these side effects and they worry you, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Tell your doctor if you notice signs or symptoms of infections, such as a fever or rashes. Some people with HIV who have had infections in the past may experience a return of symptoms soon after taking anti-HIV medicines.

If you think you are having an allergic reaction to DARUNAVIR JUNO, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

Symptoms usually include some or all of the following:

- rash, itching or hives on the skin
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

Other side effects not listed above may also occur in some people.

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

Product description

Storage

DARUNAVIR JUNO tablets should be kept out of reach of children, in a location where the temperature stays below 25°C.

What it looks like

DARUNAVIR JUNO 600 mg film-coated tablets are beige-colored, oval shaped, biconvex, film coated tablets, debossed with “D” on one side and “600” on the other side. Each carton contains 60 tablets (2 x plastic bottles of 30 tablets).

DARUNAVIR JUNO 800 mg film-coated tablets are brown colored, oval shaped, biconvex, film-coated tablets, debossed with “D” on one side and “800” on the other side. Each plastic bottle contains 30 tablets.

Ingredients

Active ingredient:

- darunavir 400 mg, 600 mg or 800 mg

Other ingredients:

- silicified microcrystalline cellulose
- colloidal anhydrous silica
- crospovidone
- magnesium stearate
- sodium chloride
- hypromellose

- polacrillin potassium

Coating composition

- polyvinyl alcohol
- macrogol (1521)
- titanium dioxide (E171)
- talc
- [400 mg & 600 mg tablets] Iron oxide yellow (E172) and iron oxide red (E172).
- [800 mg tablets] Iron oxide red (E172).

Sponsor

Juno Pharmaceuticals Pty Ltd
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VIC - 3121
Australia

Australian Registration Numbers

DARUNAVIR JUNO 400 mg:
318764

DARUNAVIR JUNO 600 mg:
318765:

DARUNAVIR JUNO 800
mg:318766

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