



# ritonavir (Norvir)

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## WHAT IS RITONAVIR?

Ritonavir, also known as RTV (brand name Norvir), is a drug used as part of [antiretroviral therapy \(ART\)](#). The FDA approved ritonavir in 1996 as an [antiretroviral drug \(ARV\)](#) for people with HIV infection. Generic versions have been approved under [PEPFAR](#). Ritonavir is manufactured by [AbbVie Inc.](#)

Ritonavir is a type of drug called a [protease inhibitor \(PI\)](#). PIs block protease (an HIV enzyme). By blocking protease, PIs prevent new (immature) HIV from becoming a mature virus that can infect other cells.

Although ritonavir is technically a PI, it is rarely used as a PI anymore. Due to frequent and severe side effects, it is difficult for people to tolerate at the full dosage required to inhibit HIV. However, ritonavir is frequently used to increase (boost) blood levels of other HIV medications, including other PIs and the integrase inhibitor [elvitegravir \(Vitekta\)](#). This is similar to the mechanism of action of the [pharmacokinetic enhancer cobicistat \(Tybost\)](#). The dose used for boosting is much smaller than the full anti-HIV dose and causes fewer side effects.

When used in combination with other ARVs to treat HIV infection, ritonavir may help:

- Reduce the amount of HIV in your blood. This is called [viral load](#).
- Increase the number of [CD4 cells](#) in your blood that help fight off other infections.

Reducing the amount of HIV and increasing CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting [opportunistic infections \(OIs\)](#) that can happen when your immune system is weak. [Read more about viral suppression.](#)

Ritonavir [does not cure](#) HIV infection or [AIDS](#). You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

## WHO SHOULD TAKE RITONAVIR?

Ritonavir is a prescription HIV medicine used in combination with other ARVs to treat HIV infection in adults and children 1 month of age and older. The safety and effectiveness of ritonavir has not been established in children under 1 month of age. Ritonavir has not been carefully studied in the elderly (65 years of age and older).

All people with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. [Read more about U.S. ART guidelines.](#)

## WHO SHOULD NOT TAKE RITONAVIR?

Do not take ritonavir if you are allergic to ritonavir or any of the ingredients in this drug.

Do not take ritonavir if you are taking any of the following medicines. Taking ritonavir with these medicines may affect how ritonavir works. Ritonavir may cause serious or life-threatening side effects or death when used with these medicines:

- Alpha 1-adrenoreceptor antagonist: alfuzosin
- [Cancer](#) medicine: apalutamide
- Anti-fungal medicines: voriconazole (if ritonavir dose is 400 mg every 12 hours or greater)
- Anti-gout medicine: colchicine (if you have liver or kidney problems)
- Anti-psychotic medicines: lurasidone, pimozide
- Benzodiazepines: midazolam (when taken by mouth), triazolam
- Cholesterol medicines: lomitapide, lovastatin, simvastatin
- Ergot-containing medicines: dihydroergotamine mesylate, ergotamine tartrate, methylergonovine maleate
- Heart medicines: amiodarone, dronedarone, flecainide, propafenone, quinidine, ranolazine
- Heartburn and reflux medicines: cisapride
- Herbal product: St. John's Wort (*Hypericum perforatum*)
- PDE-5 inhibitor: sildenafil (when used for the treatment of pulmonary arterial hypertension [PAH])

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. If you have taken any of these medicines in the past four weeks, talk to your healthcare provider or pharmacist before starting treatment with ritonavir.

Ritonavir is not recommended in people with severe liver disease.

### **WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING RITONAVIR?**

Before you take ritonavir, tell your healthcare provider about all of your medical conditions, and in particular if you:

- Have liver problems, including [hepatitis B virus \(HBV\)](#) or [hepatitis C virus \(HCV\)](#) infection
- Have [heart problems](#)
- Have [high blood sugar \(diabetes\)](#)
- Have bleeding problems or hemophilia

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with ritonavir. 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.

