

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

NORVIR®

ritonavir tablets

Read this carefully before you start taking **NORVIR** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **NORVIR**.

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

Serious Warnings and Precautions

NORVIR can cause **pancreatitis** (inflammation of the pancreas).

Tell your doctor if you develop symptoms, such as:

- **abdominal pain**
- **nausea**
- **vomiting**

These may be signs of **pancreatitis**. Your doctor must decide if these are related to pancreatitis and what to do about them.

NORVIR may react with certain drugs and cause serious and life-threatening side effects. Read the "Error! Reference source not found." and "Error! Reference source not found." sections below very carefully.

What is NORVIR used for?

- the treatment of HIV (Human Immunodeficiency Virus) Infection
- HIV is the virus that causes Acquired Human Immunodeficiency Syndrome (AIDS)
- it is used in adults and children 2 – 16 years of age
- it is used along other medicines to treat HIV infection

How does NORVIR work?

- NORVIR works by stopping the HIV virus from multiplying. This will help lower the amount of HIV in your body and keep it at a low level.
- NORVIR is not a cure for HIV infection or AIDS. You can still get infections or other serious illnesses associated with HIV infection or AIDS.

- 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.

What are the ingredients in NORVIR?

Medicinal ingredient: ritonavir

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

NORVIR comes in the following dosage forms:

As tablets containing 100 mg of ritonavir.

Do not use NORVIR if:

- you are allergic to ritonavir or to any of the ingredients in NORVIR.

Do not use NORVIR if you are currently taking any of the following medicines. Taking NORVIR with these can cause serious problems and death:

- alfuzosin, used to treat high blood pressure
- amiodarone, bepridil, dronedarone, flecainide, propafenone, quinidine, used to treat irregular heartbeats
- apalutamide, used for prostate cancer
- astemizole or terfenadine, used to relieve allergy symptoms
- cisapride, used to relieve certain stomach problems
- colchicine, when used in patients with kidney and/or liver problems, used to treat gout
- ergotamine, dihydroergotamine (used to treat headaches), ergonovine, methylergonovine (used after labour and delivery)
- fusidic acid, used as an antibiotic
- lovastatin, lomitapide or simvastatin, used to lower cholesterol
- lurasidone, pimozide, used to treat mental health problems
- neratinib, used to treat breast cancer
- ranolazine, used to treat chronic angina (chest pain)
- rifampin and saquinavir, used to treat tuberculosis, should not be used together with ritonavir
- rivaroxaban, used as an anticoagulant

- salmeterol, used for asthma and chronic obstructive pulmonary disease
- St. John's Wort (*Hypericum perforatum*), an herbal product used to treat depression
- triazolam and midazolam (oral or injected), used to relieve anxiety and/or trouble sleeping
- PDE5 inhibitors vardenafil, used to treat erectile dysfunction, or sildenafil, used for the treatment of pulmonary arterial hypertension (PAH)
- voriconazole, used as an antifungal
- venetoclax during the dose initiation and during the ramp-up phase, used to treat chronic lymphocytic leukemia

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take NORVIR. Talk about any health conditions or problems you may have, including if you:

- have liver problems.
- are infected with hepatitis B or hepatitis C. If you have liver disease, such as hepatitis B and hepatitis C, taking NORVIR may worsen your liver disease.
- have diabetes or symptoms, such as frequent urination and/or increase in thirst.
- have hemophilia, since taking NORVIR can increase bleeding in these patients.
- have heart disease or heart condition, including conditions of Congenital Long QT Syndrome.
- have been told you have high triglyceride levels in your blood.
- have had a condition called pancreatitis in the past.

Other warnings you should know about:

Pregnancy

Tell your doctor if you are pregnant or planning to become pregnant. It is not known if NORVIR can harm your unborn baby. Tell your doctor if you become pregnant while you are taking NORVIR.

Pregnancy Registry

There is a pregnancy registry for women who take antiretroviral medicines while they are pregnant. The purpose of this registry is to collect information about the health of you and your baby. If you do become pregnant while taking NORVIR, talk to your doctor about taking part in this registry.

Breastfeeding

You should not breastfeed if you are taking NORVIR. You should also not breastfeed a baby if you are infected with HIV. This is because you can pass HIV to your baby.

Severe Liver Problems

Severe liver problems, including deaths, have been reported in those using NORVIR. This has often occurred in those with advanced HIV disease, other liver disease or those taking many medications. Symptoms of serious liver problems include yellow skin and whites of eyes, nausea, tiredness, loss of appetite, fever, skin rash, pain in the upper abdomen, pale stools, and dark-coloured urine. Talk to your doctor if you get any of these symptoms.

