

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 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.

It belongs to a group of medicines called protease inhibitors.

Norvir works by interfering with the 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**

Some of the symptoms of an allergic reaction include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- hives, rash or itching of the skin.

Do not take Norvir if you are currently taking any of the medicines listed under the section "Taking other medicines".

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.

If you are not sure whether you should start taking this medicine, talk to your doctor.

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:

- liver problems or problems with your pancreas.
- you have hepatitis B or C, and are being treated with a combination of antiretroviral agents, as you are at a greater risk of developing serious side effects.
- haemophilia, as there have been reports of increased bleeding in patients with haemophilia who are taking this type of medicine.
- diabetes, as there have been reports of worsening of or the development of diabetes in some patients taking this type of medicine.

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 him or her 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 antiviral medicines, it is important that you also carefully read the leaflets that are provided with these other medicines. They may include 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:

- didanosine, zidovudine, delaviridine, efavirenz, saquinavir, amprenavir, indinavir, nelfinavir, tipranavir, maraviroc, raltegravir (other antiviral treatments);
- astemizole or terfenadine (commonly used to treat allergy symptoms - these medicines may be available without prescription);
- amiodarone, bepridil, dronedarone, encainide, flecainide, propafenone, quinidine, digoxin (used to correct irregular heartbeats);
- ranolazine to treat angina
- colchicine (a treatment for gout) if you have liver or kidney problems;
- dasatinib, ibrutinib, nilotinib, venetoclax, vincristine, vinblastine (used to treat cancer);
- dihydroergotamine, ergotamine (used to treat migraine headache);
- ergometrine, methylergometrine (used to stop excessive bleeding that may occur following childbirth or an abortion);
- clorazepate, diazepam, estazolam, flurazepam, triazolam, midazolam, zolpidem, buspirone (used to help you sleep and/or relieve anxiety);
- clozapine, blonanserin, lurasidone or pimozide, (used to treat abnormal thoughts or feelings);

- fentanyl, pethidine, piroxicam, dextropropoxyphene (used to relieve pain);
- cisapride (used to relieve certain stomach problems);
- rifabutin, bedaquiline, delamanid (used to prevent/treat certain infections);
- ketoconazole, 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 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);
- clarithromycin, sulphamethasone/trimethoprim, fusidic acid (used to treat infections);
- simeprevir (used to treat chronic hepatitis C);
- warfarin, rivaroxaban (used to thin the blood);
- trazodone (used to treat depression);
- fluticasone, budesonide or triamcinolone (cortisone used to treat inflammation);
- disulfiram (used to treat alcohol dependence);
- metronidazole (used to treat certain parasite infections);
- bupropion (used to help smoking cessation);
- bosentan (used to treat a condition called pulmonary arterial hypertension (PAH));

- colchicine (used for the treatment of gout);
- theophylline (used to treat chronic lung conditions).

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 many other medicines that may not mix with Norvir because their effects could potentially 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 or herbal products, including those you have bought yourself. Your doctor may need to prescribe different amounts of your medicine for you to take, or put you on a different medicine altogether.

Check with your doctor or pharmacist who will have a complete list of medicines which interfere with Norvir.

Norvir affects the way oral contraceptives work.

Take care when taking sildenafil, tadalafil, or vardenafil, used for erectile dysfunction. Norvir interacts with these medicines. 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.

It is not recommended that you take simeprevir with Norvir. Norvir interacts with simeprevir resulting in increased plasma concentrations of simeprevir.

How to take Norvir

Follow all directions given to you by your doctor and 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 taken twice a day (7.5mL of oral solution or 6 tablets).

How to take it

Take Norvir with food.

TABLETS:

Swallow tablets whole with a full glass of water.

Do not break, crush or chew.

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.

When to take it

Take your Norvir at regular twelve-hour intervals at about the same time each day.

Taking it at the same time each day will have the best effect. 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 is not a cure for your HIV infection, but helps control it. Therefore, Norvir must be taken every day.

Tell your doctor straight away if a side effect is preventing you from taking Norvir.

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.

Do not stop taking Norvir without talking with your doctor, even if you feel better.

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 you forget to take it and 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.

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

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

Ask your doctor or pharmacist if you are not sure what to do.

Ask your pharmacist for hints if you have trouble remembering when to take your medicine.

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, prickling, or numbness of the skin.

While you are using Norvir

Things you must do

Tell your doctor or pharmacist immediately if you become pregnant while you are taking this medicine.

Norvir may pass into breast milk. To avoid transmitting the infection, mothers with HIV should not breast feed their babies.

Remind your doctor that you are taking Norvir if you are about to be started on any new medicine.

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

Tell your surgeon that you are taking this medicine if you are going to have surgery.

Tell your doctor that you are taking this medicine if you are about to have any blood tests.

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 take 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 change the dosage, without checking with your doctor.

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, sleepiness and nausea in some people.

Make sure you know how you react to Norvir before you drive a car or operate machinery.

Norvir oral solution contains alcohol.

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
- 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 (high sugar levels in the blood which may be accompanied by symptoms like frequent

urination, excessive thirst, lack of energy)

- 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.

After using Norvir

Storage

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

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

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Keep your oral solution in a cool dry place where the temperature stays between 20°C and 25°C.

Do not store Norvir oral solution in the fridge.

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 is left over.

Product description

What it looks like

Norvir comes in two dosage forms:

- Norvir oral solution is an orange-coloured liquid supplied in 90mL bottles,
- Norvir film coated tablets are white debossed with Abbott logo and the code "NK", and are supplied in bottles containing 30 tablets.

Ingredients

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

- alcohol (43.2% v/v)
- water
- PEG 35 castor oil and
- propylene glycol.

Other ingredients include:

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

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

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

Supplier

Norvir is supplied in Australia by:

AbbVie Pty Ltd
241 O'Riordan Street
Mascot NSW 2020
Australia
ABN: 48 156 384 262

Norvir is supplied in New Zealand by:

AbbVie Limited
6th Floor, 156-158 Victoria St
Wellington, 6011
New Zealand
® Registered Trademark

Australian Registration Number(s)
Norvir Oral Solution 600mg/7.5mL:
AUST R 55004

Norvir film coated tablets 100mg:
AUST R 158301

This leaflet was prepared in
May 2018

Version 19