

# NORVIR®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

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### 1. Why am I taking Norvir?

Norvir contains the active ingredient ritonavir. Norvir is used to treat HIV (Human Immunodeficiency Virus) infection.

For more information, see Section [1. Why am I taking Norvir?](#) in the full CMI.

### 2. What should I know before I take Norvir?

Check the list of ingredients at the end of the CMI. Do not take Norvir if you have ever had an allergic reaction to any of them.

**Talk to your doctor before you take this medicine if he/she is not aware that you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I take Norvir?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Norvir and affect how it works, or Norvir may interfere with other medicines and affect how they work.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take Norvir?

- Take six tablets, all together, in the morning and six tablets, all together, in evening every day
- Take Norvir during a meal or immediately after a meal.

More instructions can be found in Section [4. How do I take Norvir?](#) in the full CMI.

### 5. What should I know while taking Norvir?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• If you have diabetes, monitor your sugar levels regularly</li><li>• Remind any doctor, dentist, or pharmacist you visit that you are taking Norvir.</li></ul>
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<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>• Do not stop taking this medicine, or change the dose unless your doctor tells you to.</li> <li>• Do not give this medicine to a child younger than 12 years of age.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>• There is no specific information on the effect of Norvir on your ability to drive or use machines.</li> </ul>
<p><b>Drinking alcohol</b></p>	<ul style="list-style-type: none"> <li>• There is no information on the effects of taking Norvir with alcohol.</li> </ul>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>• Keep Norvir in a cool dry place.</li> <li>• Keep Norvir in the bottle until it is time to take your dose.</li> </ul>

For more information, see Section [5. What should I know while taking Norvir?](#) in the full CMI.

## **6. Are there any side effects?**

Go to your nearest hospital if you experience: a sudden, intense skin reaction; symptoms of an allergic reaction, such as difficulty breathing, swelling of the face, lips or

tongue, hives, rash or itching; or you have very high sugar levels in the blood.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Norvir<sup>®</sup> (nor-veer)

**Active ingredient:** *ritonavir* (rit-on-a-veer)

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## Consumer Medicine Information (CMI)

This leaflet provides important information about taking Norvir. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Norvir.**

### Where to find information in this leaflet:

1. Why am I taking Norvir?
- [2. What should I know before I take Norvir?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Norvir?](#)
- [5. What should I know while taking Norvir?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking Norvir?

**Norvir contains the active ingredient ritonavir.**

**Norvir is used to treat HIV (Human Immunodeficiency Virus) infection, the virus that causes AIDS.**

## 2. What should I know before I take Norvir?

### Warnings

#### Do not take Norvir if:

- you are allergic to ritonavir, or any of the ingredients listed at the end of this leaflet.

#### Check with your doctor if you:

- have diabetes
- have or have had problems with your liver
- have or have had problems with your heart, such as irregular heart beats
- have high cholesterol or high triglycerides (a type of fat found in the blood)
- have or have had had any problems with your pancreas
- have haemophilia (a bleeding disorder)
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

Make sure your doctor is aware that you are pregnant or plan to become pregnant or are breastfeeding or intend to breastfeed.

## Use in children

- Norvir is not suitable for use in children younger than 12 years of age.

## 3. What if I am taking other medicines?

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

**Some medicines may interfere with Norvir and affect how it works, while Norvir may affect how other medicines work.**

**Do not take Norvir if you are taking any of the following medicines:**

- **alfuzosin**, a medicine used to treat an increase in the size of the prostate gland (not due to cancer)
- **ranolazine**, a medicine used to treat angina
- **amiodarone, flecainide, propafenone, encainide**, medicines used to treat marked changes in heart rhythm

- **bepriidil**, a medicine that causes blood vessels to relax and widen which improves oxygen supply to the heart, and lowers blood pressure
- **dronedarone, quinidine**, medicines used to treat certain heart conditions
- **fusidic acid**, a medicine used to treat infections caused by bacteria (antibiotic)
- **neratinib**, a medicine used to treat breast cancer
- **apalutamide**, a medicine used to treat prostate cancer
- **venetoclax**, a medicine used to treat certain blood cancers
- **voriconazole**, a medicine used to treat or prevent fungal infections
- **colchicine**, a medicine used to relieve pain in patients with gout
- **astemizole, terfenadine**, medicines used to treat allergies (antihistamine)
- **rifabutin**, a medicine used to treat serious infections caused by certain bacteria (antibiotic)
- **blonanserin, clozapine, lurasidone, pimozide**, medicines used to treat certain mental and emotional conditions
- **dihydroergotamine, ergometrine, ergotamine, methylergometrine**, medicines used to treat migraine and headaches, and/or in childbirth
- **cisapride**, a medicine used to treat reflux or indigestion
- **St John's wort**, a herbal product used to improve mood