Contraception

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.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.

The following medicines should only be used together with NORVIR if advised by your physician.

The following may interact with NORVIR:

- medicines used to treat erectile dysfunction, such as tadalafil
- medicines used to treat pulmonary arterial hypertension, such as bosentan or tadalafil
- medicines used to lower blood cholesterol, such as atorvastatin and rosuvastatin
- some medicines affecting the immune system, such as cyclosporin, sirolimus and tacrolimus
- some medicines used to treat seasonal allergies and ear and eye infections, such as budesonide, dexamethasone, fluticasone propionate, prednisone, and triamcinolone
- medicines used to treat AIDS and related infections, such as amprenavir, indinavir, nelfinavir, saquinavir, didanosine, rifabutin, tipranavir, delavirdine, atazanavir, maraviroc, fosamprenavir, raltegravir, tenofovir and darunavir
- medicines used to treat depression, such as trazodone, desipramine and bupropion
- certain heart medicines, such as calcium channel antagonists including diltiazem, nifedipine and verapamil
- medicines used to correct heart rhythm, such as systemic lidocaine and digoxin
- antifungals, such as ketoconazole and itraconazole
- morphine-like medicines used to treat severe pain, such as methadone and meperidine
- anticonvulsants, such as carbamazepine, phenytoin, and phenobarbital
- anticoagulants, such as warfarin
- certain antibiotics, such as rifabutin and clarithromycin
- antibiotics used in the treatment of tuberculosis, such as rifampin
- bronchodilators used to treat asthma, such as theophylline

- medicines used to treat cancer, such as abemaciclib, dasatinib, encorafenib, ibrutinib, nilotinib, vincristine and vinblastine
- medicines used for low blood platelet count, such as fostamatinib
- some heart rhythm drugs, such as mexiletine and disopyramide
- some anticonvulsants, such as clonazepam, divalproex, lamotrigine and ethosuximide
- some narcotic analgesics, such as fentanyl in all forms, tramadol and propoxyphene
- quetiapine used to treat schizophrenia, bipolar disorder and major depressive disorder
- medicines used to treat hepatitis C, such as simeprevir, glecaprevir/pibrentasvir or ombitasvir, paritaprevir and ritonavir with or without dasabuvir
- some sedatives or medicines to treat anxiety, such as buspirone, clorazepate, diazepam, flurazepam and zolpidem
- stimulants, such as methamphetamine
- medicines used to treat pain associated with endometriosis, such as elagolix

How to take NORVIR:

- Take NORVIR exactly as your doctor tells you to.
- Do not change your dose or stop taking NORVIR without talking to your doctor.
- You must stay under your doctor's care when taking NORVIR.
- Swallow the NORVIR tablets whole. Do not chew, break, or crush tablets.
- You should take NORVIR tablets with food.

Usual dose:

- Your doctor will tell you how much NORVIR you should take and when you should take it.
- The usual dose for adults is six 100 mg tablets twice a day.

Overdose:

If you think you have taken too much NORVIR, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

If you missed a dose of this medication, take it as soon as you remember. But if it is almost time for your next dose, skip the missed dose and continue with your next scheduled dose. Go back to the regular dosing schedule. Do not take 2 doses at the same time.

What are possible side effects from using NORVIR?

These are not all the possible side effects you may feel when taking NORVIR. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Changes in taste
- Diarrhea
- Dizziness
- Feeling weak or tired
- Headache
- Loss of appetite
- Tingling feeling or numbness in hands, feet or around the lips
- Some patients have large increases in triglycerides and cholesterol (forms of fat that are found in your blood)

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.

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

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Chest Pain		✓	
Diabetes or hyperglycemia (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision, and fatigue		✓	
Pancreatitis (inflammation of the pancreas): abdominal pain, nausea, and vomiting		✓	
Severe liver problems: yellow skin and whites of eyes, nausea, tiredness, loss of appetite, fever, skin rash, pain in the upper abdomen, pale stools, and dark-coloured urine		✓	
Stevens-Johnson syndrome (SJS) (severe skin rash): redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swelling			✓
Toxic Epidermal Necrolysis (TEN) (severe skin reaction): redness, blistering and/or peeling of large areas of the skin			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

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.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.

Storage:

Store between 15 and 30°C. It is recommended that the product be stored and dispensed in the original container.

Exposure of the product to high humidity outside the original container for longer than 2 weeks is not recommended.

Do not use after the expiry date on the package.

Keep out of reach and sight of children.

If you want more information about NORVIR:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>), the manufacturer's website (www.abbvie.ca), or by calling 1-888-704-8271.

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