Ritonavir may reduce how well hormonal birth control works. People who may become pregnant should use another effective form of birth control or an additional barrier method of birth control during treatment with ritonavir.

There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry [Read more about pregnancy and HIV](#).

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with ritonavir. Ritonavir may pass to your baby in your breastmilk. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

### **WHAT ABOUT DRUG RESISTANCE?**

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. [Read more about HIV drug resistance](#).

***Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.***

### **HOW IS RITONAVIR TAKEN?**

Ritonavir is taken by mouth as a tablet, oral solution, or oral powder. The full recommended dosage of ritonavir in adults (when ritonavir is the only PI) is 1,200 mg daily taken as six 100 mg tablets twice daily, in combination with other ARVs. However, ritonavir is almost never used this way anymore. Ritonavir is mostly used to increase the blood levels of other PIs, such as [atazanavir \(Reyataz\)](#) and [darunavir \(Prezista\)](#). Usually, 100-200 mg of ritonavir are taken along with each dose of other ARVs. Be sure you know how much ritonavir your healthcare provider has prescribed for you and when and how to take each dose.

The recommended dosage of ritonavir for children varies based on the child's weight, age, and other medications they are taking. Your healthcare provider will determine the correct dosage.

Ritonavir should be taken at the same time each day with food.

Swallow ritonavir tablets whole. Do not chew, break, or crush tablets before swallowing. If you or your child cannot swallow ritonavir tablets whole, tell your healthcare provider. You may need a different medicine.

**You need to take ritonavir in combination with other ARVs.** Your healthcare provider will tell you what medicines to take and how to take them.

### **WHAT ARE THE SIDE EFFECTS?**

When you start any ARV, you may have temporary [side effects](#) such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of ritonavir are [diarrhea](#), nausea, vomiting, upper and lower stomach (abdominal) pain, [tingling or numbness in the hands, feet, or lips](#), rash, and [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, it could make them sick from too much alcohol. Go to the nearest emergency room right away if this happens.

Ritonavir can cause serious side effects including:

**Liver problems.** Some people taking ritonavir in combination with other ARVs have developed liver problems which may be life-threatening. Your healthcare provider should do regular [blood tests](#) before and during your combination treatment with ritonavir.

If you have chronic HBV or HCV 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 following signs and symptoms of liver problems.

- Loss of appetite
- Pain or tenderness on your right side below your ribs
- Yellowing of your skin or whites of your eyes
- 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
- Stomach (abdomen) pain
- Vomiting

**Allergic reactions.** Sometimes these allergic reactions can become severe and require treatment in a hospital. Tell 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:

- Trouble breathing
- Wheezing
- Dizziness or fainting
- Throat tightness or hoarseness
- Fast heartbeat or pounding in your chest (tachycardia)
- Sweating
- Swelling of your face, lips, or tongue
- Muscle or joint pain
- Blisters or skin lesions
- 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 heartbeat

**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.

**Immune Reconstitution Inflammatory Syndrome (IRIS).** [IRIS](#) is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting ritonavir.

**Changes in body fat.** [Changes in body fat distribution or accumulation](#) have happened in some people taking HIV medicines, including an increased amount of fat in the upper back and neck (buffalo hump), in the breasts, and around the trunk. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these body fat changes are not known.

**Increased bleeding for hemophiliacs.** Some people with hemophilia have increased bleeding with protease inhibitors including ritonavir.

### **Kidney stones.**

These are not all the possible side effects of ritonavir. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### **HOW DOES RITONAVIR REACT WITH OTHER DRUGS?**

All ARVs can [interact](#) with other drugs or supplements you are taking. These interactions can change the amount of each drug in

your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take ritonavir with other medicines.

See above for a list of medicines that should not be taken with ritonavir.

#### ***MORE INFORMATION***

Visit the [Norvir website](#).

Download the full [Prescribing Information](#), including Patient Information and Instructions for Use.

Apply for the [AbbVie Patient Assistance Program](#).

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