

PART III: CONSUMER INFORMATION

Pr NORVIR® ritonavir oral solution

This leaflet is part III of a three-part "Product Monograph" published when NORVIR® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about NORVIR®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

NORVIR® is for adults and children 2 years of age or older who are infected with the human immunodeficiency virus (HIV), the virus which causes AIDS.

NORVIR® is prescribed for use in combination with other antiretroviral medicines.

What it does:

NORVIR® is an inhibitor of the HIV protease enzyme. It helps control HIV infection by inhibiting or interfering with the protease enzyme that HIV needs to multiply.

NORVIR® is not a cure for HIV infection or AIDS. People taking NORVIR® may still develop infections or other serious illnesses associated with HIV disease and AIDS.

When it should not be used:

NORVIR® should not be taken if you/your child:

- are allergic to ritonavir or to any of the nonmedicinal ingredients in NORVIR®. (Refer to the subheading "What the nonmedicinal ingredients are" for a complete listing)
- are currently taking any of the following medicines:
 - Xatral® (alfuzosin) - used to treat high blood pressure;
 - Cordarone® (amiodarone), Tambocor® (flecainide), Vascor® (bepiridil)**, Rythmol® (propafenone), quinidine - used to treat irregular heart beats;
 - Hismanal® (astemizole)* or Seldane® (terfenadine)* - antihistamines
 - Orap® (pimozide) - used to treat schizophrenia;
 - Propulsid® (cisapride)* - used to relieve certain stomach problems;
 - ergotamine, dihydroergotamine, ergonovine, methylegonovine (used to treat headaches), such as Cafegot®, Migranal®, D.H.E. 45®, Ergotrate Maleate, Methergine, and others;
 - Vfend® (voriconazole) – antifungal;
 - Mevacor® (lovastatin) or Zocor® (simvastatin) – used to lower blood cholesterol;
 - Halcion® (triazolam) – used to relieve anxiety and/or trouble sleeping;

- Versed® (midazolam).

* Products no longer marketed in Canada.

**Product not available in Canada.

- are taking both rifampin and saquinavir. NORVIR® should not be taken with rifampin and saquinavir. Rifampin is also known as Rimactane®, Rifadin®, Rifater®, or Rifamate®; saquinavir is also known as Invirase®.
- are taking products containing St. John's Wort (*Hypericum perforatum*) as this may stop NORVIR® from working properly.
- are currently taking any of these medications, your doctor may switch your medication.

What the medicinal ingredient is:

ritonavir

What the important nonmedicinal ingredients are:

NORVIR® oral solution also contains ethanol, water, polyoxyl 35 castor oil, propylene glycol, anhydrous citric acid to adjust pH, saccharin sodium, peppermint oil, creamy caramel flavoring, and FD&C Yellow No. 6.

What dosage forms it comes in:

This medicine comes in:

- Oral solution (NORVIR® 80 mg/mL)
- Soft elastic capsules (NORVIR® SEC 100 mg)

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Tell your doctor if you or your child develop symptoms such as nausea, vomiting and abdominal pain. These may be signs of problems with your pancreas (pancreatitis). Your doctor must decide if these are related to pancreatitis and what to do about them.

BEFORE using NORVIR® talk to your doctor or pharmacist if:

- you/your child have liver problems or are infected with Hepatitis B or Hepatitis C.
- you/your child have diabetes, or symptoms such as frequent urination, and/or increase in thirst.
- you/your child have hemophilia: Patients taking NORVIR® may have increased bleeding.
- you/your child are taking or planning to take other medicines, including prescription, herbal and other medicines you can buy without a prescription.
- you have heart disease or heart condition.
- you are pregnant or breast-feeding: Pregnant or breast-feeding mothers should not take NORVIR® unless specifically directed by the doctor. Be sure to tell your doctor

immediately if you are or may be pregnant or if you are breast-feeding a baby. It is recommended that HIV-infected women should not breast-feed their infants because of the possibility your baby can be infected with HIV through your breast milk.

NORVIR[®] does not reduce the risk of passing HIV to others with sexual contact or blood contamination. You should use appropriate precautions, such as practicing safe sex, and not reusing or sharing needles.

Changes in body fat have been seen in some patients taking antiretroviral therapy (see **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**).

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with NORVIR[®] include:

NORVIR[®] may interact with certain other medications with possible clinical effects. The use of the following medicines together with NORVIR[®] should only take place on the basis of medical advice:

