

NORVIR (ritonavir oral solution) is an orange-colored liquid, supplied in amber-colored, multi-dose bottles containing 600 mg ritonavir per 7.5 mL marked dosage cup (80 mg/mL) in the following size:

240 mL bottles (NDC 0074-1940-63).

### Recommended Storage

Store NORVIR oral solution at room temperature 68°F to 77°F (20°C to 25°C). Do not refrigerate. Shake well before each use. Use by product expiration date.

Product should be stored and dispensed in the original container.

Avoid exposure to excessive heat. Keep cap tightly closed.

### REFERENCES

1. Sewester CS. Calculations. In: Drug Facts and Comparisons. St. Louis, MO: J.B. Lippincott Co; January, 1997:xix.
2. Bertz RJ and Granneman GR. Use of *in vitro* and *in vivo* data to estimate the likelihood of metabolic pharmacokinetic interactions. *Clin Pharmacokinet* 1997; 32(3):210-258.

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**NORVIR®**

**(ritonavir capsules) Soft Gelatin**

**(ritonavir oral solution)**

**ALERT: Find out about medicines that should NOT be taken with NORVIR. Please also read the section "MEDICINES YOU SHOULD NOT TAKE WITH NORVIR."**

**Patient Information**

**NORVIR® (NOR - VEER)****Generic name: ritonavir (rit-ON-uh-veer)**

Please read this leaflet carefully before you start taking NORVIR. Also, read it each time you get your NORVIR prescription refilled, just in case something has changed.

Remember that this information does not take the place of careful discussions with your doctor when you start this medication and at check ups.

You should remain under a doctor's care when taking NORVIR and you should not change or stop treatment without first talking with your doctor.

You should tell your doctor about any medicine you are taking or planning to take because taking NORVIR with some medications can result in serious or life-threatening problems.

Talk to your doctor if you have any questions about NORVIR. Your doctor or pharmacist can also give you more information about NORVIR.

**What is NORVIR and How Does it work?**

NORVIR 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 > 1 month and older.

HIV infection leads to the destruction of CD<sub>4</sub> (T) cells, which are important to the immune system. After a large number of CD<sub>4</sub> (T) cells have been destroyed, acquired immune deficiency syndrome (AIDS) develops.

NORVIR blocks HIV protease, a chemical which is needed for HIV to multiply. NORVIR reduces the amount of HIV and helps to increase the number of CD<sub>4</sub> (T) cells in your blood. Patients who took NORVIR in clinical studies had significant reductions in both death and AIDS defining diseases; however NORVIR may not have these effects in all patients.

**Does NORVIR Cure HIV or AIDS?**

NORVIR does not cure HIV infection or AIDS. The long-term effects of NORVIR are not known at this time. 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.

## Does NORVIR Reduce the Risk of Passing HIV to Others?

NORVIR does not reduce the risk of passing HIV to others through sexual contact or blood contamination. Continue to practice safe sex and do not use or share dirty needles.

## How Should I Take NORVIR?

- You should stay under a doctor's care when taking NORVIR. Do not change your treatment or stop treatment without first talking with your doctor.
- It is very important that you take NORVIR every day exactly as your doctor prescribed it.
- The usual dose for adults is six 100 mg capsules or 7.5 mL of the oral solution twice a day (morning and night), in combination with other anti-HIV medicines.
- The dosing of NORVIR may be different for you than for other patients. Follow the directions from your doctor, exactly as written on the label.
- Children from > 1 month to 21 years of age can also take NORVIR. The child's doctor will decide the right dose based on the child's height and weight.
- Take NORVIR with food if possible.
- NORVIR Oral Solution is peppermint/caramel flavored. You can take it alone, or may improve the taste by mixing it with 8 ounces of chocolate milk, Ensure®, or Advera®. NORVIR Oral Solution should be taken within 1 hour if mixed with these items. Ask your doctor, nurse or pharmacist about other ways to improve the taste of NORVIR Oral Solution.
- Do not change or stop taking NORVIR without first talking with your health care provider.
- When your NORVIR supply starts to run low, get more from your doctor or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to NORVIR and become harder to treat.
- Be sure to set up a schedule and follow it carefully.
- Only take medicine that has been prescribed specifically for you. Do not give NORVIR to others or take medicine prescribed for someone else.