- **lovastatin, simvastatin, lomitapide**, medicines used to lower cholesterol
- **salmeterol**, a medicine used to treat severe lung conditions, including asthma and chronic obstructive pulmonary disease (COPD)
- **piroxicam**, a medicine used to treat the symptoms of arthritis
- **sildenafil**, when used to treat high blood pressure in the lungs
- **pethidine**, a medicine used in surgery, during childbirth and to treat strong pain
- **dextropropoxyphene**, a medicine used to treat pain
- **clorazepate, diazepam, estazolam, flurazepam, midazolam, triazolam, zolpidem**, medicines that work in the brain to help you sleep.

**Medicines that may increase the effect of Norvir include:**

- delaviridine, a medicine used to treat HIV
- fluconazole, a medicine used to treat or prevent fungal infections.

**Medicines that may reduce the effect of Norvir include:**

- St John's wort, a herbal product used to improve mood (*See above list of medicines to avoid while taking Norvir.*)
- elagolix, a medicine used to treat pain associated with endometriosis in women.

**Medicines where Norvir may increase their effect include:**

- alfuzosin, a medicine used to treat an increase in the size of the prostate gland (not due to cancer) (*See above list of medicines to avoid while taking Norvir.*)
- ranolazine, a medicine used to treat angina (*See above list of medicines to avoid while taking Norvir.*)
- amiodarone, flecainide, propafenone, ecainide, medicines to treat marked changes in heart rhythm (*See above list of medicines to avoid while taking Norvir.*)
- bepridil, a medicine that causes blood vessels to relax and widen which improves oxygen supply to the heart and lowers blood pressure (*See above list of medicines to avoid while taking Norvir.*)
- dronedarone, quinidine, medicines used to treat certain heart conditions (*See above list of medicines to avoid while taking Norvir.*)
- fusidic acid, a medicine used to treat infections caused by bacteria (antibiotic) (*See above list of medicines to avoid while taking Norvir.*)
- neratinib, a medicine used to treat breast cancer (*See above list of medicines to avoid while taking Norvir.*)
- apalutamide, a medicine used to treat prostate cancer (*See above list of medicines to avoid while taking Norvir.*)
- venetoclax, a medicine used to treat certain blood cancers (*See above list of medicines to avoid while taking Norvir.*)
- colchicine, a medicine used to relieve pain in patients with gout (*See above list of medicines to avoid while taking Norvir.*)

- astemizole, terfenadine, medicines used to treat allergies (antihistamine) (*See above list of medicines to avoid while taking Norvir*)
- rifabutin, a medicine used to treat serious infections caused by certain bacteria (antibiotic) (*See above list of medicines to avoid while taking Norvir.*)
- blonanserin, clozapine, lurasidone, pimozide, medicines used to treat certain mental and emotional conditions (*See above list of medicines to avoid while taking Norvir.*)
- dihydroergotamine, ergometrine, ergotamine medicines used to treat migraine and headaches (*See above list of medicines to avoid while taking Norvir.*)
- methylergometrine a medicine used in childbirth (*See above list of medicines to avoid while taking Norvir*)
- cisapride, a medicine used to treat reflux or indigestion (*See above list of medicines to avoid while taking Norvir.*)
- lovastatin, simvastatin, lomitapide, medicines used to lower cholesterol (*See above list of medicines to avoid while taking Norvir.*)
- salmeterol, a medicine used to treat severe lung conditions, including asthma and chronic obstructive pulmonary disease (COPD) (*See above list of medicines to avoid while taking Norvir.*)
- piroxicam, a medicine used to treat the symptoms of arthritis (*See above list of medicines to avoid while taking Norvir.*)
- sildenafil, when used to treat high blood pressure in the lungs (*See above list of medicines to avoid while taking Norvir.*)

- pethidine, a medicine used in surgery, during childbirth and to treat strong pain (*See above list of medicines to avoid while taking Norvir.*)
- dextropropoxyphene, a medicine used to treat pain (*See above list of medicines to avoid while taking Norvir.*)
- clorazepate, diazepam, estazolam, flurazepam, midazolam, triazolam, zolpidem, medicines that work in the brain to help you sleep (*See above list of medicines to avoid while taking Norvir.*)
- lignocaine, a medicine taken to treat irregular heart beats
- disopyramide, mexiletine, medicines used to treat marked changes in heart rhythm
- efavirenz, saquinavir, aprenavir, indinavir, nelfinavir, tipranavir, atazanavir, darunavir, fosamprenavir, maraviroc, medicines used to treat HIV
- simeprevir, glecaprevir, pibrentasvir, medicines used to treat hepatitis C
- fentanyl, hydrocodone, oxycodone, tramadol, medicines used to treat strong pain
- alfentanil, a medicine used to treat strong pain or to put you to sleep while you have a procedure or operation
- methadone, a medicine used to treat strong pain and to help with addiction to drugs like heroin
- digoxin, a medicine used to treat certain heart conditions
- abemaciclib, tamoxifen medicines used to treat breast cancer

