

PART III: CONSUMER INFORMATION

Pr NORVIR® film-coated tablets ritonavir

This leaflet is PART III of a three-part Product Monograph published when NORVIR tablets 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 tablets. Contact your doctor or pharmacist if you have any questions about the drug.

When co-administering NORVIR with other protease inhibitors, consult the PART III of that protease inhibitor's Product Monograph.

ABOUT THIS MEDICATION

What the medication is used for:

- NORVIR is for adults 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:

Do not take NORVIR if you:

- are allergic to ritonavir or to any of the non-medicinal ingredients in NORVIR. See **What the important non-medicinal ingredients are** for a complete listing.
- are currently taking any of the following medicines:
 - alfuzosin (e.g., Xatral®) - used to treat high blood pressure
 - amiodarone (e.g., Cordarone®*), bepridil* (e.g., Vasacor®), dronedarone (e.g., Multaq®), flecainide (e.g., Tambocor®), propafenone (e.g., Rythmol®), quinidine - used to treat irregular heart beats
 - apalutamide (e.g., Erleada™) - used for prostate cancer
 - colchicine, if you have kidney and/or liver problems - used to treat gout
 - fusidic acid (e.g., Fucidin®) - antibiotic
 - astemizole* or terfenadine* - antihistamines
 - lurasidone (e.g., Latuda®), pimozide (e.g., Orap®) - used to treat abnormal thoughts or feelings
 - cisapride* - used to relieve certain stomach problems

- ergotamine*, dihydroergotamine, ergonovine, methylergonovine* (used to treat headaches), such as Cafegot®, Migranal®, D.H.E. 45®* and others
- voriconazole (e.g., Vfend®) - antifungal
- lovastatin (e.g., Mevacor®), lomitapide (e.g., Juxtapid™) or simvastatin (e.g., Zocor®) - used to lower blood cholesterol
- neratinib (e.g., Nerlynx®) - used for breast cancer
- triazolam, oral midazolam - used to relieve anxiety and/or trouble sleeping
- rivaroxaban (e.g., Xarelto®) - anticoagulant
- salmeterol (e.g., Advair®, Serevent®) - used in the treatment of asthma
- sildenafil (e.g., Revatio®) - only when used for the treatment of pulmonary arterial hypertension
- vardenafil (e.g., Levitra®) - used in the treatment of erectile dysfunction

- 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.

* Products not marketed in Canada.

What the medicinal ingredient is:

ritonavir

What the important non-medicinal ingredients are:

NORVIR 100 mg tablets also contain copovidone, colloidal silicon dioxide/colloidal anhydrous silica, dibasic calcium phosphate anhydrous/calcium hydrogen phosphate anhydrous, hydroxypropyl cellulose, hypromellose, polyethylene glycol 400/macrogol type 400, polyethylene glycol 3350/macrogol type 3350, polysorbate 80, sorbitan monolaurate/sorbitan laurate, sodium stearyl fumarate, talc and titanium dioxide E171.

What dosage forms it comes in:

NORVIR is available as film-coated tablets containing 100 mg ritonavir.

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

- **Tell your doctor if you 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:

- have liver problems or are infected with hepatitis B or hepatitis C.
- have diabetes or symptoms, such as frequent urination and/or increase in thirst.
- have hemophilia: patients taking NORVIR may have increased bleeding.
- are taking or planning to take other medicines, including prescription, herbal and other medicines you can buy without a prescription.
- have heart disease or heart condition.
- are pregnant or planning to become pregnant. Pregnant women should not take NORVIR unless specifically directed by the doctor. Be sure to tell your doctor immediately if you are or may be pregnant. If you take NORVIR while you are pregnant, talk to your doctor about how you can be included in the Antiretroviral Pregnancy Registry.
- are breast-feeding or planning to breast-feed. It is recommended that HIV-infected women should not breast-feed their infants because of the possibility the baby could be infected with HIV through 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.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with NORVIR include:

NORVIR may interact with certain other medications with possible clinical effects. The following medicines should only be used together with NORVIR if advised by your physician:

- medicines used to treat erectile dysfunction, such as sildenafil (e.g., Viagra®) or tadalafil (e.g., Cialis®); vardenafil (e.g., Levitra®) should not be taken with NORVIR
- medicines used to treat pulmonary arterial hypertension, such as bosentan (e.g., Tracleer®) or tadalafil (e.g., Adcirca®)
- medicines used to lower blood cholesterol, such as atorvastatin (e.g., Lipitor®), rosuvastatin (e.g., Crestor®), lomitapide (e.g., Juxtapid™)
- some medicines affecting the immune system, such as

