

NORVIR(R)

NORVIR(R) Ritonavir Soft Capsules 100mg

NORVIR(R) Ritonavir Oral Solution 600mg/7.5ml

CONSUMER MEDICINE INFORMATION

PLEASE READ THIS INFORMATION CAREFULLY

What is in this leaflet

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.

What NORVIR is used for

NORVIR is used in the treatment of HIV (Human Immunodeficiency Virus) infections. 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 belongs to a group of medicines called HIV protease

inhibitors. It helps control the HIV infection by inhibiting or interfering with the protease enzyme that the HIV virus needs to infect new cells.

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.

Before you take NORVIR

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
- * 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 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.

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.

Some medicines should not be used with NORVIR. Your doctor or pharmacist will advise you which medicines to be careful with or avoid while taking NORVIR.

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

Anti-Migraine Drugs:

Ergotamine

Dihydroergotamine

Anticoagulant Drugs:

Warfarin

Analgesics/Narcotics:

Pethidine, Dextropropoxyphene,

Piroxicam, Meperidine,

Propoxyphene

Antidepressants:

Bupropion

Antiinfectives:

Rifabutin

Cardiovascular agent:

Amiodarone, Flecainide, Quinidine

Gastrointestinal agents:

Cisapride

Lipid Lowering Agents:

Simvastatin

Psychotropics:

Clozapine, Pimozide Alprazolam,

Clorazepate, Diazepam, Midazolam,

Triazolam, Zolpidem

Other:

St. John's Wort (Hypericum perforatum).

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.

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

How to take NORVIR

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(R), ADVERA(R) 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. 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.

While you are taking NORVIR

Things you must do:

Tell your doctor if you become pregnant while taking NORVIR.

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.

Side Effects

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
- * abdominal pain
- * headache
- * tingling sensation
- * change in taste sensation

These are the more common side effects of NORVIR.

Side effects including fits, body fat changes, dehydration (possibly from nausea and/or diarrhoea), fainting and renal problems have been reported.

Rare side effects include throat irritation, dizziness, muscle aches and pains, and rash.

Other effects include diabetes or increased sugar levels in the blood.

Other side effects not listed may also occur in some patients. The longterm 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.

After using NORVIR

Storage

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

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

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.

Product Description

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 and 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 and 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 Australasia Pty Ltd
32-34 Lord Street
Botany NSW 2019
Ph: 1800 225 311

Australian registration numbers

**NORVIR Ritonavir Soft Capsules
100mg:**

AUST R 70048

**NORVIR Ritonavir Oral Solution
600mg/7.5mL:**

AUST R 55004

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5 July 2006

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