- decatinib, ibrutinib, ivosidenib, nilotinib, fostamatinib, dasatinib, ivosidenib, medicines used to treat certain blood cancers
- encorafenib, a medicine used to treat melanoma, a type of skin cancer
- vincristine, vinblastine, paclitaxel, everolimus, medicines used to treat several different cancers
- etoposide, a medicine used to treat certain cancers, including some blood cancers.
- bromocriptine, a medicine used to treat certain conditions due to problems with hormone balance
- warfarin a medicine used to thin the blood
- rivaroxaban, a medicine used to prevent blood clots
- trazodone, amitriptyline, imipramine, nortriptyline, trimipramine, nefazodone, sertraline, fluoxetine, venlafaxine, medicines used to treat depression
- ketoconazole, itraconazole, miconazole, medicines used to treat or prevent fungal infections
- clarithromycin, erythromycin, trimethoprim, medicines used to treat infections caused by bacteria (antibiotic)
- bedaquiline, delamanid, rifampicin, medicines used to treat tuberculosis and other serious infections
- quetiapine, chlorpromazine, haloperidol risperidone, thioridazine, clomipramine, paroxetine, medicines used to treat certain mental and emotional conditions
- fluticasone, a steroid used to treat conditions of the nasal passages and asthma
- budesonide, dexamethasone, prednisone, triamcinolone, steroids used in various conditions where there is inflammation

- finasteride a medicine used to treat an increase in the size of the prostate gland (not due to cancer)
- flutamide, a medicine used to treat prostate cancer
- levonorgestrel, medroxyprogesterone, norethisterone, medicines used in certain contraceptive pills and hormone replacement therapies
- testosterone, the male hormone, used when levels are low
- disulfiram a medicine used to treat alcohol dependency
- metronidazole, a medicine used to treat serious infections caused by bacteria and parasites
- avanafil, sildenafil, tadalafil, vardenafil, when used to treat erectile dysfunction
- atorvastatin, rosuvastatin, fluvastatin, pravastatin, medicines used to lower cholesterol
- bosentan, a medicine used to treat high blood pressure in the lungs
- triamterene, a medicine used to treat a buildup of fluid
- carbamazepine, ethosuximide, medicines used to treat epilepsy to prevent convulsions, fits
- clonazepam, a medicine that works in the brain used to treat anxiety and to relax muscles
- buspirone, a medicine used to help relieve anxiety symptoms
- loratadine, a medicine used to treat allergies (antihistamine)
- ondansetron, a medicine used to treat nausea and vomiting
- quinine, a medicine used to treat malaria

- metoprolol, pindolol, medicines used to treat high blood pressure and other heart conditions such as abnormal heart rhythms and angina
- timolol, a medicine used to reduce pressure inside the eye
- amlodipine, diltiazem, felodipine, nifedipine, verapamil, medicines that cause blood vessels to relax and widen which improves oxygen supply to the heart, and lowers blood pressure
- nimodipine, a medicine used in the treatment of patients who have experienced bleeding on the brain
- ciclosporin, a medicine used for suppressing the immune system to treat various conditions
- tacrolimus, sirolimus, medicines used to help in organ transplants
- dextromethorphan, a medicine used in some cough mixtures.

**Medicines where Norvir may reduce their effect include:**

- apalutamide, a medicine used to treat prostate cancer (*See above list of medicines to avoid while taking Norvir.*)
- voriconazole, a medicine used to treat or prevent fungal infections (*See above list of medicines to avoid while taking Norvir*)
- didanosine, zidovudine, raltegravir, medicines used to treat HIV
- sulfamethoxazole, a medicine used to treat infections caused by bacteria (antibiotic)

- alprazolam, a medicine used to treat certain mental and emotional conditions
- ethinyloestradiol, a medicine used in certain contraceptive pills and hormone replacement therapies
- contraceptive patch, a small sticky patch that releases hormones into your body through your skin to prevent pregnancy
- bupropion, a medicine used to assist in giving up smoking cigarettes
- theophylline, a medicine used to prevent and treat certain lung conditions, such as asthma, bronchitis, emphysema.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Norvir.**

## **4. How do I take Norvir?**

### **How much to take**

- Take six tablets all together in the morning and six tablets all together in the evening every day.

