

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
 - 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[®]), pimozone (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[®]) or simvastatin (e.g., Zocor[®]) – used to lower blood cholesterol
- 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 in the following dosage forms:

- Film-coated tablets containing 100 mg ritonavir
- Oral solution containing 80 mg/mL 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.
- 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[®])
- 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 dasatinib (Sprycel[®]), ibrutinib (Imbruvica[®]), nilotinib (Tasigna[®]), venetoclax (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[®]) 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)

***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 in your immune system (Immune Reconstitution Inflammatory Syndrome) can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time, or you could develop an autoimmune disease in which your immune system reacts against your own body (e.g., Grave's disease [which affects the thyroid gland], Guillain-Barre syndrome [which affects the nervous system] or polymyositis [which affects the muscles] and it may develop at any time, sometimes months later after the start of HIV therapy). Sometimes symptoms can be severe, so if you develop high temperature (fever), joint or muscle pain, redness, rash, swelling, or fatigue or any new symptoms, contact your doctor straight away.

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 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 three ways:

- Report on line at:
www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting
- 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 1908C
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:

www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting

Note: Should you require information related to the management of side effects, contact your healthcare professional. 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

This leaflet was prepared by AbbVie Corporation.

Last revised: September 25, 2018

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PART III: CONSUMER INFORMATION

PrNORVIR[®] oral solution ritonavir

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

- 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[®]) or simvastatin (e.g., Zocor[®]) – used to lower blood cholesterol
- 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

ABOUT THIS MEDICATION

What the medication is used for:

- NORVIR is for adults and children two 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. 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
 - 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

- 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/your child's 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

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/your child's pancreas (pancreatitis). Your/your child's 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.
- 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/your child's doctor immediately if you/your child are or may be pregnant. If you/ your child take NORVIR while you/your child are pregnant, talk to your/your child's doctor about how you/your child 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/your child's 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[®])
- 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[®]), prednisone and 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 dasatinib (Sprycel[®]), ibrutinib (Imbruvica[®]), nilotinib (Tasigna[®]), venetoclax (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, lamotrigene 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[®]) 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)

***Products not marketed in Canada.**

If you/your child are taking oral contraceptives (“the pill”) or the contraceptive patch (i.e., ethinyl estradiol) to prevent pregnancy, you/your child 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.

NORVIR oral solution contains propylene glycol which could cause adverse effects for those with kidney problems. Talk to your doctor if you have kidney problems. Stop taking NORVIR and contact your doctor immediately if you develop symptoms of propylene glycol toxicity, such as seizures, rapid heartbeat (tachycardia), and blood in the urine, rapid breathing, weakness, nausea and vomiting.

*** 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/your child’s doctor. Using NORVIR as recommended should give you/your child the best chance to delay the development of resistance to the product.

It is therefore important that you/your child remain under the supervision of your/your child’s 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 two years of age will be determined by your/your child’s doctor based on the child’s height and weight.

Take NORVIR with food, if possible, 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.

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

Overdose:

If you/your child realize you have taken more NORVIR than you/your child were supposed to, contact your/your child’s 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 27% propylene glycol 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/your child’s doctor if you/your child 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/your child’s 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/your child’s doctor know if you/your child 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 in your/your child’s immune system (Immune Reconstitution Inflammatory Syndrome) can happen when you start taking HIV medicines. Your/your child’s immune system may get stronger and begin to fight infections that have been hidden in your/your child’s body for a long time, or

you/your child could develop an autoimmune disease in which your/your child's immune system reacts against your own body (e.g. Grave's disease [which affects the thyroid gland], Guillain-Barre syndrome [which affects the nervous system] or polymyositis [which affects the muscles] and it may develop at any time, sometimes months later after the start of HIV therapy). Sometimes symptoms can be severe, so if you/your child develop high temperature (fever), joint or muscle pain, redness, rash, swelling, or fatigue or any new symptoms contact your/your child's doctor straight away.

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 package.

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 oral solution should be stored at room temperature, between 20 and 25°C. **DO NOT REFRIGERATE. SHAKE**

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 three ways:

- **Report on line at:**
www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting
- **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 1908C
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:
www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting

NOTE: Should you require information related to the management of side effects, contact your healthcare professional. 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

This leaflet was prepared by AbbVie Corporation.

Last revised: September 25, 2018

Adalat, Adcirca, Advair, Advera, Antabuse, Aptivus, Biaxin, Cafegot, Celsentri, Cialis, Cordarone, Crestor, Crixivan, Demerol, D.H.E. 45, Dilantin, Duragesic, Ensure, Flagyl, Flonase,

Fucidin, Galexos, Imbruvica, Invirase, Isentress, Isoptin, Latuda, Levitra, Lipitor, Mevacor, Migranal, Multaq, Mycobutin, Nizoral, Orap, Prezista, Rapamune, Rescriptor, Revatio, Reyataz, Rifadin, Rifamate, Rifater, Rimactane, Rythmol, Serevent, Sporanox, Sprycel, Tambocor, Tasigna, Tegretol, Telzir, Tiazac, Tracleer, 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.