

NORVIR[®]

ritonavir (ri-TO-na-veer)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Norvir.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Norvir is used for

Norvir is used to treat HIV (Human Immunodeficiency Virus) infections.

This medicine belongs to a group of medicines called protease inhibitors.

Norvir works by inhibiting or interfering with the protease enzyme that the HIV virus needs to infect new cells. It may be given alone or with certain other anti-HIV medicines. Your doctor will determine which medicines are best for you.

Norvir has not been shown to decrease the chance of transmitting HIV to a sexual partner. You must continue to use safe sexual practices (e.g. condoms) while taking Norvir.

Ask your doctor or pharmacist if you have any questions about why it has been prescribed for you.

Your doctor may have prescribed it for another purpose.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children under the age of 12 years.

Before you take Norvir

When you must not take it

Do not take Norvir if you have an allergy to:

- any medicine containing (ritonavir)
- any of the ingredients listed at the end of this leaflet
- you are currently taking any of the medications listed under the section "Taking other medicines"

If Norvir is taken with other antiretroviral medicines, it is important that you also carefully read the leaflets that are provided with these medicines. There may be additional information in those leaflets about situations when Norvir should be avoided.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not give Norvir to a child under the age of 12 years.

Safety and effectiveness in children younger than 12 years have not been established.

Do not take it after the expiry date printed on the bottle or if the

packaging is damaged or shows signs of tampering.

If it has expired or is damaged return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor or pharmacist if you have any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you have or have had any of the following medical conditions:

- you have, or have ever had, any other health problems or medical conditions, including liver problems.
- you are allergic to any other medicines, foods, dyes or preservatives.
- you have hepatitis B or C and are being treated with a combination of antiretroviral agents, as you are at a greater risk of a severe and potentially life threatening reaction because of the effect on the liver. Regular blood tests may be required to check your liver is working properly.
- you have haemophilia, as there have been reports of increased bleeding in patients with haemophilia who are taking this type of medicine (protease inhibitors). The reason for this is not known. You may need additional medicine to help your blood clot (factor VIII), in order to control any bleeding.
- you have diabetes, as there have been reports of worsening of or the development of diabetes (diabetes mellitus) in some patients taking protease inhibitors.

Tell your doctor or pharmacist if you are pregnant, intend to become pregnant, or are breastfeeding

Your doctor or pharmacist can discuss the risks and benefits involved.

If you have not told your doctor or pharmacist about any of the above, tell them before you take Norvir.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

If Norvir is taken in combination with other antiretroviral medicines, it is important that you also carefully read the leaflets that are provided with these other medicines. There may be additional information in those leaflets about situations when Norvir should be avoided. If you have any further questions about Norvir or the other medicines prescribed, please ask your doctor or pharmacist.

Some medicines and Norvir may interfere with each other. These include:

- astemizole or terfenadine (commonly used to treat allergy symptoms – these medicines may be available without prescription);
- amiodarone, bepridil, encainide, flecainide, propafenone, quinidine (used to correct irregular heartbeats);
- dihydroergotamine, ergotamine (used to treat migraine headache);
- ergometrine, methylethergometrine (used to stop excessive bleeding that may occur following childbirth or an abortion);
- clorazepate, diazepam, estazolam, flurazepam, triazolam, midazolam, zolpidem (used to help you sleep and/or relieve anxiety);
- clozapine, blonanserin, pimozide, (used to treat abnormal thoughts or feelings);

- pethidine, piroxicam, dextropropoxyphene (used to relieve pain);
- cisapride (used to relieve certain stomach problems);
- rifabutin (used to prevent/treat certain infections);
- voriconazole (used to treat fungal infections);
- simvastatin, lovastatin (used to lower blood cholesterol);
- alfuzosin (used to treat enlarged prostate gland);
- sildenafil if you suffer from a lung disease called pulmonary arterial hypertension that makes breathing difficult. Patients without this disease may use sildenafil for impotence (erectile dysfunction) under their doctor's supervision
- products containing St John's wort (*Hypericum perforatum*) as this may stop Norvir from working properly. St John's wort is often used in herbal medicines that you can buy yourself.
- salmeterol (used as a long acting reliever of asthma symptoms)
- fusidic acid (used to treat infections)

These medicines may be affected by Norvir, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Norvir.