## What Should I Do if I Miss a Dose of NORVIR?

It is important that you do not miss any doses. If you miss a dose of NORVIR, 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.

### **What Happens If I Take Too Much NORVIR?**

If you think that you took more than the prescribed dose of this medicine, contact your local poison control center or emergency room immediately.

As with all prescription medicines, NORVIR should be kept out of the reach of young children. NORVIR liquid contains a large amount of alcohol. If a toddler or young child accidentally drinks more than the recommended dose of NORVIR, it could make him/her sick from too much alcohol. Contact your local poison control center or emergency room immediately if this happens.

### **Who Should Not Take NORVIR?**

Together with your doctor, you need to decide whether NORVIR is right for you.

- Do not take NORVIR if you are taking certain medicines. These could cause serious side effects that could cause death. 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.

For more information about medicines you should not take with NORVIR, please read the section "MEDICINES YOU SHOULD NOT TAKE WITH NORVIR."

- Do not take NORVIR if you have had a serious allergic reaction to NORVIR or any of its ingredients.

### **Can I Take NORVIR With Other Medications?\***

NORVIR may interact with other medicines, including those you take without a prescription. You must tell your doctor about all the medicines you are taking or are planning to take.

### **MEDICINES YOU SHOULD NOT TAKE WITH NORVIR.**

- *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)
  - Hismanal® (astemizole)
  - Orap® (pimozide)
  - Propulsid® (cisapride)
  - Quinidine, also known as Quinaglute®, Cardioquin®, Quinidex®, and others
  - Rythmol® (propafenone)
  - Seldane® (terfenadine)
  - Tambocor® (flecainide)
  - Uroxatral® (alfuzosin hydrochloride)
  - Vascor® (bepridil)
  - Versed® (midazolam)
  - Vfend® (voriconazole)
- Do not take NORVIR with St. John's wort (*hypericum perforatum*), an herbal product sold as a dietary supplement or products containing St. John's wort. Talk with your doctor if you are taking or are planning to take St. John's wort. Taking St. John's wort may decrease NORVIR levels and lead to increased viral load and possible resistance to NORVIR or cross-resistance to other antiretroviral medicines.
- Do not take NORVIR with the cholesterol-lowering medicines Mevacor® (lovastatin) or Zocor® (simvastatin) because of possible serious reactions. There is also an increased risk of drug interactions between NORVIR and Lipitor® (atorvastatin); talk to your doctor before you take any of these cholesterol-lowering medicines with NORVIR.

## **Medicines That May Require Dosage Adjustments**

It is possible that your doctor may need to increase or decrease the dose of other medicines when you are also taking NORVIR. Remember to tell your doctor all medicines you are taking or plan to take.

- The following medicines require dose reduction if taken with NORVIR:

If you are taking PDE5 inhibitors for erectile dysfunction including Viagra® (sildenafil), Cialis® (tadalafil), or Levitra® (vardenafil), your doctor may lower your dose of these medications.

**Before you take Viagra®, Cialis® or Levitra® with NORVIR, talk to your doctor about possible drug interactions and side effects. If you take these medications with NORVIR you may be at risk of side effects such as low blood pressure, visual changes, and penile erection lasting more than 4 hours. If an erection lasts longer than 4 hours, you should get medical help immediately to avoid permanent damage to your penis. Your doctor can explain these symptoms to you.**

- If you are taking Oral contraceptives ("the pill") or 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® (rifabutin), your doctor will lower the dose of Mycobutin.

**• Other Special Considerations:**

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

**• If you are taking both didanosine (Videx) and NORVIR:**

Didanosine and NORVIR should be separated by at least 2.5 hours.

- 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.
- If you are taking or before you begin using inhaled Flonase® (fluticasone propionate), talk to your doctor about problems these two medicines may cause when taken together. Your doctor may choose not to keep you on inhaled Flonase®.
- Rifampin and saquinavir should not be taken with NORVIR. Be sure to tell your doctor if you are taking rifampin and saquinavir.

