

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 inhibitors 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[®]. (Refer to the subheading “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^{®*}), flecainide (e.g. Tambocor[®]), bepridil* (e.g. Vasacor[®]), propafenone (e.g. Rythmol[®]), quinidine - used to treat irregular heart beats;
 - fusidic acid (e.g. Fucidin[®]) – antibiotic;
 - astemizole* (e.g. Hismanal[®]) or terfenadine* (e.g. Seldane[®]) - antihistamines;
 - pimozide (e.g. Orap[®]) - used to treat schizophrenia;
 - cisapride* (e.g. Propulsid[®]) - used to relieve certain stomach problems;
 - ergotamine, dihydroergotamine, ergonovine, methylergonovine (used to treat headaches), such as Cafegot[®], Migranal[®], D.H.E. 45^{®*}, Ergotrate[®] Maleate*,

- and others;
- voriconazole (e.g. Vfend[®]) – antifungal;
- lovastatin (e.g. Mevacor[®]) or simvastatin (e.g. Zocor[®]) – used to lower blood cholesterol;
- triazolam – used to relieve anxiety and/or trouble sleeping;
- midazolam;
- salmeterol (e.g. Advair[®], Serevent[®]);
- sildenafil (e.g. Revatio[®]) – only when used for the treatment of pulmonary arterial hypertension;
- vardenafil (e.g. Levitra[®]).

- 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 in the following dosage forms:

- Film-coated tablets containing 100 mg ritonavir
- Oral solution containing 80 mg/mL of ritonavir
- Soft elastic capsules containing 100 mg of 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.
- you have diabetes, or symptoms such as frequent urination, and/or increase in thirst.
- you have hemophilia: Patients taking NORVIR[®] may have increased bleeding.
- you 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 of the baby being infected with HIV through the 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 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[®]);
- 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 dexamethasone, fluticasone propionate (e.g. Flonase[®]), and prednisone;
- medicines used to treat AIDS and related infections such as amprenavir (e.g. Agenerase[®]), 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[®]) 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;
- warfarin;
- certain antibiotics such as rifabutin (e.g. Mycobutin[®]) and clarithromycin (e.g. Biaxin[®]);
- rifampin, also known as Rimactane^{®*}, Rifadin[®], Rifater[®], or Rifamate^{®*};
- theophylline;
- medicines used to treat cancer such as vincristine and vinblastine;
- fentanyl (e.g. Duragesic[®]) in all forms
- colchicine used for the treatment of gout.

*Product not available 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.

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.

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 of children.

NORVIR® film-coated tablets should be stored between 15 and 25°C. Exposure of the product to high humidity outside the original or USP equivalent tight container (60 mL or less) for longer than 2 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 pack.

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.
- 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.
- 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.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report on line at:
www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at
<http://www.healthcanada.gc.ca/medeffect>

Note: Should you require information related to the management of side effects, contact your health professional. 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, Saint-Laurent, Qc H4S 1Z1 at:
1-800-699-9948

This leaflet was prepared by Abbott Laboratories, Limited.

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Adalat[®], Adcirca[®], Advair[®], Aptivus[®], Agenerase[®], Cafegot[®], Celsentri[®], Cialis[®], Cordarone[®], Crestor[®], Crixivan[®], DHE 45[®], Demerol[®], Dilantin[®], Flonase[®], Fucidin[®], Hismanal[®], Invirase[®], Levitra[®], Lipitor[®], Mevacor[®], Migranal[®], Mycobutin[®], Nizoral[®], Orap[®], Prezista[®], Propulsid[®], Rapamune[®], Rescriptor[®], Revatio[®], Reyataz[®], Rifadin[®], Rifamate[®], Rifater[®], Rimactane[®], Seldane[®], Serevent[®], Sporanox[®], Tambocor[®], Tegretol[®], Telzir[®], Tiazac[®], Tracleer[®], Vasacor[®], Vfend[®], Viagra[®], Videx[®], Viracept[®], Xatral[®] and Zocor[®] are trademarks of their respective owners and are not trademarks of Abbott Laboratories, Limited.

PART III: CONSUMER INFORMATION

PrNORVIR® oral solution ritonavir

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.

When co-administering NORVIR® with other protease inhibitors, consult the Part III of that protease inhibitors Product Monograph.

