

ZADURNA (Darunavir/Ritonavir Film-coated Tablets 400 mg/50 mg)

Darunavir 400 mg and Ritonavir 50 mg

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What ZADURNA Tablets used for

Darunavir and ritonavir tablets is a prescription HIV-1 (Human Immunodeficiency Virus-type 1) medicine used with other antiretroviral medicines to treat HIV-1 infection in adults and children weighing at least 40 kg (88 pounds).

How ZADURNA works

When used with other antiretroviral medicines to treat HIV-1 infection, darunavir and ritonavir 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.

Darunavir and ritonavir tablets 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.

Before you use ZADURNA Tablets

Do not take darunavir and ritonavir tablets with any medicine that contains:

- alfuzosin
- apalutamide
- 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
- 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 and ritonavir tablets. This is not a complete list of medicines. Therefore, tell your healthcare provider about all medicines you take.

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 and ritonavir tablets.
- are breastfeeding or plan to breastfeed. Darunavir and ritonavir may pass into your breast milk. Talk to your healthcare provider about the following risks to your baby from breastfeeding during or after treatment with darunavir and ritonavir tablets:
 - the HIV-1 virus may pass to your baby if your baby does not have HIV-1 infection.
 - the HIV-1 virus may become harder to treat if your baby has HIV-1 infection.
 - your baby may get side effects from darunavir and ritonavir tablets.

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 and ritonavir tablets. **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 and ritonavir tablets.
- **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 and ritonavir tablets with other medicines

How to use ZADURNA Tablets

- Take darunavir and ritonavir tablets exactly as your healthcare provider tells you.
- Do not change your dose or stop treatment with darunavir and ritonavir tablets without talking to your healthcare provider.
- Swallow darunavir and ritonavir tablets whole. Do not chew, break, or crush darunavir and ritonavir tablets.
- Take darunavir and ritonavir tablets with food.
- It is important that you do not miss or skip doses of darunavir and ritonavir tablets during treatment.
- If you take too much darunavir and ritonavir tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

While you are using it

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.

What are the possible side effects of

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darunavir and ritonavir tablets?

Darunavir and ritonavir tablets may cause serious side effects, including:

- **Inflammation of your pancreas (pancreatitis).** Ritonavir, a component of darunavir and ritonavir tablets, 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:
 - o nausea
 - o vomiting
 - o stomach (abdomen) pain
- **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:
 - o dizziness
 - o lightheadedness
 - o feel faint or pass out
 - o abnormal heart beat
- **Diabetes and high blood sugar (hyperglycemia).** Some people who take protease inhibitors including darunavir and ritonavir, components of darunavir and ritonavir tablets, 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 and ritonavir tablets.
- **Increase in cholesterol and triglyceride levels.** Treatment with ritonavir, a component of darunavir and ritonavir tablets, may increase your blood levels of cholesterol and triglycerides. Your healthcare provider should do blood tests before you start your treatment with darunavir and ritonavir tablets and regularly to check for an increase in your cholesterol and triglycerides levels.
- **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 and ritonavir tablets.
- **Kidney stones**

The most common side effects of darunavir and ritonavir tablets 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 and ritonavir tablets.

Call your doctor for medical advice about side effects

- Things to be careful of

Darunavir and ritonavir tablets 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 tablets 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
- vomiting
- yellowing of your skin or

whites of your eyes

- pain or tenderness on your right side below your ribs
- pale colored stools (bowel movements)
- loss of appetite
- nausea
- tiredness

Darunavir and ritonavir tablets 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 tablets and tell your healthcare provider right away if you have any skin changes with symptoms below:

- fever
- blisters or skin lesions
- tiredness
- mouth sores or ulcers
- muscle or joint pain
- red or inflamed eyes, like "pink eye" (conjunctivitis) Rash occurred more often in people taking darunavir and ritonavir tablets and raltegravir together than with either drug separately, but was generally mild.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers --> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of ZADURNA

Storage

- Store darunavir and ritonavir tablets below 30°F (86°C). Protect from light.
- Keep darunavir and ritonavir tablets in the original container.
- Keep the bottle tightly closed. The bottle contains a desiccant that helps to keep the tablets dry. Do not remove desiccant.

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- Use darunavir and ritonavir tablets by the expiration date.

Disposal:

Medicines should not be disposed of through sewage or household waste. Please consult your pharmacist about the correct way to dispose of medicines that are no longer needed. These measures can help protect the environment.

Product Description

What it looks like

A light yellow film-coated, ovaloid, biconvex, beveled edge tablet debossed with “M” on one side of the tablet and “DRL” on the other side.

Ingredients

darunavir and ritonavir

Inactive ingredients

Microcrystalline Cellulose, Crospovidone, Copovidone, Colloidal Silicon Dioxide, Ferric Oxide Yellow, Sodium Stearyl Fumarate, Sorbitan Monolaurate, Sodium Chloride, Hypromellose, Titanium Dioxide, Macrogols, Talc, Hydroxypropyl Cellulose, Polysorbate 80, Colloidal anhydrous silica, Iron Oxide Yellow, Iron Oxide Red

- MALnumber: MALXXXXAZ

Manufacturer

Mylan Laboratories Limited
F-4 & F-12, MIDC, Malegaon, Sinnar,
Nashik - 422 113, Maharashtra, INDIA

Product Registration Holder

NVS Regulatory Services Sdn Bhd,
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