- medicines used to treat erectile dysfunction: [*e.g.*, Viagra[®] (sildenafil), or Cialis[®] (tadalafil)]. Levitra[®] (vardenafil) should not be taken with NORVIR[®];
- medicines used to lower blood cholesterol [*e.g.*, Lipitor[®] (atorvastatin), Crestor[®] (rosuvastatin)];
- some medicines affecting the immune system [*e.g.*, cyclosporin, Rapamune[®] (sirolimus), tacrolimus];
- some medicines used to treat seasonal allergies and ear and eye infections [*e.g.*, Decadron[®] (dexamethasone), Flonase[®] (fluticasone propionate), prednisone];
- medicines used to treat AIDS and related infections [*e.g.*, Agenerase[®] (amprenavir), Crixivan[®] (indinavir), Viracept[®] (nelfinavir), Invirase[®] (saquinavir), Videx[®] (didanosine), Mycobutin[®] (rifabutin), Aptivus[®] (tipranavir), Rescriptor[®] (delavirdine), Reyataz[®] (atazanavir), Celsentri[®] (maraviroc), Telzir[®] (fosamprenavir), Prezista[®] (darunavir)];
- medicines used to treat depression [*e.g.*, Serzone[®] (trazodone), desipramine, bupropion];
- certain heart medicines such as calcium channel antagonists (*e.g.*, Tiazac[®] (diltiazem), Adalat[®] (nifedipine), Isoptin[®] (verapamil));
- medicines used to correct heart rhythm [*e.g.*, systemic lidocaine, digoxin];
- antifungals [*e.g.*, Nizoral[®] (ketoconazole), Sporanox[®] (itraconazole)];
- morphine-like medicines [*e.g.*, methadone; Demerol[®] (meperidine)];
- anticonvulsants [*e.g.*, Tegretol[®] (carbamazepine), Dilantin[®] (phenytoin), phenobarbital];
- warfarin;
- certain antibiotics [*e.g.*, Mycobutin[®] (rifabutin), Biaxin[®] (clarithromycin)];
- rifampin, also known as Rimactane[®], Rifadin[®], Rifater[®], or Rifamate[®];

- theophylline.
- medicines used to treat cancer (vincristine, vinblastine)

If you are taking oral contraceptives (“the pill”) or the contraceptive patch (*i.e.*, ethinyl estradiol) to prevent pregnancy, you should use a different type of contraception since NORVIR[®] may reduce the effectiveness of oral or patch contraceptives.

NORVIR[®] Oral Solution contains alcohol. Talk with your/your child’s doctor if you/your child are taking or planning to take Flagyl[®] (metronidazole) or Antabuse[®] (disulfiram). Severe nausea and vomiting can occur.

PROPER USE OF THIS MEDICATION

It is important that you/your child take NORVIR[®] every day exactly as your doctor prescribed it. Even if you/your child feel better, do not stop taking NORVIR[®] without talking to your doctor. Using NORVIR[®] as recommended should give you the best chance to delay the development of resistance to the product.

It is therefore important that you remain under the supervision of your doctor while taking NORVIR[®].

Usual dose:

The usual dose for adults is 7.5 mL of the oral solution twice a day (morning and night), in combination with other anti-HIV medicines.

The dose for children over 2 years of age will be determined by your doctor based on the child’s height and weight.

Take NORVIR[®] with food to help it work better.

After use, clean the dosage cup immediately with hot water and dish soap and dry. The dosage cup **must** be dry before use.

Overdose:

If you/your child realize you have taken more NORVIR[®] than you were supposed to, contact your doctor or local poison centre right away. If you cannot reach your/your child’s doctor, go to the hospital. NORVIR[®] Oral Solution contains 43% alcohol and accidental ingestion could be toxic and potentially lethal to a young child.

Missed Dose:

If you/your child miss a dose of NORVIR[®], it should be taken as soon as possible, and the next scheduled dose taken at its regular time. If it is almost time for your/your child’s next dose, do not take the missed dose. Wait and take the next dose at the regular time. Do not double the next dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

- If you/your child have liver disease such as Hepatitis B and Hepatitis C, taking NORVIR® may worsen your liver disease.
- 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 (forms of fat that are found in your blood).
- Diabetes and high blood sugar (hyperglycemia) may occur in patients taking protease inhibitors such as NORVIR®. Symptoms of diabetes or high blood sugar may include frequent urination or increased thirst. Let your doctor know if you have or develop these symptoms while taking NORVIR®.
- Some patients with hemophilia have increased bleeding with protease inhibitors.
- 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”), 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 conditions are not known at this time.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Diarrhea	✓		
	Rash	✓		
	Headache	✓		
	Nausea	✓		
	Vomiting	✓		
	Tingling feeling in hands, feet and around lips	✓		
Uncommon	Chest Pain		✓	
	Pancreatitis		✓	
	- Abdominal Pain		✓	
	- Nausea		✓	
	- Vomiting		✓	

This is not a complete list of side effects. For any unexpected effects while taking NORVIR®, contact your doctor or pharmacist.

HOW TO STORE IT

Keep NORVIR® and all other medicines out of the reach of children.

NORVIR® oral solution should be stored at room temperature, between 20°C-25°C. **DO NOT REFRIGERATE. SHAKE WELL BEFORE EACH USE.** Avoid exposure to excessive heat. Keep cap tightly closed.

It is important to keep NORVIR® in the original package. Do not transfer to any other container.

Do not use after the expiry date stated on the pack.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345
 By toll-free fax: 866-678-6789
 Online: www.healthcanada.gc.ca/medeffect
 By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:
 Canada Vigilance National Office
 Marketed Health Products Safety and Effectiveness Information Bureau
 Marketed Health Products Directorate
 Health Products and Food Branch
 Health Canada
 Tunney’s Pasture, AL 0701C
 Ottawa ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
<http://www.abbott.ca>
 or by contacting the sponsor, Abbott Laboratories Limited, at:
 1-800-699-9948.

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