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 non-medicinal ingredients in NORVIR®. (Refer to the subheading “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®*), flecainide (e.g. Tambocor®), bepridil* (e.g. Vasacor®), propafenone (e.g. Rythmol®), quinidine - used to treat irregular heart beats;
 - fusidic acid (e.g. Fucidin®) – antibiotic;
 - astemizole* (e.g. Hismanal®) or terfenadine* (e.g. Seldane®) - antihistamines;
 - pimozide (e.g. Orap®) - used to treat schizophrenia;
 - cisapride* (e.g. Propulsid®) - used to relieve certain stomach problems;
 - ergotamine, dihydroergotamine, ergonovine, methylethylergonovine (used to treat headaches), such as

Cafergot®, Migranal®, D.H.E. 45®*, Ergotrate® Maleate*, and others;

- voriconazole (e.g. Vfend®) – antifungal;
 - lovastatin (e.g. Mevacor®) or simvastatin (e.g. Zocor®) – used to lower blood cholesterol;
 - triazolam – used to relieve anxiety and/or trouble sleeping;
 - midazolam;
 - salmeterol (e.g. Advair®, Serevent®);
 - sildenafil (e.g. Revatio®) – only when used for the treatment of pulmonary arterial hypertension;
 - vardenafil (e.g. Levitra®).
- 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® oral solution also contains anhydrous citric acid to adjust pH, creamy caramel flavouring, ethanol, FD&C Yellow No.6, peppermint oil, polyoxyl 35 castor oil, propylene glycol, and sodium saccharin.

What dosage forms it comes in:

NORVIR® is available in the following dosage forms:

- Film-coated tablets containing 100 mg ritonavir
- Oral solution containing 80 mg/mL of ritonavir
- Soft elastic capsules containing 100 mg of ritonavir

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 you use 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 of the baby being infected with HIV through the 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 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®);
- 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 dexamethasone, fluticasone propionate (e.g. Flonase®), and prednisone;
- medicines used to treat AIDS and related infections such as amprenavir (e.g. Agenerase®), 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®) 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;
- warfarin;
- certain antibiotics such as rifabutin (e.g. Mycobutin®) clarithromycin (e.g. Biaxin®);
- rifampin, also known as Rimactane®* Rifadin®, Rifater®, or Rifamate®*;
- theophylline;
- medicines used to treat cancer such as vincristine and vinblastine;
- fentanyl (e.g. Duragesic®) in all forms
- colchicine used for the treatment of gout.

***Product not available 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.

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

*** Product no longer marketed in Canada.**

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 control centre right away, even if you have no symptoms. 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.
- 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.

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.

This leaflet was prepared by Abbott Laboratories, Limited.

Last revised: November 28, 2011

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 and 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.

Adalat[®], Adcirca[®], Advair[®], Aptivus[®], Agenerase[®], Antabuse[®], Cafegot[®], Celsentri[®], Cialis[®], Cordarone[®], Crestor[®], Crixivan[®], DHE 45[®], Demerol[®], Dilantin[®], Flagyl[®], Flonase[®], Fucidin[®], Hismanal[®], Invirase[®], Levitra[®], Lipitor[®], Mevacor[®], Migranal[®], Mycobutin[®], Nizoral[®], Orap[®], Prezista[®], Propulsid[®], Rapamune[®], Rescriptor[®], Revatio[®], Reyataz[®], Rifadin[®], Rifamate[®], Rifater[®], Rimactane[®], Seldane[®], Serevent[®], Sporanox[®], Tambocor[®], Tegretol[®], Telzir[®], Tiazac[®], Tracleer[®], Vasacor[®], Vfend[®], Viagra[®], Videx[®], Viracept[®], Xatral[®] and Zocor[®] are trademarks of their respective owners and are not trademarks of Abbott Laboratories, Limited.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report on line at:**
www.healthcanada.gc.ca/medeffect
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
 - **Fax toll-free to 1-866-678-6789**
 - **Mail to: Canada Vigilance Program**
Health Canada
Postal Locator 0701C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect[™] Canada Web site at <http://www.healthcanada.gc.ca/medeffect>

NOTE: Should you require information related to the management of side effects, contact your health professional. 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, Saint-Laurent, Qc H4S 1Z1 at:
1-800-699-9948

PART III: CONSUMER INFORMATION

^{Pr}NORVIR[®] SEC soft elastic capsules ritonavir

This leaflet is PART III of a three-part “Product Monograph” published when NORVIR[®] SEC 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[®] SEC. 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 inhibitors Product Monograph.

ABOUT THIS MEDICATION

What the medication is used for:

- NORVIR[®] SEC is for adults who are infected with the human immunodeficiency virus (HIV), the virus which causes AIDS.
- NORVIR[®] SEC is prescribed for use in combination with other antiretroviral medicines.