Other interactions

There are medicines that may not mix with Norvir because their effects could increase or decrease when taken together. In some cases your doctor may need to perform certain tests, change the dose or monitor you regularly. This is why you should tell your doctor if you are taking any medicines, including those you have bought yourself or herbal products, but it is especially important to mention these:

- analgesics (morphine and morphine-like medicines) used to treat severe pain (eg alfentanil,

fentanyl, methadone, hydrocodone, oxycodone, tramadol, codeine, heroin, hydromorphone, morphine, naloxone, naltrexone)

- analgesics (NSAIDs) used to treat pain (eg diclofenac, flurbiprofen, ibuprofen, indomethacin, sulindac, ketoprofen, ketorolac, naproxen, paracetamol)
- anti-arrhythmics or heart medicines (eg lignocaine, disopyramide, mexiletine, digoxin, and calcium channel antagonists such as amlodipine, diltiazem, felodipine, nifedipine, nimodipine, verapamil)
- anti-asthmatics or asthma medicines (eg theophylline)
- anti-cancer treatments (eg tamoxifen, dasatinib, nilotinib, etoposide, paclitaxel, vinblastine, vincristine, cyclophosphamide, ifosfamide, daunorubicin, doxorubicin);
- anti-coagulant medicines used to thin the blood (eg warfarin)
- anti-convulsant medicines (eg carbamazepine, clonazepam, ethosuximide, phenytoin, phenobarbitone, sodium valproate, lamotrigine)
- anti-depressants (eg amitriptyline, clomipramine, imipramine, nortriptyline, trimipramine, doxepin, desipramine, fluoxetine, paroxetine, venlafaxine, moclobemide, fluvoxamine, nefazodone, sertraline, trazodone);
- anti-diarrhoeal medicines used to treat diarrhoea (eg diphenoxylate, loperamide)
- anti-emetic medicines used to treat nausea and vomiting (eg ondansetron, prochlorperazine, promethazine, metoclopramide)
- anti-fungals (eg ketoconazole, itraconazole, miconazole);
- anti-gout medicine (eg colchicine)
- anti-histamines (eg loratidine, azatadine, brompheniramine, chlorpheniramine, diphenhydramine, mepyramine, triprolidine, cyproheptadine);

- anti-hypertensive medicines used to treat high blood pressure (eg bosentan, triamterene, losartan, prazosin, terazosin)
- anti-infective medicines (eg erythromycin, clarithromycin, clindamycin, tinidazole);
- anti-mycobacterial medicines used to treat fungal infections (eg rifampicin)
- anti-parasitic medicines used to treat infections (eg quinine, proguanil, albendazole, chloroquine, mebendazole, mefloquine, metronidazole, pentamide, praziquantel, primaquine, pyrimethamine, thiabendazole, atovaquone)
- antiretroviral medicines including HIV protease inhibitors, non-nucleoside reverse transcriptase inhibitors (NNRTI) and nucleoside reverse transcriptase inhibitors (NRTI);
- anti-ulcer medicines used to treat ulcers (eg lansoprazole, omeprazole, cimetidine)
- anxiety medicine (eg buspirone)
- beta-blockers or medicines used to treat the heart (eg metoprolol, pindolol, timolol, propranolol, betazolol, labetalol)
- immune system medicines (eg cyclosporine, everolimus, tacrolimus, sirolimus)
- medicine used to help you stop smoking (eg bupropion)
- medicines used to treat erectile dysfunction (eg sildenafil, tadalafil, vardenafil)
- medicines used to treat migraines (eg bromocriptine, ergonovine, methysergide)
- medicines used to treat high blood sugar levels (eg glimepiride, glipizide, glibenclamide, glyburide, tolbutamide)
- medicines used to treat high cholesterol (eg fluvastatin, atorvastatin, pravastatin, rosuvastatin, gemfibrozil)
- sleeping pills (eg alprazolam, clonazepam, buspirone, other benzodiazepines, zopiclone,

lorazepam, oxazepam, propofol, temazepam)

- steroid-like hormones (eg dexamethasone, finasteride, flutamide, prednisone, fluticasone propionate, anabolic steroids, levonorgestrel, medroxyprogesterone, norethindrone, testosterone) ethinyloestradiol)
- tranquillisers (eg chlorpromazine, haloperidol, risperidone, thioridazine, other phenothiazines)
- stimulants / decongestants (eg dextromethorphan, methylphenidate, caffeine)

Norvir affects the way oral contraceptives work. Another form of contraception should be used whilst you are taking Norvir.

Norvir interacts with sildenafil, tadalafil, vardenafil which are used for impotence (erectile dysfunction). The dosage of these medicines should be reduced to avoid damage to the penis. You must not take Norvir with sildenafil if you also suffer from pulmonary arterial hypertension.

Grapefruit juice is not expected to affect the absorption of ritonavir.

How to take Norvir

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

How much to take and when to take it

The usual dose is 600mg of ritonavir twice a day (7.5mL of oral solution or 6 tablets).

How to take it

NORVIR is administered orally and should be taken with food.

Tablets:

Norvir tablets should be swallowed whole and not chewed, broken or crushed.

Oral Solution:

Shake the bottle well and accurately measure the dose with the dosage cup provided.

The oral solution dosage cup should be cleaned immediately with hot soapy water after use. The dosage cup **must** be dry prior to use.

The oral solution has a lingering aftertaste. It can be mixed with Ensure® or chocolate milk to improve the taste. Do not mix Norvir with water.

Eating salty foods or drinking fluids before and after taking Norvir may help clear the aftertaste from your mouth.

Taking antacids with Norvir has not been studied.

