

Patient Information Leaflet

SCHEDULING STATUS

Schedule 4

PRODUCT NAME strength pharmaceutical form

NORVIR 100 mg TABLET

NORVIR® Oral Powder 100 mg Powder for Oral Suspension

Active Substance

Ritonavir

Sugar /sweetner status

NORVIR 100 mg TABLET sugar free

NORVIR® Oral Powder sugar free

Read all this leaflet carefully before you start taking NORVIR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- NORVIR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What NORVIR is used for
2. What you need to know before you take NORVIR
3. How to take NORVIR
4. Possible side effects
5. How to store NORVIR
6. Contents of the pack and other information

1. What NORVIR is and what it is used for

NORVIR is in a class of medicines called the HIV protease inhibitors. NORVIR is used in combination with other anti-HIV medicines to treat human immunodeficiency virus (HIV) infection.

2. What you need to know before you take NORVIR

Do not take NORVIR:

- If you are hypersensitive (allergic) to ritonavir or any of the other ingredients of NORVIR as listed in 'other ingredients' see below section 6
- If you have severe liver disease
- Do not take NORVIR if you are taking any of the following medications
 - amiodarone, bepridil, encainide, flecainide, propafenone, quinidine, digoxin
(used to correct irregular heart beat)
 - apalutamide (used for prostate cancer)
 - neratinib (used for breast cancer)
 - cisapride (used to relieve some types of stomach problems)
 - dihydroergotamine, ergotamine, (used to treat migraine headache)
 - lovastatin and simvastatin (used to treat elevated cholesterol)
 - midazolam, triazolam (used to relieve anxiety and/or trouble sleeping)
 - pimozide (used to treat schizophrenia)
 - quetiapine (used to treat schizophrenia, bipolar disorder and major depressive disorder)
 - lurasidone (used to treat depression)
 - ranolazine (used to treat chronic chest pain [angina])
 - lomitapide (used to lower blood cholesterol)
 - alfuzosin (used to treat enlarged prostate gland)
 - fusidic acid (used to treat infections)
 - avanafil or vardenafil (used to treat erectile dysfunction)

- colchicine (used to treat gout) if you have kidney and/or liver problems
- rifampicin (used to treat tuberculosis and leprosy)
- salmeterol (used to treat asthma)
- sildenafil (used to treat pulmonary arterial hypertension)
- St. John's Wort (herbal product sold as a dietary supplement)
- Voriconazole (used for treatment of fungal infections)

Warnings and precautions

- If you are taking certain medicines (see **Other medicines and NORVIR**). These could cause serious side effects that could cause death. Before you take NORVIR, you must tell your doctor about all the medicines you are taking or are planning to take. These include other prescription and non-prescription medicines and herbal supplements.
- Some patients taking NORVIR can develop serious problems with their pancreas (pancreatitis), which may cause death. Tell your doctor as soon as possible if you have nausea, vomiting, or abdominal pain. These may be signs of pancreatitis.
- Blood tests in patients taking NORVIR may show possible liver problems. People with liver disease such as Hepatitis B and Hepatitis C who take NORVIR may have worsening liver disease. Liver problems including rare cases of death have occurred in patients taking NORVIR. It is unclear if NORVIR caused these liver problems because some patients had other illnesses or were taking other medicines.
- Some patients have large increases in triglycerides and cholesterol (fats in the blood).
- Diabetes and high blood sugar (hyperglycemia) may occur if you are taking protease inhibitors such as NORVIR. You may develop diabetes before starting protease inhibitors. If you are taking NORVIR your diabetes medication may need changing.

- If you have liver problems or are infected with Hepatitis B or Hepatitis C (an infection of the liver). Talk to your doctor before taking NORVIR.

- If you have haemophilia (a disease that affects the ability of your blood to clot properly and causes increased bleeding) and are taking protease inhibitors such as NORVIR you may have increased bleeding. It is not known whether the protease inhibitors caused these problems. Be sure to tell your doctor if you have haemophilia types A and B.

