Patient Frequently Asked Questions

Helpful information about the new NORVIR® 100 mg Tablets







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NORVIR® (ritonavir) is in a class of medicines called the HIV protease (PRO-tee-ase) inhibitors. NORVIR is used in combination with other anti-HIV medicines to treat people with human immunodeficiency virus (HIV) infection. NORVIR is for adults and for children age greater than 1 month and older.

NORVIR does not cure HIV infection or AIDS and does not reduce the risk of passing HIV to others. People taking NORVIR may still get opportunistic infections or other conditions that happen with HIV infection. Some of these conditions are pneumonia, herpes virus infections, and *Mycobacterium avium* complex (MAC) infections.

Safety Considerations

Do not take NORVIR with certain medicines, as these can cause serious or life-threatening problems such as irregular heartbeat, breathing difficulties, or excessive sleepiness. Do not take NORVIR if you have had a serious allergic reaction to any of its ingredients. Some patients taking NORVIR may develop liver and pancreas problems, which can cause death. Patients may develop large increases in triglycerides and cholesterol, diabetes, high blood sugar, changes in body fat, increased bleeding in people with hemophilia, allergic reactions, and/or changes in heart rhythm. You may develop signs and symptoms of infections that you already have after starting anti-HIV medicines. Please see the Important Safety Information for more details.

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When will the new NORVIR tablets be available?	The new NORVIR tablets are available now.
Do the new NORVIR tablets contain the same medicine as the NORVIR soft gelatin capsules?	Yes, the new NORVIR tablet contains the same medicine as the NORVIR soft gelatin capsules. There is 100 mg of ritonavir in both the new NORVIR tablet and the NORVIR soft gelatin capsule. Patients who take the 600 mg twice daily soft gelatin capsule NORVIR dose may experience more gastrointestinal side effects when switching from the soft gel capsule to the tablet formulation. These side effects may diminish as therapy is continued.
How should I take the new NORVIR tablet?	The new NORVIR tablets should be taken every day exactly as prescribed by your doctor. The dose of NORVIR may be different for you than for other patients.
	Follow the directions from your doctor, exactly as written on the label.
	The new NORVIR tablet should be swallowed whole and not chewed, broken, or crushed.
	The new NORVIR tablet must be taken with meals.
What should I do with my current supply of NORVIR capsules?	Talk to your doctor, pharmacist or healthcare provider.
How should I store the new tablets?	The new NORVIR tablets do not need to be refrigerated. You should store the tablets at 68-77°F (room temperature). Exposure of this product to high humidity outside the container it comes in for longer than 2 weeks is not recommended.
Are NORVIR soft gelatin capsules and oral solution still available?	Yes, the NORVIR soft gelatin capsules and oral solution are still available.
Where can I find out more about NORVIR?	You can always ask your doctor, pharmacist or healthcare provider for more information. You may also contact Abbott Medical Information by calling 1-800-633-9110 or visiting www.abbottmedinfo.com.

Please see Use and Important Safety Information, including warning about drug interactions, on page two.

Please visit http://www.rxabbott.com/pdf/norvirtab_pi.pdf to view the full Prescribing Information for NORVIR Tablets and Oral Solution.

Please visit http://www.rxabbott.com/pdf/norpi2a.pdf to view the full Prescribing Information for NORVIR Soft Gelatin Capsules.





Use and Important Safety Information¹

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Important Safety Information

Do not take NORVIR if you have had a serious allergic reaction to NORVIR or any of its ingredients. Allergic reactions ranging from hives, asthma, severe breathing issues and mild to severe skin reactions have occurred.

Drug Interactions:

The below list of drug interactions is not complete. Before you take NORVIR, you must tell your doctor about all the medicines you are taking or are planning to take. These include other prescription and non-prescription medicines and herbal supplements.

Do not take the following medicines with NORVIR because they can cause serious or life-threatening problems such as irregular heartbeat, breathing difficulties or excessive sleepiness: Cordarone® (amiodarone); ergotamine, ergonovine, methylergonovine, and dihydroergotamine such as Cafergot®, Migranal®, D.H.E. 45® and others; Halcion® (triazolam); Orap® (pimozide); Propulsid® (cisapride); quinidine, also known as Quinaglute®, Cardioquin®, Quinidex® and others; Revatio® (sildenafil) only when used for the treatment of pulmonary arterial hypertension; Rythmol® (propafenone); Tambocor® (flecainide); Uroxatral® (alfuzosin hydrochloride); Vascor® (bepridil); Versed® (oral midazolam); and Vfend® (voriconazole).