- cyclosporin, sirolimus (e.g., Rapamune®) and tacrolimus
- some medicines used to treat seasonal allergies and ear and eye infections, such as budesonide, dexamethasone, fluticasone propionate (e.g., Flonase®) and prednisone, triamcinolone
- medicines used to treat AIDS and related infections, such as amprenavir*, indinavir (e.g., Crixivan®*), nelfinavir (e.g., Viracept®), saquinavir (e.g., Invirase®), didanosine (e.g., Videx®), rifabutin (e.g., Mycobutin®), tipranavir (e.g., Aptivus®), delavirdine (e.g., Rescriptor®*), atazanavir (e.g., Reyataz®), maraviroc (e.g., Celsentri®), fosamprenavir (e.g., Telzir®), raltegravir (e.g., Isentress®), tenofovir and darunavir (e.g., Prezista®)
- medicines used to treat depression, such as trazodone, desipramine and bupropion
- certain heart medicines, such as calcium channel antagonists including diltiazem (e.g., Tiazac®), nifedipine (e.g., Adalat®) and verapamil (e.g., Isoptin®)
- medicines used to correct heart rhythm, such as systemic lidocaine and digoxin
- antifungals, such as ketoconazole (e.g., Nizoral®) and itraconazole (e.g., Sporanox®)
- morphine-like medicines, such as methadone and meperidine (e.g., Demerol®)
- anticonvulsants, such as carbamazepine (e.g., Tegretol®), phenytoin (e.g., Dilantin®) and phenobarbital
- anticoagulants, such as warfarin
- certain antibiotics, such as rifabutin (e.g., Mycobutin®) and clarithromycin (e.g., Biaxin®)
- antibiotics used in the treatment of tuberculosis, such as rifampin, also known as Rimactane®*, Rifadin®, Rifater®*, or Rifamate®*
- bronchodilators used to treat asthma, such as theophylline
- medicines used to treat cancer, such as abemaciclib (e.g. Verzenio™), dasatinib (e.g., Sprycel®), ibrutinib (e.g., Imbruvica®), nilotinib (e.g., Tasigna®), venetoclax (e.g., Venclexta®), vincristine and vinblastine
- colchicine used for the treatment of gout
- some heart rhythm drugs, such as mexiletine and disopyramide
- some anticonvulsants, such as clonazepam, divalproex, lamotrigine and ethosuximide
- some narcotic analgesics, such as fentanyl (e.g., Duragesic®*) in all forms, tramadol and propoxyphene*
- quetiapine used to treat schizophrenia, bipolar disorder and major depressive disorder
- medicine used to treat hepatitis C, such as simeprevir (e.g., Galeos®*), glecaprevir/pibrentasvir (e.g., Maviret™) or ombitasvir, paritaprevir and ritonavir with or without dasabuvir (e.g., Holkira® Pak*, Technivie™*)
- some sedatives or medicines to treat anxiety, such as buspirone, clorazepate, diazepam (e.g., Valium®), flurazepam (e.g., Dalmane®*) and zolpidem (e.g., Sublinox®)
- stimulants, such as methamphetamine
- medicine to treat anxiety and/or trouble sleeping, such as midazolam (injected)

- medicines used to treat moderate to severe pain associated with endometriosis such as elagolix (Orilissa™)
- * **Products not marketed in Canada.**

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.

PROPER USE OF THIS MEDICATION

It is important that you take NORVIR every day exactly as your doctor prescribed it. Even if you 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 six 100 mg tablets (600 mg) twice daily orally and should be taken with a meal. NORVIR tablets should be swallowed whole with water and not chewed, broken or crushed.

Your doctor may monitor blood levels of fats (lipids), cholesterol and glucose before and during NORVIR treatment.

Overdose:

If you realize you have taken more NORVIR than you were supposed to, contact your doctor or local poison control centre right away, even if you have no symptoms. If you cannot reach your doctor, go to the hospital.

Missed dose:

If you 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 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 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.
- Severe skin reactions, such as Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported with NORVIR use, with symptoms, such as peeling, inflamed, blistering skin and mucous membranes in mouth, nose and throat, flu-like symptoms, fever, and redness in the eye. If these symptoms occur, stop taking the drug and contact a doctor immediately.

Changes to your immune system (Immune Reconstitution Inflammatory 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.

Autoimmune disorders (when the immune system attacks healthy body tissue), may also occur after you start taking medicines for HIV infection. Examples of this include: Grave's disease (which affects the thyroid gland), Guillain-Barré syndrome (which affects the nervous system), polymyositis (which affects the muscles), or autoimmune hepatitis (which affects the liver). Autoimmune disorders may occur many months after the start of treatment. Look for any other symptoms such as:

- high temperature (fever), redness, rash or swelling
- fatigue
- joint or muscle pain
- numbness or weakness beginning in the hands and feet and moving up towards the trunk of the body
- palpitations (chest pain) or rapid heart rate
- yellowing of the skin or eyes

If you notice these or any symptoms of inflammation or infection, tell your doctor immediately.

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		✓	
	Severe skin reactions, such as Stevens-Johnson syndrome and toxic epidermal necrolysis			

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 and sight of children.

NORVIR film-coated tablets should be stored between 15 and 30°C. Exposure of the product to high humidity outside the original container for longer than two weeks is not recommended.

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 package.

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345

Note: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice

MORE INFORMATION

The most recent version of this document plus the full Product Monograph, prepared for healthcare professionals, can be found at:

www.abbvie.ca

or by contacting the sponsor, AbbVie Corporation, Saint-Laurent, QC H4S 1Z1 at: 1-888-704-8271

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Adalat, Adcirca, Advair, Aptivus, Biaxin, Cafegot, Celsentri, Cialis, Cordarone, Crestor, Crixivan, Dalmane, Demerol, D.H.E. 45, Dilantin, Duragesic, Erleada, Flonase, Fucidin, Galexos, Imbruvica, Invirase, Isentress, Isoptin, Juxtapid, Latuda, Levitra, Lipitor, Mevacor, Migranal, Multaq, Mycobutin, Nerlynx, Nizoral, Orap, Prezista, Rapamune, Rescriptor, Revatio, Reyataz, Rifadin, Rifamate, Rifater, Rimactane, Rythmol, Serevent, Sporanox, Sprycel, Sublinox, Tambocor, Tassigna, Tegretol, Telzir, Tiazac, Tracleer, Valium, Vasacor, Verzenio, Vfend, Viagra, Videx, Viracept, Xarelto, Xatral and Zocor are trademarks of their respective owners and are not trademarks of AbbVie Corporation. The makers of these brands are not affiliated with and do not endorse AbbVie or its products.