- Changes in body fat have been seen in patients taking medicines such as NORVIR to treat HIV. These changes may include increased amount of fat in the upper back and neck ('buffalo hump'), breast and around the trunk. Loss of fat from the legs, arms and face may also happen.

- NORVIR does not reduce the risk of passing HIV to others through sexual contact or blood contamination. Continue to practice safe sex and do not use or share dirty needles.

- NORVIR does not cure HIV infection or AIDS. People taking NORVIR may still get opportunistic infections or other conditions that happen with HIV infection.

- If you are feeling sick (nausea), vomiting (throwing up) or have stomach pain, these may be signs of inflammation of the pancreas (pancreatitis). Some patients taking NORVIR can develop serious problems with their pancreas. Tell your doctor as soon as possible if this applies to you.

- Some patients with advanced HIV infection (AIDS) who then start anti-HIV treatment may develop the symptoms of infections they have had in the past even if they didn't know they had had them. It is believed that this happens because the body's immune response improves and helps the body to fight these infections.

- Autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.
- Joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty moving, may occur and this may be a sign of a problem that can destroy bone (osteonecrosis).
- If you are taking NORVIR with some medicines used to treat allergies, medicines used to relieve anxiety and/or trouble sleeping, medicines used to correct irregular heart beat and medicines used to treat migraine headache they may cause serious adverse events.

Other medicines and NORVIR

Always tell your healthcare professional if you are taking any other medicine, this includes all complementary or traditional medicines.

Talk to your healthcare professional if your taking any of the medicines below:

- antibiotics (e.g. erythromycin, clarithromycin)
- Anticancer treatment such as encorafenib (used for skin cancer), abemaciclib, afatinib, apalutamide, ceritinib, dasatinib, ibrutinib, neratinib, nilotinib, venetoclax, vincristine, vinblastine)
- anticoagulants (e.g. dabigatran etexilate, edoxaban, rivaroxaban, warfarin)
- antidepressants (e.g. amitriptyline, desipramine, fluoxetine, imipramine, nefazodone, paroxetine, sertraline)
- antifungals (e.g. ketoconazole, itraconazole)

- antiretroviral medicines, including HIV protease inhibitors (amprenavir, atazanavir, darunavir, fosamprenavir, indinavir, nelfinavir, saquinavir, tipranavir), non-nucleoside reverse transcriptase inhibitors (NNRTI) (delavirdine, efavirenz, nevirapine), and others (didanosine, maraviroc, raltegravir, zidovudine)
- anti-tuberculosis medicine (bedaquiline and delamanid)
- elagolix (used for moderate to severe pain associated with endometriosis)
- fostamatinib (used to treat low blood platelet count)
- antiviral medicine used to treat chronic hepatitis C virus (HCV) infection in adults glecaprevir/pibrentasvir and simeprevir)
- bupropion (used to help you stop smoking)
- epilepsy medicines (e.g. carbamazepine, lamotrigine, phenytoin)
- ivosidenib (used for a type of leukemia)
- loratadine used for allergies
- Morphine and morphine like medicines for severe pain (methadone, fentanyl)
- asthma medicine such as theophylline, salmeterol.
- Bosentan (used for pulmonary arterial hypertension) as NORVIR may increase the blood levels of this medicine.
- Trazodone (a medicine for depression) as, unwanted side effects like nausea, dizziness, low blood pressure and fainting may occur when taken with NORVIR .
- Do not take NORVIR with St. John's wort (*Hypericum perforatum*), an herbal product sold as a mild antidepressant or product containing St. John's wort. Taking St. John's wort may decrease NORVIR levels and lead to increased viral load and possible resistance to NORVIR or cross-resistance to other antiretroviral medicines.
- Do not take NORVIR with the cholesterol-lowering medicines lovastatin or simvastatin because of possible serious reactions. There is also an increased risk of medicine interactions between NORVIR and atorvastatin.