### **When to take Norvir**

- Take Norvir during a meal or immediately after a meal.
- Do not break, crush, or chew the tablets. Swallow them whole with a full glass of water

In some instances, Norvir needs to be taken with other medicines. Your doctor will let you know which medicines, how to take them and how long to take them.

Please look for the QR code on the medicine pack. Scan this code with your smart phone for more information on Norvir.

## **If you forget to take Norvir**

It is important that you take Norvir at the same time each day.

If you miss your dose, and it is nearly time for your next dose, skip the missed tablets and take your next dose at the usual time.

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

## **If you take too much Norvir**

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there appear to be no signs of discomfort or poisoning.**

## **5. What should I know while taking Norvir?**

### **Things you should do**

Speak to your doctor about how to avoid passing on HIV to others, even though you are taking Norvir.

### **Call your doctor straight away if you:**

- become pregnant while you are taking Norvir
- are diabetic and your blood sugar levels are no longer controlled
- notice blurred vision.

Keep all your appointments, including for blood tests. Some side effects are picked up in blood tests even before you have any symptoms.

When you are having any blood tests, tell the clinic you are taking Norvir.

Remind any doctor, dentist or pharmacist you visit that you are taking Norvir.

### **Things you should not do**

- Do not stop using this medicine suddenly or change the dose without checking with your doctor.
- Do not give this medicine to a child younger than 12 years of age.

## **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how Norvir affects you.

## **Looking after your medicine**

Follow the instructions on the bottle on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example:

- do not store it in the bathroom or near a sink, or
- do not store it in the car or on window sills.

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If your doctor advises that you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

**Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<p><b>Gut:</b></p> <ul style="list-style-type: none"><li>• diarrhoea</li><li>• feeling sick or vomiting</li><li>• heartburn</li><li>• loss of appetite</li><li>• change in how certain foods taste</li><li>• dry mouth</li><li>• mouth ulcer</li><li>• tummy pain</li><li>• indigestion</li><li>• wind</li></ul> <p><b>Brain and nerves:</b></p> <ul style="list-style-type: none"><li>• headache</li><li>• feeling dizzy</li><li>• difficulty sleeping</li></ul> <p><b>Skin:</b></p> <ul style="list-style-type: none"><li>• rash</li><li>• tingling, prickling or numbness on the skin</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<p><b>General:</b></p> <ul style="list-style-type: none"> <li>• feeling weak or tired</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>General:</b></p> <ul style="list-style-type: none"> <li>• symptoms of a build-up of lactic acid in the body, including nausea, vomiting, pain in the tummy, difficulty breathing, severe weakness in the legs and arms</li> <li>• symptoms of diabetes, including feeling thirsty, needing to pass urine frequently, blurred vision, sudden loss of weight</li> <li>• symptoms of an infection, including fever, chills, a cold or flu, problems with your teeth or gums, pain when passing urine, blood in the urine</li> </ul>	<p><b>Call your doctor straight away, if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● stiffness, aches and pains in the joints, especially the hip, knee or shoulder, and difficulty moving</li> <li>● yellowing of the skin or eyes</li> <li>● sharp pain in the side or back, burning when passing urine, blood in the urine.</li> </ul>	

### **Very serious side effects**

<b>Very serious side effects</b>	<b>What to do</b>
<p><b>Skin:</b></p> <ul style="list-style-type: none"> <li>● a sudden, intense skin reaction</li> </ul> <p><b>General:</b></p> <ul style="list-style-type: none"> <li>● symptoms of very high sugar levels, including headache, blurred vision, confusion, needing to pass urine frequently, nausea and vomiting, tummy pain</li> </ul>	<p><b>Go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</b></p>

<b>Very serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>symptoms of a severe allergic reaction (anaphylaxis), including difficulty breathing, swelling of the face, lips, tongue or other parts of the body, hives, rash or itching of the skin.</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

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

## What Norvir contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"><li>● ritonavir</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>● copovidone</li><li>● calcium hydrogen phosphate</li><li>● sorbitan monolaurate</li><li>● hypromellose</li><li>● colloidal anhydrous silica</li><li>● titanium dioxide</li><li>● sodium stearyl fumarate</li><li>● macrogol 400</li><li>● hypromellose</li><li>● purified talc</li><li>● macrogol 3350</li><li>● polysorbate 80</li></ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

## What Norvir looks like

Ritonavir tablets are white film-coated oval tablets debossed with "NK" on one side.

Norvir are supplied in a bottle of 30 or 60 tablets (Aust R 158301).

(Not all presentations may be available)

## **Who distributes Norvir?**

Norvir is distributed in Australia by:

AbbVie Pty Ltd

241 O’Riordan Street

MASCOT NSW 2020

Australia

This leaflet was prepared in 16 December 2022.

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