



Darunavir and Ritonavir Tablets 800mg/100mg

MODULE – 1

1.5. Product Information

1.5.3 PATIENT INFORMATION LEAFLET (PIL)



Darunavir and Ritonavir Tablets 800mg/100mg

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

What is in this leaflet

1. What Darunavir and Ritonavir Tablets is and what it is used for
2. Before you take Darunavir and Ritonavir Tablets
3. How to take Darunavir and Ritonavir Tablets
4. Possible side effects
5. How to store Darunavir and Ritonavir Tablets
6. Further information.

a) What Darunavir Tablets is and what it is used for

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.

- Ritonavir tablets and oral solution are prescription medicines that are used with other antiviral medicines to treat people with human immunodeficiency virus (HIV-1) infection.

HIV-1 is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

2. What you need to know before you take Darunavir and Ritonavir Tablets

Before taking Darunavir

- Have liver problems, including hepatitis B or hepatitis C
- Are allergic to sulfa medicines
- Have high blood sugar (diabetes)
- Have haemophilia
- 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 breast feed. 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, 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.

Do not take Darunavir with any medicine that contains:

- Alfuzosin
- Cisapride
- 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
- Pimozide



Module 1

- 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.

Before taking Ritonavir

- Have liver problems, including Hepatitis B or Hepatitis C
- Have heart problems
- Have high blood sugar (diabetes)
- Have bleeding problems or hemophilia
- Are pregnant or plan to become pregnant.
 - Ritonavir oral solution contains alcohol. You should not take Ritonavir oral solution during pregnancy because there is no known safe level of alcohol exposure during pregnancy. Tell your healthcare provider if you become pregnant during treatment with Ritonavir.
 - Ritonavir may reduce how well hormonal birth control works. Females who may become pregnant should use another effective form of birth control or an additional barrier method of birth control during treatment with Ritonavir.
 - **Pregnancy Registry:** There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of the 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 breast feed. **Do not breastfeed if you take Ritonavir.**
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
 - Ritonavir may 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, vitamins, and herbal supplements. Some medicines interact with Ritonavir.

Keep a list of your medicines to show our healthcare provider and pharmacist.

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

Do not take Ritonavir if you or your child:

- Are allergic to ritonavir or any of the ingredients in Ritonavir. See the end of this leaflet for a complete list of ingredients in Ritonavir.
- If you take any of the following medicines:
 - Alfuzosin
 - Apalutamide
 - Ranolazine
 - Dronedarone
 - Colchicine, if you have kidney or liver problems.
 - Lurasidone
 - Pimozide
 - Amiodarone
 - Ergot-containing medicines including:
 - Dihydroergotamine mesylate
 - Ergotamine tartrate
 - Methylergonovine maleate
 - Cisapride
 - Flecainide
 - Lovastatin
 - Simvastatin
 - Lomitapide



- Sildenafil (REVATIO®) only when used for treating the lung problem, pulmonary arterial hypertension (PAH)
- Triazolam
- Midazolam when taken by mouth
- Propafenone
- Quinidine
- St. John's Wort (*Hypericum perforatum*) or a product that contains St. John's wort
- voriconazole if your Ritonavir dose is 400 mg every 12 hours or greater.

Serious problems can happen if you or your child takes any of these medicines with Ritonavir.

3. How To Take Darunavir And Ritonavir Tablets

- Take Darunavir 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.
- Darunavir oral suspension should be given with the supplied oral dosing syringe. Shake the suspension well before each use.
- 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.



How should I take Ritonavir

- Take Ritonavir exactly as your healthcare provider tells you to take it.
- You should stay under a healthcare provider's care during treatment with Ritonavir. Do not change your dose of Ritonavir or stop your treatment without talking with your healthcare provider first.
- If your child is taking Ritonavir, your child's healthcare provider will decide the right dose based on your child's height and weight. Tell your healthcare provider if your child's weight changes. If your child does not tolerate Ritonavir oral solution or Ritonavir oral powder, ask your child's healthcare provider for advice.
- Swallow Ritonavir tablets whole. Do not chew, break, or crush tablets before swallowing. If you cannot swallow Ritonavir tablets whole, tell your healthcare provider. You may need a different medicine.
- Take Ritonavir with meals.