- Do not take NORVIR with voriconazole. Taking NORVIR with voriconazole may reduce the levels of voriconazole.

- Talk to your doctor if you are taking or are planning to take -Steroids (e.g. dexamethasone, fluticasone propionate, prednisone, triamcinolone) as Norvir may raise the blood levels of these medicines which may lead to Cushing's syndrome (development of a rounded face) and reduce production of the hormone cortisol. Your doctor may wish to reduce the steroid dose or monitor your side effects more closely.

- If you are taking sildenafil, tadalafil or vardenafil to treat erectile dysfunction, your doctor may lower your dose of these medicines. Before you take sildenafil, tadalafil or vardenafil with NORVIR, talk to your doctor about possible medicine interactions and side effects.

- Do not take NORVIR if you are taking sildenafil to treat pulmonary arterial hypertension.

- If you are using birth control pills or birth control patches or implants to prevent pregnancy, your doctor should increase the dose of your birth control treatment or you should use a different type of birth control method since NORVIR may reduce the effectiveness of these medicines.

- If you are taking rifabutin, your doctor may lower the dose of rifabutin.

- If you are taking both didanosine and NORVIR, the dosage times of Didanosine and NORVIR should be separated by at least 2.5 hours.

- Tell your doctor if you are taking rifampin as it may reduce blood levels of NORVIR. (see "**Do not take NORVIR**")

NORVIR with food, drink and alcohol

NORVIR should preferably be taken with food.

Pregnancy and Breastfeeding

- If you are pregnant or planning to become pregnant, you should not be taking NORVIR. The effects of NORVIR on pregnant women or their unborn babies are not known.
- If you are breastfeeding: Do not breastfeed your baby if you are taking NORVIR. You should not breastfeed if you have HIV. You should be aware that if your baby does not already have HIV, there is a chance that HIV can be transmitted through breastfeeding.

Driving and using machines

Sleepiness and dizziness are known undesirable effects of NORVIR which may interfere with the ability to perform potentially hazardous tasks like driving a car or operating heavy machinery.

3. How to take NORVIR

Always take **NORVIR** exactly as your doctor has instructed you. Do not change your treatment or stop treatment without first talking with your doctor. If you are not sure, you should check with your doctor or pharmacist.

Dosage:

- Your doctor will prescribe the correct dose for you.
- Take NORVIR oral powder or solution with food if possible.
- Take NORVIR tablets with food.
- NORVIR tablets should be swallowed whole and not chewed, broken or crushed.

- NORVIR oral powder can be sprinkled on soft food such as apple sauce or dessert pudding or mixed with a suitable liquid such as water, chocolate milk, or infant formula.
- For doses of exactly 100 mg amounts (100, 200, 300, 400, 500, or 600 mg) pour the entire content of each sachet over soft food (apple sauce or vanilla pudding) or mix with a small amount of liquid (water, chocolate milk, or infant formula) and consume entire serving.
- For doses less than 100 mg amounts or doses between 100 mg amounts, the content of the entire sachet is to be mixed with a liquid and then dosed by the appropriate ml volume as told to you by your doctor using the oral dosing syringe.

Administering with food

- The entire contents of each sachet are to be poured over a small amount of soft food (e.g. apple sauce or vanilla pudding). All the mixed soft food must be administered within 2 hours.

Administering with liquid

- The entire contents of each sachet should be suspended in 9.4 mL of liquid (water, chocolate milk, or infant formula)
- The oral dosing syringe and mixing cup should be dry prior to use.
- Draw up 9.4 mL of liquid using the provided oral dosing syringe, remove the bubbles, and transfer the liquid to the mixing cup. All measuring should be done in mL using the syringe.
- Pour the entire contents of 1 sachet (100 mg) into the mixing cup.
- Close the lid and shake hard for at least 90 seconds until all the lumps have dissolved.
- Let the liquid stand for 10 minutes for most of the bubbles to disappear.
- Use the provided oral dosing syringe to measure and administer the prescribed volume is sure to remove the bubbles prior to dose administration
- Once the powder is mixed, the dosage must be consumed within 2 hours. Discard any mixture remaining in the mixing cup

