

PATIENT INFORMATION

Ritonavir Tablets USP (ri ton' na vir) Rx only

What is the most important information I should know about ritonavir?

- Ritonavir can interact with other medicines and cause serious side effects. It is important to know the medicines that should not be taken with ritonavir. See the section "Who should not take ritonavir?"

What is ritonavir?

- Ritonavir tablets are a prescription medicine that is 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).

Do not take ritonavir if you or your child:

- are allergic to ritonavir or any of the ingredients in ritonavir tablets. See the end of this leaflet for a complete list of ingredients in ritonavir tablets.
- If you take any of the following medicines:
 - alfuzosin
 - apalutamide
 - ranolazine
 - dronedarone
 - colchicine, if you have kidney or liver problems.
 - lurasidone
 - pimozone
 - 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 Tablets.

Before taking ritonavir, tell your healthcare provider about all of your medical conditions, including if you or your child:

- 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 oral solution.
 - 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 breastfeed. **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 breastmilk.
 - 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 your 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.

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.
- Do not run out of ritonavir. Get your ritonavir prescription refilled from your healthcare provider or pharmacy before you run out.
- If you miss a dose of ritonavir, take it as soon as possible and then take your next scheduled dose at its regular time. If it is almost time for your next dose, wait and take the next dose at the regular time. Do not double the next dose.
- If you take too much ritonavir, call your local poison control center or go to the nearest hospital emergency room right away.

What are the possible side effects of ritonavir?

Ritonavir can cause serious side effects including:

- See "What is the most important information I should know about ritonavir?"
- **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:
 - loss of appetite
 - yellowing of your skin or whites of your eyes

- pain or tenderness on your right side below your ribs
- itchy skin
- **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:
 - nausea
 - vomiting
 - stomach (abdomen) pain
- **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 Tablets and get medical help right away if you have any of the following symptoms of a severe allergic reaction:
 - trouble breathing
 - sweating
 - wheezing
 - swelling of your face, lips or tongue
 - dizziness or fainting
 - muscle or joint pain
 - throat tightness or hoarseness
 - blisters or skin lesions
 - fast heartbeat or pounding in your chest (tachycardia)
 - mouth sores or ulcers

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:

- dizziness
- lightheadedness
- feel faint or pass out
- abnormal heart beat
- **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:

- diarrhea
- nausea
- vomiting
- upper and lower stomach (abdominal) pain
- tingling feeling or numbness in hands or feet or around the lips
- rash
- feeling weak or tired

Ritonavir oral solution contains a large amount of alcohol. If a toddler or young child accidentally drinks more than the recommended dose of ritonavir oral solution, it could make him/her sick from too much alcohol. Go to the nearest emergency room right away if this happens.

These are not all of the possible side effects of ritonavir. 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 Ritonavir Tablets USP?

- Store Ritonavir Tablets USP in the original container given to you by the pharmacist.
- Use Ritonavir Tablets USP by the expiration date.

Store Ritonavir Tablets USP:

- Store below 30°C (86°F). Exposure to temperatures up to 50°C (122°F) for seven days permitted.
- Exposure to high humidity outside the original container for longer than 2 weeks is not recommended.

Keep Ritonavir Tablets and all medicines out of the reach of children.

General information about the safe and effective use of ritonavir

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet.

Do not use ritonavir for a condition for which it was not prescribed. Do not give ritonavir to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ritonavir that is written for healthcare professionals.

What are the ingredients in Ritonavir Tablets USP?

Active ingredient: ritonavir USP

Inactive ingredients: anhydrous dibasic calcium phosphate, colloidal silicon dioxide, copovidone, hypromellose, isopropyl alcohol, polysorbate 80, polyethylene glycol, purified water, sodium stearyl fumarate, sorbitan monolaurate and titanium dioxide.

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

Manufactured by:

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Revised September 2022