**What Are the Possible Side Effects of NORVIR?**

- This list of side effects is **not** complete. If you have questions about side effects, ask your doctor, nurse, or pharmacist. You should report any new or continuing symptoms to your doctor right away. Your doctor may be able to help you manage these side effects.
- 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.
- Blood tests in patients taking NORVIR may show possible liver problems. People with liver disease such as Hepatitis B and Hepatitis C who take NORVIR may have worsening liver disease. Liver problems including rare cases of death have occurred in patients taking NORVIR. It is unclear if NORVIR caused these liver problems because some patients had other illnesses or were taking other medicines.
- Some patients taking NORVIR can develop serious problems with their pancreas (pancreatitis) which may cause death. Tell your doctor if you have nausea, vomiting, or abdominal pain. These may be signs of pancreatitis.
- Some patients have large increases in triglycerides and cholesterol. 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) have occurred in patients taking protease inhibitors. Some patients had diabetes before starting protease inhibitors, others did not. Some patients need changes in their diabetes medication. Others needed new diabetes medication.
- Changes in body fat have been seen in some patients taking antiretroviral therapy. These changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast 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 conditions are not known at this time.
- Some patients with hemophilia have increased bleeding with protease inhibitors.
- Allergic reactions ranging from mild to severe have occurred in patients taking NORVIR.

- Changes in the electrocardiogram (EKG). Consult your physician if you experience dizziness, lightheadedness, fainting spells or abnormal heart beat, Patients with heart defects or conduction defects should avoid NORVIR.

There have been other side effects noted in patients receiving NORVIR; however, these side effects may have been due to other medicines that patients were taking or to the illness itself. Some of these side effects can be serious. If you have questions about side effects, ask your doctor, nurse, or pharmacist. You should report any new or persistent symptoms to your doctor immediately.

### What Should I Tell My Doctor Before Taking NORVIR?

- *If you are pregnant or planning to become pregnant.* The effects of NORVIR on pregnant women or their unborn babies are not known.
- *If you are breast-feeding.* Do not breast-feed if you are taking NORVIR. You should not breast-feed if you have HIV. If you are a woman who has or will have a baby, talk with your doctor about the best way to feed your baby. You should be aware that if your baby does not already have HIV, there is a chance that HIV can be transmitted through breast-feeding.
- *If you have liver problems.* If you have liver problems or are infected with Hepatitis B or Hepatitis C, you should tell your doctor before taking NORVIR.
- *If you have diabetes.* Some people taking protease inhibitors develop new or more serious diabetes or high blood sugar. Be sure to tell your doctor if you have diabetes or an increase in thirst and/or frequent urination.
- *If you have hemophilia.* Some people with hemophilia have had increased bleeding. It is not known whether the protease inhibitors caused these problems. Be sure to tell your doctor if you have hemophilia types A and B.

### How Do I Store NORVIR?

- Keep NORVIR and all other medicines out of the reach of children.
- Store NORVIR Oral Solution at room temperature. Do not refrigerate NORVIR Oral Solution. Avoid exposing NORVIR Oral Solution to excessive heat or cold.
- Refrigeration of NORVIR soft gelatin capsules by the patient is recommended, but not required if used within 30 days and stored below 77°F (25°C). Avoid exposing NORVIR soft gelatin capsules to excessive heat or cold.



- Store NORVIR soft gelatin capsules and NORVIR Oral Solution in the original container.
- Shake NORVIR Oral Solution well before each use.
- Use NORVIR soft gelatin capsules and NORVIR Oral Solution by the expiration date on the bottle.

Do not keep medicine that is out of date or that you no longer need. Be sure that if you throw any medicine away, it is out of the reach of children.

### **General Advice About Prescription Medicines**

Talk to your doctor or other health care provider if you have any questions or concerns about this medicine or your condition. Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Your doctor or pharmacist can give you information about this medicine that was written for health care professionals. Do not use this medicine for a condition for which it was not prescribed. Do not share this medicine with other people.

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