- Prepare only one dose at a time using the correct number of sachets. When mixing the powder with food or liquid, be sure to take the whole dose within 2 hours. Do not mix Norvir with anything else without talking to your doctor or pharmacist.
- You should always use the measuring cup provided with the medicine to take your NORVIR in order to make sure you take the right dose. Wash the measuring cup after use with dish soap and warm water as soon as you can. The cup should be dry prior to re-use.
- When your NORVIR supply starts to run low, get more from your doctor or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to NORVIR and become harder to treat.
- Be sure to set up a schedule and follow it carefully.
- Only take medicine that has been prescribed specifically for you. Do not give NORVIR to others or take medicine prescribed for someone else.

If you take more NORVIR than you should

If you think that you took more than the prescribed dose of NORVIR, contact your doctor or go to the nearest hospital.

NORVIR should be kept out of reach of young children.

If you forget to take NORVIR

It is important that you do not miss any dose. If you miss a dose of NORVIR, take it as soon as possible and then take your next scheduled dose at its regular time. If it is almost time for your next dose, wait and take the next dose at the regular time. Do not double the next dose. Call your doctor or pharmacist if you have any questions about how to take NORVIR.

4. Possible side effects

NORVIR can have side effects. Not all side effects reported for **NORVIR** are included in this leaflet. Should your general health worsen while taking **NORVIR**, please consult your doctor, pharmacist or other health care professional for advice.

- The frequent side effects reported are: diarrhoea, vomiting, nausea, abdominal pain, feeling weak/tired, headache and dizziness, loss of appetite, changes in taste and tingling feeling or numbness in hands or feet or around the lips.
- Less frequent side effects are: heart attack, diabetes and kidney failure.
- Allergic reactions ranging from mild to severe have occurred in patients taking NORVIR.

Frequent side effects

Sore throat

Allergic reaction including rash (may be red, raised, and itchy) severe swelling of the skin and other tissues

Weight loss

Dehydration, increase in cholesterol, gout, swelling of hands and feet

Agitation, confusion, mood alteration, nervousness

Tingling sensation or numbness in the hands, feet or around the lips and mouth.

Bad taste in the mouth; dizziness

Blurred vision, painful eye, sensitivity to light

Low blood pressure and feeling faint, when getting up, increase in heart beat/rate

Cough

Stomachache, vomiting, diarrhoea, nausea, dry mouth, wind, indigestion, mouth ulcer

Inflammation of the liver and yellowing of the skin or whites of the eye

Skin disorders (rash, redness dry skin, inflammation, swelling of the skin, itchiness), acne

Muscular pain

Joint pain and back pain

Increase/decrease in urination, reduced kidney function

Feeling weak/tired, fever

Changes in liver function tests

Flushing, feeling hot

Less frequent side effects

Changes in blood test results, Low levels of blood platelets

High levels of sugar in the blood

Buzzing/roaring sound in the ear, Pain in the ear, Imbalance

Abnormal dream, difficulty in paying attention, convulsions (fits)

Change in the heart rate, fainting

Shortness of breath, nose bleeding

Decreased sexual drive

Severe diarrhoea, constipation, blood in the stool

- Tell your doctor if you feel sick (nauseous), are vomiting, or have stomach pain, because these may be signs of an inflamed pancreas. Also tell your doctor if you experience joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty moving, as this may be a sign of osteonecrosis.
- Abnormal liver function tests, hepatitis (inflammation of the liver), and rarely jaundice, have been reported in patients taking Norvir. Some people had other illnesses or were taking other medicines. People with liver disease or hepatitis may have worsening liver disease.
- There have been reports of muscle pain, tenderness or weakness, particularly when taking medicines to lower cholesterol in combination with antiretroviral therapy, including protease inhibitors and nucleoside analogues. On rare occasions these muscle disorders have been serious (rhabdomyolysis). In the event of unexplained or continual muscle pain, tenderness, weakness or cramps, stop taking the medicine, contact your doctor as soon as possible or go to the nearest hospital.