Do not take NORVIR with St. John's wort (*Hypericum perforatum*) as this may decrease NORVIR levels and lead to increased viral load and possible resistance to NORVIR or other antiretroviral medicines.

Do not take NORVIR with Mevacor® (lovastatin) or Zocor® (simvastatin) because of possible serious reactions. There is an increased risk of drug interactions between NORVIR and Lipitor® (atorvastatin) and Crestor® (rosuvastatin); you should talk to your doctor before you take any of these cholesterol-lowering medicines with NORVIR.

If you are taking Viagra® (sildenafil), Cialis® (tadalafil), or Levitra® (vardenafil) with NORVIR, your doctor may lower your dose of these medicines because you may be at risk of side effects such as low blood pressure, visual changes, and penile erection lasting more than 4 hours. Tell your doctor right away if you experience any of these side effects.

If you are taking oral contraceptives ("the pill") or using the contraceptive patch to prevent pregnancy, you should use a different type of contraception since NORVIR may reduce the effectiveness of oral or patch contraceptives.

If you are taking Mycobutin $\!\!\!^{\text{\tiny{(P)}}}$ (rifabutin), your doctor will lower the dose of Mycobutin.

NORVIR oral solution contains alcohol. Talk with your doctor if you are taking or planning to take Flagyl® (metronidazole) or Antabuse® (disulfiram). Severe nausea and vomiting can occur.

Rifampin, also known as Rimactane®, Rifadin®, Rifater®, or Rifamate®, may reduce blood levels of NORVIR. Be sure to tell your doctor if you are taking rifampin.

Rifampin and saquinavir should not be taken together with NORVIR. Be sure to tell your doctor if you are taking rifampin and saquinavir.

If you are taking or before you begin using inhaled Flonase® (fluticasone propionate), Serevent® (salmeterol), or Advair® (salmeterol in combination with fluticasone propionate), talk to your doctor about problems these medicines may cause when taken with NORVIR. Your doctor may choose not to keep you on inhaled Flonase®, Serevent®, or Advair®.

Side Effects: (This list is not complete):

Blood tests in patients taking NORVIR® (ritonavir) may show possible liver problems. People with liver disease such as hepatitis B and C who take NORVIR may have worsening liver disease. Liver problems, including death, have occurred in people who take NORVIR and in people taking Aptivus® (tipranavir) with NORVIR. Tell your doctor right away if you have any of the following signs and symptoms: loss of appetite, yellowing of skin or eyes (jaundice), dark-colored urine, pale-colored stools, itchy skin and/or stomach area (abdominal) pain.

Pancreas problems (pancreatitis), which may cause death, have been reported in some people taking NORVIR. Tell your doctor if you have nausea, vomiting or abdominal pain as these may be signs of pancreatitis.

Large increases in triglycerides and cholesterol have occurred in some people taking NORVIR. The long-term chance of getting complications such as heart attacks or stroke due to increases in triglycerides and cholesterol caused by protease inhibitors is not known at this time.

Diabetes and high blood sugar (hyperglycemia), changes in body fat, and increased bleeding in people with hemophilia have occurred in some people taking protease inhibitors, including NORVIR. You should tell your doctor if you notice an increase in thirst or urinate often. The cause and long-term effects of body fat changes are not known at this time.

Changes in the electrocardiogram (EKG) can occur when taking NORVIR. Consult your doctor if you experience dizziness, lightheadedness, fainting spells or abnormal heartbeat. People with heart defects or conduction defects should avoid NORVIR.

Immune reconstitution syndrome may occur after starting anti-HIV medicines, including NORVIR. This happens when you develop signs and symptoms of serious infections you already have or had, which may require additional treatment.

The most commonly reported side effects are feeling weak/tired, nausea, vomiting, diarrhea, loss of appetite, abdominal pain, changes in taste, tingling feeling or numbness (in hands or feet or around the lips), headache, and dizziness.

If you are pregnant or planning to become pregnant, it is not known if NORVIR can harm your unborn baby. If you take NORVIR while you are pregnant, talk to your doctor about how you can take part in the Antiretroviral Pregnancy Registry. You should not breast-feed because you may pass HIV on to your baby or your baby could experience side effects from NORVIR.

The long-term effects of NORVIR are not known at this time. This is the most important information you should know about NORVIR. For more information, talk to your doctor.

Reference: 1. Norvir [package insert]. North Chicago, IL: Abbott Laboratories.

Please visit http://www.rxabbott.com/pdf/norvirtab_pi.pdf to view the full Prescribing Information for NORVIR Tablets and Oral Solution.

Please visit http://www.rxabbott.com/pdf/norpi2a.pdf to view the full Prescribing Information for NORVIR Soft Gelatin Capsules.