When to take it

Take your Norvir at regular twelve-hour intervals at about the same time each day. This will have the best effect on the HIV infection. It will also help you remember when to take your medicine

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Norvir helps control your HIV infection but does not cure it. Therefore, Norvir must be taken every day. Continue taking Norvir for as long as your doctor prescribes. If a side effect is preventing you

from taking Norvir, tell your doctor straight away.

Always keep enough Norvir on hand so you don't run out. When you travel or need to stay in the hospital, make sure you have enough Norvir to last until you can get a new supply.

Even if you feel better, do not stop taking Norvir without talking to your doctor. Taking Norvir as recommended should give you the best chance of delaying resistance to the medicines. You may continue to develop infections or other illnesses associated with HIV disease while you are taking Norvir.

If you forget to take it

If it is almost time for you to take your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for hints.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 764766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Norvir. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include tingling, pricking, or numbness of the skin.

While you are using Norvir

Things you must do

If you become pregnant while you are taking this medicine, tell your doctor or pharmacist immediately.

It is not known if Norvir passes into breast milk. To avoid transmitting the infection, mothers with HIV should not breast feed their babies.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Norvir.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon that you are taking this medicine.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not stop taking Norvir, or lower the dosage, without checking with your doctor.

Do not let yourself run out of medicine over weekends or on holidays.

Things to be careful of

Be careful driving or operating machinery until you know how Norvir affects you.

Norvir generally does not cause problems with your ability to drive a

car or operate machinery. However, as with many medicines, Norvir may cause dizziness in some people. Make sure you know how you react to Norvir before you drive a car or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Norvir.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Frequently, it is difficult to tell whether side effects are the result of taking Norvir, effects of the HIV disease or side effects of other medicines you may be taking. For this reason, it is very important to inform your doctor of any change in your condition. Your doctor may want to change your dose or advise you to stop taking Norvir.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea, vomiting
- diarrhoea
- feeling of weakness
- stomach ache
- headache
- tingling sensation
- change in taste sensation
- feeling weak / tired

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

The following side effects have also been reported:

- allergic reactions including skin rashes (may be red, raised, itchy), severe swelling of the skin and other tissues

- difficulty in breathing
- flushing of the skin (vasodilation)
- changes in fat distribution
- dizziness
- inability to sleep (insomnia)
- anxiety
- sleepiness
- numbness
- unusual sensitivity of the skin
- heartburn
- sore throat
- increased cough
- wind (flatulence)
- loss of appetite
- dry mouth
- belching
- mouth ulcer
- sweating
- muscle aches
- fever
- pain
- weight loss
- laboratory test results: changes in blood test results (such as blood chemistry and blood count)

Tell your doctor as soon as possible if you notice any of the following:

- dehydration (thirst)
- diabetes
- jaundice (yellowing of the skin or whites of eyes)
- muscle pain, tenderness or weakness
- hepatitis (inflammation of the liver)

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- severe or life threatening skin reaction including blisters (Stevens Johnson syndrome and Toxic Epidermal Necrolysis)

- serious allergic reaction (anaphylaxis)
- high levels of sugar in the blood

The above list includes very serious side effects. You may need urgent medical attention. These side effects are rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some people. The long-term effects of Norvir are unknown at this time. Tell your doctor if you notice any other effects.

After using Norvir

Storage

Keep your tablets and solution in the pack/bottle until it is time to take them.

If you take the tablets or oral solution out of the box or the blister pack they may not keep well.

Norvir oral solution should NOT be refrigerated. Store at room temperature between 20°C and 25°C. Use before expiry date. It should be stored in the original container with the cap tightly closed and protected from excessive heat. Shake well before use.

Norvir tablets should be stored below 30°C . Store in the original bottle in order to protect from moisture.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill. Do not leave it in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine, or the medicine has passed its expiry

date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Norvir comes in two dosage forms:

Norvir oral solution is an orange-coloured liquid supplied in amber-coloured bottles.

Norvir film coated tablets are white debossed with Abbott logo and the code “NK”

Ingredients

Norvir oral solution contains 600mg/7.5ml of ritonavir dissolved in:

- alcohol
- water
- PEG 35 castor oil and
- propylene glycol.

Other ingredients include:

- saccharin sodium
- citric acid anhydrous
- peppermint oil
- caramel flavouring
- sunset yellow dye (E110)

Norvir film coated tablets contain 100mg ritonavir with the following inactive ingredients:

- copovidone
- calcium hydrogen phosphate anhydrous
- sorbitan monolaurate
- silica - colloidal anhydrous
- sodium stearyl fumarate
- hypromellose
- titanium dioxide
- macrogol 400
- hydroxypropylcellulose
- talc –purified
- macrogol 3350
- polysorbate 80

Supplier

Norvir is supplied in Australia by:

Abbott Australasia Pty Ltd
32-34 Lord St
Botany NSW 2019

Norvir is supplied in New Zealand
by:

Abbott Laboratories NZ Ltd
4 Pacific Rise
Mt Wellington

® Registered Trademark

Australian Registration Number(s)
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AUST R 55004

Norvir film coated tablets 100mg:
AUST R 158301

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