If you have questions about side effects, ask your doctor, or pharmacist.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of NORVIR.

Healthcare professionals, patients and caregivers are also asked to report any suspected adverse reaction to AbbVie (Pty) Ltd via this e-mail address: MEAPV@abbvie.com

5. How to store NORVIR

Keep NORVIR and all other medicines out of reach of children.

NORVIR ORAL POWDER

- NORVIR oral powder must be stored below 30 °C. The reconstituted powder must be consumed within 2 hours.
- Avoid exposure to excessive heat.
- The oral dosing syringe and mixing cup should be cleaned immediately with warm water and soap after use. When cleaned immediately, the residue is removed. The oral dosing syringe and mixing cup should be dry prior to use.

NORVIR 100 mg Tablet

- Should be stored at room temperature (below 30 °C).

- Do not keep medicine that is out of date or that you no longer need. Be sure that if you throw any medicine away, and it is out of reach of children.
- Do not use NORVIR if you notice 'visible sign of deterioration'.
- Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains of sewerage systems (e.g toilets).

6. Contents of the pack and other information

What NORVIR contains

NORVIR 100 mg Tablet

The active substance is ritonavir. Each film-coated-tablet contains ritonavir 100 mg

Other ingredients include copovidone, sorbitan laurate, colloidal anhydrous silica, sodium stearyl fumarate, calcium hydrogen phosphate anhydrous, hypromellose, titanium dioxide E171, macrogols type 400, hydroxypropyl cellulose, talc, macrogols type 3350 and polysorbate 80.

NORVIR ORAL POWDER

The active substance is ritonavir. Each sachet of oral powder contains 100 mg of ritonavir.

The other ingredients are copovidone, sorbitan laurate, and colloidal anhydrous silica.

The recommended dose of **NORVIR** oral powder by mouth should either be sprinkled on soft food such as apple sauce or dessert pudding or mixed with a suitable liquid such as water, chocolate milk, or infant formula.

How to reconstitute NORVIR ORAL POWDER

- The entire contents of each sachet should be suspended in 9.4 mL of liquid (water, chocolate milk, or infant formula) in a mixing cup.

- The oral dosing syringe and mixing cup should be dry prior to use.
- Draw up 9.4 mL of liquid using the provided oral dosing syringe, remove the bubbles, and transfer the liquid to the mixing cup. All measuring should be done in mL using the syringe.
- Pour the entire contents of 1 sachet (100 mg) into the mixing cup.
- Close the lid and shake hard for at least 90 seconds until all the lumps have dissolved.
- Let the liquid stand for 10 minutes in order for most of the bubbles to disappear.
- Use the provided oral dosing syringe to measure and administer the prescribed volume is sure to remove the bubbles prior to dose administration-
- Once the powder is mixed, the dosage must be consumed within 2 hours. Discard any mixture remaining in the mixing cup.

What NORVIR looks like and contents of the pack

NORVIR 100 mg Tablet is a white, oval film-coated tablet debossed with “NK” on one side.

NORVIR 100 mg tablets are contained in a white plastic bottle containing either 30 or 60 tablets

NORVIR oral powder is beige/pale yellow to yellow in colour.

Reconstituted powder with water: When reconstituted with water the colour may range from white to yellow.

NORVIR oral powder is available in 30 foil-laminate single-use, child-resistant sachets per carton. The carton also contains a mixing cup and 10 mL calibrated oral dosing syringe.

Holder of Certificate of Registration

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Zambia: 128/030

NORVIR oral powder 51/20.2.8/0154

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Access to the corresponding Professional Information

The corresponding PI will only be available electronically. For the professional information please email medicalinfo.za@abbvie.com