4. Possible side effects

Darunavir may cause serious side effects, including:

- **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:

<ul style="list-style-type: none"> • Diarrhea • Nausea • Rash 	<ul style="list-style-type: none"> • Headache • Stomach-area (abdominal) pain • Vomiting
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Ritonavir can cause serious side effects including:

Liver problems. Some people taking Ritonavir in combination with other antiviral medicines have developed liver problems which may be life-threatening. Your healthcare provider should do regular blood tests during your combination treatment with Ritonavir. 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 right away if you get any of the following signs and symptoms of liver problems:

<ul style="list-style-type: none"> • Loss of appetite • Pain or tenderness on your right side below your ribs 	<ul style="list-style-type: none"> • Yellowing of your skin or whites of your eyes • Itchy skin
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- **Inflammation of your pancreas (pancreatitis).** Ritonavir can cause serious pancreas problems, which may lead to death. Tell your healthcare provider right away if you have signs or symptoms of pancreatitis such as:

<ul style="list-style-type: none"> • Nausea • Stomach (abdomen) pain 	<ul style="list-style-type: none"> • Vomiting
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Allergic reactions. Sometimes these allergic reactions can become severe and require treatment in a hospital. Call your healthcare provider right away if you develop a rash. Stop taking Ritonavir and get medical help right away if you have any of the following symptoms of a severe allergic reaction:



<ul style="list-style-type: none"> • Trouble breathing • Wheezing • Dizziness or fainting • Throat tightness or hoarseness • Fast heartbeat or pounding in your chest (tachycardia) 	<ul style="list-style-type: none"> • Sweating • Swelling of your face, lips or tongue • Muscle or joint pain • Blisters or skin lesions • Mouth sores or ulcers
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Changes in the electrical activity of your heart called PR prolongation. PR prolongation can cause irregular heartbeats. Tell your healthcare provider right away if you have symptoms such as:

<ul style="list-style-type: none"> • Dizziness • Lightheadedness 	<ul style="list-style-type: none"> • Feel faint or pass out • Abnormal heart beat
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- **Increase in cholesterol and triglyceride levels.** Treatment with Ritonavir may increase your blood levels of cholesterol and triglycerides. Your healthcare provider should do blood tests before you start your treatment with Ritonavir and regularly to check for an increase in your cholesterol and triglycerides levels.
- **Diabetes and high blood sugar (hyperglycemia).** Some people who take protease inhibitors including Ritonavir 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 during treatment with Ritonavir.
- **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. Call your healthcare provider right away if you start having new symptoms after starting your HIV-1 medicine.
- **Change in body fat** can happen in some people who taking HIV-1 medicines. These changes may include an increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the middle part 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.

- **Increased bleeding for hemophiliacs.** Some people with hemophilia have increased bleeding with protease inhibitors including RITONAVIR.
- **Kidney stones**

The most common side effects of Ritonavir include:

<ul style="list-style-type: none">• Diarrhea• Nausea• Vomiting• upper and lower stomach (abdominal) pain	<ul style="list-style-type: none">• Tingling feeling or numbness in hands or feet or around the lips• Rash• Feeling weak or tired
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5. How to store Darunavir tablets.

Store below 30°C and protect from moisture

6. Further information

Contents Of The Pack And Other Information:

What Darunavir and Ritonavir Tablets 800/100 mg contains

Each Film coated tablets contains 867.28 mg of Darunavir Ethanolate equivalent to 800 mg of Darunavir and Ritonavir USP 100 mg

Crospovidone, Hypromellose 5 cps, Silicified microcrystalline cellulose, Copovidone, Colloidal Silicon Dioxide, Magnesium stearate, Sorbitan monolaurate, Dibasic Calcium phosphate anhydrous, Di basic calcium phosphate dihydrate, Microcrystalline cellulose, Corn starch, Mannitol, Sodium stearyl Fumarate, Opadry Yellow 16C82767, Purified water.

What Darunavir and Ritonavir Tablets looks like and contents of the pack

Darunavir and Ritonavir Tablets 800/100 mg are Yellow, capsule shaped, bevel edged, biconvex film coated tablets debossed with 'H' on one side and 'D24' on the other side.



60's HDPE container with Silica gel & Cotton:

Container: High Density Polyethylene Container 200cc with 38mm Neck (heavy weight)

Closure: Child resistant plastic caps with pulp liners, 38 mm.

Desiccant: Desiccant canister 3.0g silica gel.

180's HDPE container with Silica gel & Cotton:

Container: High Density Polyethylene Container 625cc with 53 mm neck (Heavy weight).

Closure: Child resistant plastic caps with pulp liners 53 mm.

Desiccant: Desiccant canister 3.0g silica gel.

Name and full physical address of Marketing Authorization Holder and Manufacturing site

Manufacturing site

Marketing Authorization Holder and Manufacturer

Marketing Authorisation Holder:

M/s. Hetero Labs Limited,
7-2-A2, Hetero Corporate,
Industrial Estates, Sanath Nagar,
Hyderabad-500 018, Telangana.

Manufactured by:

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