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## PATIENT INFORMATION

### DARUNAVIR (dar-UE-na-vir) TABLETS Rx only

Read this Patient Information before you start taking darunavir and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Also read the Patient Information leaflet for ritonavir.

#### What is the most important information I should know about Darunavir?

- **Ask your healthcare provider or pharmacist about medicines that should not be taken with darunavir. For more information, see “Who should not take darunavir?” and “What should I tell my healthcare provider before taking darunavir?”**
- **Darunavir may cause liver problems.** Some people taking darunavir in combination with ritonavir have developed liver problems, which may be life-threatening. Your healthcare provider should do blood tests before and during your darunavir and ritonavir combination treatment. If you have chronic hepatitis B or C infection, your healthcare provider should check your blood tests more often because you have an increased chance of developing liver problems. Tell your healthcare provider if you have any of the below signs and symptoms of liver problems.
  - dark (tea colored) urine
  - yellowing of your skin or whites of your eyes
  - pale colored stools (bowel movements)
  - nausea
  - vomiting
  - pain or tenderness on your right side below your ribs
  - loss of appetite
  - tiredness
- **Darunavir may cause severe or life-threatening skin reactions or rash.** Sometimes these skin reactions and skin rashes can become severe and require treatment in a hospital. Tell your healthcare provider right away if you develop a rash. **Stop** taking darunavir and ritonavir combination treatment and tell your healthcare provider right away if you have any skin changes with symptoms below:
  - fever
  - tiredness
  - muscle or joint pain
  - blisters or skin lesions
  - mouth sores or ulcers
  - red or inflamed eyes, like “pink eye” (conjunctivitis)

Rash occurred more often in people taking darunavir and raltegravir together than with either drug separately but was generally mild.

See “**What are the possible side effects of darunavir?**” for more information about side effects.

### **What is darunavir?**

Darunavir is a prescription HIV-1 (Human Immunodeficiency Virus-type 1) medicine used with ritonavir and other antiretroviral medicines to treat HIV-1 infection in adults and children 3 years of age and older. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

Darunavir should not be used in children under 3 years of age.

When used with other antiretroviral medicines to treat HIV-1 infection, darunavir may help:

- reduce the amount of HIV-1 in your blood. This is called “viral load”.
- increase the number of CD4+ (T) cells in your blood that help fight off other infections.

Reducing the amount of HIV-1 and increasing the CD4+ (T) cells in your blood may improve your immune system. This may reduce your risk of death or getting infections that can happen when your immune system is weak (opportunistic infections).

**Darunavir does not cure HIV-1 infection or AIDS.** You must keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses.

### **Avoid doing things that can spread HIV-1 infection to others:**

- Do not share or re-use needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.
- Do not have any kind of sex without protection. Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

Ask your healthcare provider if you have any questions on how to prevent passing HIV to other people.

### **Who should not take darunavir?**

**Do not take darunavir** with any medicine that contains:

- alfuzosin
- colchicine, if you have liver or kidney problems
- dronedarone
- elbasvir and grazoprevir
- ergot-containing medicines:
  - dihydroergotamine
  - ergotamine tartrate
  - methylergonovine
- ivabradine
- lomitapide
- lovastatin
- lurasidone
- midazolam, when taken by mouth
- naloxegol

- pimozone
- ranolazine
- rifampin
- sildenafil, when used for the treatment of pulmonary arterial hypertension (PAH)
- simvastatin
- St. John's wort (*Hypericum perforatum*)
- triazolam

Serious problems can happen if you or your child take any of these medicines with darunavir. This is not a complete list of medicines. Therefore, tell your healthcare provider about **all** medicines you take.

