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## WHAT IS IN THIS LEAFLET

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This leaflet answers some common questions about NORVIR.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking NORVIR against the benefits they expect it will have on you.

**If you have any concerns about taking this medicine, talk to your doctor or pharmacist.**

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

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## WHAT IS NORVIR USED FOR

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NORVIR contains ritonavir which is a protease inhibitor used to control HIV (Human Immunodeficiency Virus) infections. It helps control the HIV infection 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.

The safety and efficacy in children under 12 years of age has not been established

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.

NORVIR is available only with a doctor's prescription. NORVIR is not addictive.

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## BEFORE YOU TAKE NORVIR

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### Do not take NORVIR if

- you have an allergy to the active ingredient, ritonavir
- you are allergic to 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".
- the packaging is torn or shows signs of tampering
- the expiry date printed on the pack has passed. If you take this medicine after the expiry date has passed, it may not work.

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.

**If you are not sure whether you should start taking NORVIR, talk to your doctor.**

### Before you start to take or are given NORVIR you must tell your doctor if

- you are pregnant or plan to become pregnant. Your doctor will discuss the risks and benefits of taking NORVIR when pregnant.
- you are breastfeeding or plan to breastfeed. Your doctor will discuss the risks and benefits of taking NORVIR when breastfeeding.
- 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.
- 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 for impotence (erectile dysfunction) if you also suffer from a lung disease called pulmonary arterial hypertension that makes breathing difficult. Patients without this disease may use sildenafil 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)
- bupropion (used to help quit smoking)

**If you have not told your doctor or pharmacist about any of the above, tell them before you start taking or are given NORVIR.**

## **Taking other medicines**

**It is important to tell your doctor if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.**

Your doctor or pharmacist has a complete list of medicines which interfere with NORVIR. Some of the medicines you must avoid while taking NORVIR are listed below:

- 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, methylergometrine (used to stop excessive bleeding that may occur following childbirth or an abortion);

There are many other drugs which may be affected by NORVIR. Your doctor may need to prescribe different amounts of your medicine for you to take. Check with your doctor who will have a complete list of medicines which interfere with NORVIR.

## **Other interactions**

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.

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## HOW TO TAKE NORVIR?

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### How much to take and when to take it

**Take NORVIR only when prescribed by your doctor. Norvir may be prescribed in combination with other appropriate medicines. Your doctor will tell you 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 capsules).

**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.

**Follow all directions given to you by your doctor carefully.** This 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 to take it

NORVIR is administered orally and should preferably be taken with meals.

The oral solution dosage cup should be cleaned immediately with hot soapy water after use. The dosage cup must be dry prior to use. Shake the bottle well before 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.

### How long to take it

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.**

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

If you have trouble remembering to take your NORVIR, ask your pharmacist for some hints.

### If you take too much NORVIR (overdose)

**Immediately telephone your doctor or Poisons Information Centre (telephone 13**

11 26) for advice, or go to casualty at your nearest hospital if you think that 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. Keep telephone numbers for these places/services handy.

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## WHILE YOU ARE TAKING NORVIR

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### Things you must do

**Tell your doctor if you become pregnant while taking NORVIR.**

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

**Tell your doctor or pharmacist that you are taking NORVIR if you are about to be started on any new medicine.**

**Tell all the doctors, dentists, and pharmacists who are treating you that you are taking NORVIR.**

### Things you must not do:

**Do not stop taking NORVIR or change the dose without first checking with your doctor. Do not let yourself run out of medicine over weekends or on holidays.**

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

### 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.

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## POSSIBLE SIDE EFFECTS

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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.**

### While you are taking NORVIR

Tell your doctor if you experience any of the following:

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

These are the more common side effects of NORVIR.

Side effects including allergic reactions, difficulty in breathing, flushing of the skin, inability to sleep, anxiety, sleepiness, numbness, unusual sensitivity of the skin, heart burn, sore throat, increased cough, wind, loss of appetite, dry mouth, belching, mouth ulcer, sweating, muscle aches, fever, pain, body fat changes, and weight loss have also been reported.

Rare side effects include severe or life threatening skin reaction including blisters, severe allergic reaction and high levels of sugar in the blood.

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

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

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## AFTER USING NORVIR

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### Storage

NORVIR soft capsules should be refrigerated at 2-8o C. However, refrigeration is not required if you use the capsules within 30 days and store them below 25o C. Do not freeze the capsules and protect them from excessive heat.

NORVIR oral solution should NOT be refrigerated. Store at room temperature between 20oC and 25oC. 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.

### Disposal

**If your doctor tells you to stop taking NORVIR, or your medicine has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.**

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## PRODUCT DESCRIPTION

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### What it looks like

NORVIR comes in two dosage forms:

**NORVIR Soft capsules** are white capsules imprinted with the Abbott logo, "DS" and

"100", and are available in bottles containing 84 capsules.

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

### Ingredients

Each NORVIR capsule contains:

- 100mg of ritonavir dissolved in ethanol
- oleic acid
- butylated hydroxytoluene
- PEG 35 castor oil

Other ingredients include:

- gelatin
- sorbitol special
- glycerol
- titanium dioxide (white colour)
- coconut oil
- lecithin and black ink containing propylene glycol
- black iron oxide
- polyvinyl acetate phthalate
- polyethylene glycol
- ammonium hydroxide

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 and sunset yellow dye (E110).

### Manufacturer

NORVIR is distributed by:

Abbott Laboratories (NZ) Ltd  
4 Pacific Rise  
Mt Wellington  
Auckland  
New Zealand

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