

# **Consumer Medicine Information (CMI) summary**

The <u>full CMI</u> on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

# 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, while 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 in the morning and six tablets in the evening every day
- The six tablets in each dose should be taken together. Do not break, crush, or chew the tablets. Swallow them whole with a full glass of water.
- 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/using [Medicine name]?

Things you should do	<ul> <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>
Things you should not do	<ul> <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>
Driving or using machines	Do not drive or use machines if you feel dizzy while taking Norvir.
Drinking alcohol	There is no information on the effects of taking Norvir with alcohol.
Looking after your medicine	<ul> <li>Keep Norvir in a cool dry place, below 30°C.</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.



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

# **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 takeNorvir?
- 3. What if I am taking other medicines?
- 4. How do I takeNorvir?
- 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 <u>6</u>. 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.

## **Smoking**

Tobacco can decrease the effect of ritonavir.

# 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 enlarged 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
- bepridil, 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
- 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 (antihistamines)
- 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 during 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)
- **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 (when taken by mouth), triazolam, zolpidem, medicines that work in the brain to help you sleep.

## Medicines that may <u>increase</u> the effect of Norvir include:

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

# Medicines that may reduce the effect of Norvir include:

 elagolix, a medicine used to treat pain associated with endometriosis in women

# Medicines where Norvir may <u>increase</u> their effect include:

- lignocaine, a medicine taken to treat irregular heart beats
- disopyramide, mexiletine, medicines used to treat marked changes in heart rhythm
- efavirenz, saquinavir, amprenavir, indinavir, nelfinavir, tipranavir, atazanavir, darunavir, fosamprenavir, maraviroc, medicines used to treat HIV infection
- 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
- digoxin, a medicine used to treat certain heart conditions
- abemaciclib, tamoxifen, medicines used to treat breast cancer
- ibrutinib, ivosidenib, nilotinib, fostamatinib, dasatinib, venetoclax, 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
- 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
- avanafil, sildenafil, tadalafil, vardenafil, when used to treat erectile dysfunction
- atorvastatin, rosuvastatin, medicines used to lower cholesterol
- bosentan, a medicine used to treat high blood pressure in the lungs
- 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
- loratidine, 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 <u>reduce</u> their effect include:

- didanosine, zidovudine, raltegravir, medicines used to treat HIV infection
- 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.
- methadone, a medicine used to treat strong pain and to help with addiction to drugs like heroin
- warfarin a medicine used to thin the blood

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 in the morning and six tablets in the evening every day.
- The six tablets in each dose should be taken together.

#### 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 National Poisons Centre by calling 0800 POISON (0800 764766), 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**

Do not drive or use machines if you feel dizzy while taking Norvir.

This medicine is not addictive.

# 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, below 30°C, 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 windowsills.

## 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

Less serious side effects	What to do
Less serious side effects  Gut:  diarrhoea feeling sick or vomiting heartburn change in how certain foods taste mouth ulcer sore throat tummy pain indigestion wind Brain and nerves: feeling dizzy Skin: rash flushing or feeling hot tingling, prickling or numbness on the skin  General: feeling weak or tired increased cough abnormally heavy periods.	What to do  Speak to your doctor if you have any of these less serious side effects and they worry you.

# **Serious side effects**

Serious side effects	What to do
<ul> <li>Symptoms of inflammation of the pancreas, including pain in the belly, that can be felt in your back, or feels worse after eating, fever, rapid pulse, feeling sick, vomiting</li> <li>symptoms of diabetes, including feeling thirsty, needing to pass urine frequently, blurred vision, sudden loss of weight</li> <li>symptoms of immune reconstitution syndrome including nausea, vomiting, abdominal pain, difficulty breathing, severe weakness, headache, swollen glands</li> <li>muscle aches (pain), tenderness or weakness; stiffness, aches and pains in the joints, especially the hip, knee or shoulder, and difficulty moving</li> <li>symptoms of jaundice, including yellowing of the skin or whites of the eyes</li> <li>sharp pain in the side or back, burning when passing urine, blood in the urine.</li> </ul>	Call your doctor straight away, if you notice any of these serious side effects.

# Very serious side effects

Very serious side effects	What to do
Skin:  a sudden, intense skin reaction  General:  symptoms of very high sugar levels, including headache, blurred vision, confusion, needing to past urine frequently, nausea and vomiting, tummy pain  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.	Go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.

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 any side effects to <a href="https://pophealth.my.site.com/carmreportnz/s/">https://pophealth.my.site.com/carmreportnz/s/</a>. 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**

Active ingredient (main ingredient)	Ritonavir
Other ingredients (inactive ingredients)	<ul> <li>copovidone</li> <li>calcium hydrogen phosphate</li> <li>silica, colloidal anhydrous</li> <li>sodium stearyl fumarate</li> <li>sorbitan laurate</li> <li>hypromellose</li> <li>titanium dioxide (E171)</li> <li>macrogols</li> <li>hydroxypropyl cellulose</li> <li>talc</li> <li>polysorbate 80</li> </ul>

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

# What Norvir looks like

Norvir 100 mg film-coated tablets are white oval tablets debossed with "NK" on one side.

Norvir tablets are supplied in a bottle of 30 tablets.

# Who distributes Norvir?

Norvir is distributed in New Zealand by:

AbbVie Limited

6th Floor, 156-158 Victoria St

Wellington, 6011

**New Zealand** 

Phone: 0800 900 030

This leaflet was prepared in December 2023.

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