### **What should I tell my healthcare provider before taking darunavir?**

#### **Before taking darunavir, tell your healthcare provider if you:**

- have liver problems, including hepatitis B or hepatitis C
- are allergic to sulfa medicines
- have high blood sugar (diabetes)
- have hemophilia
- have any other medical conditions
- are pregnant or plan to become pregnant. Tell your healthcare provider if you become pregnant while taking darunavir.
  - **Pregnancy Registry:** There is a pregnancy registry for women who take antiretroviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.
- are breastfeeding or plan to breastfeed. Do not breastfeed if you take darunavir.
  - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
  - It is not known if darunavir can pass into your breast milk.
  - Talk to your healthcare provider about the best way to feed your baby.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, topical creams, vitamins, and herbal supplements. Some medicines interact with darunavir. **Keep a list of your medicines to show your healthcare provider and pharmacist.**

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with darunavir.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take darunavir with other medicines.

### **How should I take Darunavir Tablets?**

- Take darunavir tablets exactly as your healthcare provider tells you.
- You must take ritonavir at the same time as darunavir.

- Do not change your dose or stop treatment with darunavir without talking to your healthcare provider.
- Take darunavir and ritonavir with food.
- If you have difficulty swallowing darunavir tablets, darunavir oral suspension is also available. Your healthcare provider will help decide whether darunavir tablets or oral suspension is right for you.
- If your child is taking darunavir, your child’s healthcare provider will decide the right dose based on your child’s weight. Your child’s healthcare provider will tell you how much darunavir (tablets or oral suspension) and how much ritonavir (capsules, tablets or solution) your child should take. Your child should take darunavir with ritonavir with food. If your child does not tolerate ritonavir oral solution, ask your child’s healthcare provider for advice.
- It is important that you do not miss or skip doses of darunavir during treatment.
- If you take too much darunavir, call your healthcare provider or go to the nearest hospital emergency room right away.

**What are the possible side effects of darunavir?**

Darunavir may cause serious side effects, including:

- See “**What is the most important information I should know about darunavir?**”
- **Diabetes and high blood sugar (hyperglycemia).** Some people who take protease inhibitors including darunavir can get high blood sugar, develop diabetes, or your diabetes can get worse. Tell your healthcare provider if you notice an increase in thirst or urinate often while taking darunavir.
- **Changes in body fat** can happen in people who take HIV-1 medicines. The changes may include an increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these conditions are not known.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you start having new symptoms after starting your HIV-1 medicine.
- **Increased bleeding for hemophiliacs.** Some people with hemophilia have increased bleeding with protease inhibitors including darunavir.

The most common side effects of darunavir include:

- |            |                                 |
|------------|---------------------------------|
| • diarrhea | • headache                      |
| • nausea   | • stomach-area (abdominal) pain |
| • rash     | • vomiting                      |

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of darunavir.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### **How should I store Darunavir Tablets?**

- Store Darunavir Tablets at room temperature 77°F (25°C).

### **Keep darunavir tablets and all medicines out of the reach of children.**

### **General information about the safe and effective use of Darunavir Tablets.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use darunavir for a condition for which it was not prescribed. Do not give darunavir to other people even if they have the same condition you have. It may harm them.

This leaflet summarizes the most important information about darunavir. If you would like more information, talk to your healthcare provider. You can ask your healthcare provider or pharmacist for information about darunavir that is written for health professionals. For more information, call 1-800-399-2561 or visit [www.lupinpharmaceuticals.com](http://www.lupinpharmaceuticals.com).

### **What are the ingredients in Darunavir Tablets?**

Active ingredient: darunavir

Inactive ingredients:

**Darunavir Tablets, 600 mg:** colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose, and the film-coating contains FD & C yellow #6/sunset yellow FCF aluminium lake, polyethylene glycol 3350, polyvinyl alcohol-part hydrolyzed, talc and titanium dioxide.

**Darunavir Tablets, 800 mg:** colloidal silicon dioxide, crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, and the film-coating contains iron oxide red, polyethylene glycol 3350, polyvinyl alcohol-part hydrolyzed, talc and titanium dioxide.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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