What it does:

NORVIR[®] SEC 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[®] SEC is not a cure for HIV infection or AIDS. People taking NORVIR[®] SEC 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-medical ingredients in NORVIR[®]. (Refer to the subheading “What the important non-medical 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[®]), flecainide (e.g. Tambocor[®]), bepridil* (e.g. Vasacor[®]), propafenone (e.g. Rythmol[®]), quinidine - used to treat irregular heart beats;
 - fusidic acid (e.g. Fucidin[®]) – antibiotic;
 - astemizole* (e.g. Hismanal[®]) or terfenadine* (e.g. Seldane[®]) - antihistamines;
 - pimozide (e.g. Orap[®]) - used to treat schizophrenia;
 - cisapride* (e.g. Propulsid[®]) - used to relieve certain stomach problems;
 - ergotamine, dihydroergotamine, ergonovine, methylergonovine (used to treat headaches), such as Cafegot[®], Migranal[®], D.H.E. 45[®]*, Ergotrate[®] Maleate*,

- and others;
- voriconazole (e.g. Vfend[®]) – antifungal;
- lovastatin (e.g. Mevacor[®]) or simvastatin (e.g. Zocor[®]) – used to lower blood cholesterol;
- triazolam – used to relieve anxiety and/or trouble sleeping;
- midazolam;
- salmeterol (e.g. Advair[®], Serevent[®]);
- sildenafil (e.g. Revatio[®]) – only when used for the treatment of pulmonary arterial hypertension;
- vardenafil (e.g. Levitra[®]).

- 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-medical ingredients are:

NORVIR[®] SEC capsules also contain butylated hydroxytoluene, ethanol, gelatin, black opacode ink (iron oxide), oleic acid, polyoxyl 35 castor oil, purified water, titanium dioxide, sorbitol and glycerin.

What dosage forms it comes in:

NORVIR[®] is available in the following dosage forms:

- Film-coated tablets containing 100 mg ritonavir
- Oral solution containing 80 mg/mL of ritonavir
- Soft elastic capsules containing 100 mg of 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[®] SEC talk to your doctor or pharmacist if:

- you have liver problems or are infected with hepatitis B or hepatitis C.
- you have diabetes, or symptoms such as frequent urination, and/or increase in thirst.
- you have hemophilia: Patients taking NORVIR[®] SEC may have increased bleeding.
- you 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[®] SEC 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 of the baby being infected with HIV through the breast milk.

NORVIR[®] SEC 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[®] SEC 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 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[®]);
- 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 dexamethasone, fluticasone propionate (e.g. Flonase[®]), and prednisone;
- medicines used to treat AIDS and related infections such as amprenavir (e.g. Agenerase[®]), 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[®]) 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;
- warfarin;
- certain antibiotics such as rifabutin (e.g. Mycobutin[®]) clarithromycin (e.g. Biaxin[®]);
- rifampin, also known as Rimactane^{®*}, Rifadin[®], Rifater[®], or Rifamate^{®*};
- theophylline;
- medicines used to treat cancer such as vincristine and vinblastine;
- fentanyl (e.g. Duragesic[®]) in all forms
- colchicine used for the treatment of gout.

***Product not available 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[®] SEC every day exactly as your doctor prescribed it. Even if you feel better, do not stop taking NORVIR[®] SEC without talking to your doctor. Using NORVIR[®] SEC 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[®] SEC.

Usual dose:

The usual dose for adults is 600 mg (6 capsules) twice daily, in combination with other anti-HIV medicines.

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

Overdose:

If you realize you have taken more NORVIR® SEC 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® SEC, 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® SEC may worsen your liver disease.
- Some patients taking NORVIR® SEC 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® SEC. 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® SEC.
- 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.
- 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.

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® SEC, contact your doctor or pharmacist.

HOW TO STORE IT

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

NORVIR® SEC soft gel capsules should be stored between 2 and 8°C in a refrigerator. If you keep NORVIR® SEC outside of the refrigerator, do not store above 25°C and discard any unused contents after 30 days. Avoid exposure to excessive heat. Protect from light.

It is important to keep NORVIR® SEC 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

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report on line at:**
www.healthcanada.gc.ca/medeffect
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
 - **Fax toll-free to 1-866-678-6789**
 - **Mail to: Canada Vigilance Program**
Health Canada
Postal Locator 0701C
Ottawa, ON K1A 0K9

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This leaflet was prepared by Abbott Laboratories, Limited.

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Adalat[®], Adcirca[®], Advair[®], Aptivus[®], Agenerase[®], Cafegot[®], Celsentri[®], Cialis[®], Cordarone[®], Crestor[®], Crixivan[®], DHE 45[®], Demerol[®], Dilantin[®], Flonase[®], Fucidin[®], Hismanal[®], Invirase[®], Levitra[®], Lipitor[®], Mevacor[®], Migranal[®], Mycobutin[®], Nizoral[®], Orap[®], Prezista[®], Propulsid[®], Rapamune[®], Rescriptor[®], Revatio[®], Reyataz[®], Rifadin[®], Rifamate[®], Rifater[®], Rimactane[®], Seldane[®], Serevent[®], Sporanox[®], Tambocor[®], Tegretol[®], Telzir[®], Tiazac[®], Tracleer[®], Vasacor[®], Vfend[®], Viagra[®], Videx[®], Viracept[®], Xatral[®] and Zocor[®] are trademarks of their respective owners and are not trademarks of Abbott Laboratories, Limited.