

Package leaflet: Information for the user

Norvir 100 mg powder for oral suspension ritonavir

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you or your child.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Norvir is and what it is used for
2. What you need to know before you or your child takes 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 contains the active substance ritonavir. Norvir is a protease inhibitor used to control HIV infection. Norvir is used in combination with other anti-HIV medicines (antiretrovirals) to control your HIV infection. Your doctor will discuss with you the best combination of medicines for you

Norvir is used by children 2 years of age or older, adolescents and adults who are infected with HIV, the virus which causes AIDS.

2. What you need to know before you or your child takes Norvir

Do not take Norvir

- if you are allergic to ritonavir or any of the other ingredients of Norvir (see section 6).
- if you have severe liver disease.
- if you are currently taking any of the following medicines:
 - astemizole or terfenadine (commonly used to treat allergy symptoms – these medicines may be available without prescription);
 - amiodarone, bepridil, dronedarone, encainide, flecainide, propafenone, quinidine (used to correct irregular heartbeats);
 - dihydroergotamine, ergotamine (used to treat migraine headache);
 - ergonovine, methylergonovine (used to stop excessive bleeding that may occur following childbirth or an abortion);
 - clorazepate, diazepam, estazolam, flurazepam, triazolam or oral (taken by mouth) midazolam (used to help you sleep and/or relieve anxiety);
 - clozapine, pimozide, (used to treat abnormal thoughts or feelings);
 - quetiapine (used to treat schizophrenia, bipolar disorder and major depressive disorder);
 - lurasidone (used to treat depression);
 - ranolazine (used to treat chronic chest pain [angina]);
 - pethidine, piroxicam, propoxyphene (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);
- neratinib (used to treat breast cancer);
- lomitapide (used to lower blood cholesterol);
- alfuzosin (used to treat enlarged prostate gland);
- fusidic acid (used to treat bacterial infections);
- sildenafil if you suffer from a lung disease called pulmonary arterial hypertension that makes breathing difficult. Patients without this disease may use sildenafil for impotence (erectile dysfunction) under their doctor's supervision (see the section on **Other medicines and Norvir**);
- avanafil or vardenafil (used to treat erectile dysfunction);
- colchicine (used to treat gout) if you have kidney and/or liver problems (see the section on **Other medicines and Norvir**);
- 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.

* Your doctor may decide that you can take rifabutin and/or voriconazole with a booster (lower dose) of Norvir but a full dose of Norvir must not be taken together with these two medicines.

If you are currently taking any of these medicines, ask your doctor about switching to a different medicine while you are taking Norvir.

Also read the list of medicines under 'Other medicines and Norvir' for use with certain other medicines which require special care.

Warnings and precautions

Talk to your doctor before taking Norvir.

Important information

- If Norvir is taken in combination with other antiretroviral medicines, it is important that you also carefully read the leaflets that are provided with these other medicines. There may be additional information in those leaflets about situations when Norvir should be avoided. If you have any further questions about Norvir (ritonavir) or the other medicines prescribed, please ask your doctor or pharmacist.
- Norvir is not a cure for HIV infection or AIDS.
- People taking Norvir may still develop infections or other illnesses associated with HIV infection or AIDS. It is therefore important that you remain under the supervision of your doctor while taking Norvir.
- You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your physician the precautions needed to avoid infecting other people.

Tell your doctor if you have/had:

- A history of **liver disease**.
- **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.
- **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.

- **Erectile dysfunction**, as the medicines used to treat erectile dysfunction can cause hypotension and prolonged erection.
- **Diabetes**, as there have been reports of worsening of or the development of diabetes (diabetes mellitus) in some patients taking protease inhibitors.
- **Kidney (renal) disease**, since your doctor may need to check the dose of your other medicines (such as protease inhibitors).

Tell your doctor if you experience:

- **Diarrhoea or vomiting** that is not improving (persistent), as this may reduce how well the medicines you are taking work.
- **Feeling sick** (nausea), **vomiting** or have **stomach pain**, because 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.
- **Symptoms of infection** – inform your doctor immediately. 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.

In addition to the opportunistic 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, tell your doctor, as this may be a sign of a problem that can destroy bone (osteonecrosis). Some patients taking a number of antiretroviral medicines may develop this disease.
- **Muscle pain, tenderness or weakness**, particularly in combination with antiretroviral therapy including protease inhibitors and nucleoside analogues. On rare occasions these muscle disorders have been serious. (See section 4. **Possible side effects**)
- **Dizziness, lightheadedness, fainting spells or abnormal heartbeat**. Some patients taking Norvir may experience changes in the electrocardiogram (ECG). Tell your doctor if you have a heart defect or conduction defect.
- If you have any other health concerns, discuss these with your doctor as soon as you can.

Children and adolescents

Norvir is not recommended in children below 2 years of age.

Other medicines and Norvir

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. There are some medicines you cannot take at all with Norvir. These are listed earlier in section 2, under '**Do not take Norvir**'. There are some other medicines that can only be used under certain circumstances as described below.

The following warnings apply when Norvir is taken as a full dose. However, these warnings may also apply when Norvir is used in lower doses (a booster) with other medicines.

Tell your doctor if you are taking any of the medicines listed below, as special care should be taken.

- **Sildenafil or tadalafil** for impotence (erectile dysfunction).
The dose and/or frequency of use of these medicines may need to be reduced to avoid hypotension and prolonged erection. You must not take Norvir with sildenafil if you suffer from pulmonary arterial hypertension (see also section 2. **What you need to know before you or your child takes Norvir**). Tell your doctor if you are taking tadalafil for pulmonary arterial hypertension.
- **Colchicine** (for gout) as Norvir may raise the blood levels of this medicine. You must not take Norvir with colchicine if you have kidney and/or liver problems (see also '**Do not take Norvir**' above).
- **Digoxin** (heart medicine). Your doctor may need to adjust the dose of digoxin and monitor you while you are taking digoxin and Norvir in order to avoid heart problems.
- **Hormonal contraceptives** containing ethinyl oestradiol as Norvir may reduce the effectiveness of these medicines. It is recommended that a condom or other non-hormonal method of contraception is used instead. You may also notice irregular uterine bleeding if you are taking this type of hormonal contraceptive with Norvir.
- **Atorvastatin or rosuvastatin** (for high cholesterol) as Norvir may raise the blood levels of these medicines. Talk to your doctor before you take any cholesterol-reducing medicines with Norvir (see also '**Do not take Norvir**' above).
- **Steroids** (e.g. dexamethasone, fluticasone propionate, prednisolone, 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.
- **Trazodone** (a medicine for depression) as, unwanted effects like nausea, dizziness, low blood pressure and fainting can occur when taken with Norvir.
- **Rifampicin and saquinavir** (used for tuberculosis and HIV, respectively) as serious liver damage can occur when taken with Norvir.
- **Bosentan, riociguat** (used for pulmonary arterial hypertension) as Norvir may increase the blood levels of this medicine.

There are medicines that may not mix with Norvir because their effects could increase or decrease when taken together. In some cases your doctor may need to perform certain tests, change the dose or monitor you regularly. This is why you should tell your doctor if you are taking any medicines, including those you have bought yourself or herbal products, but it is especially important to mention these:

- amphetamine or amphetamine derivatives;
- antibiotics (e.g. erythromycin, clarithromycin);
- anticancer treatments (e.g. abemaciclib, afatinib, apalutamide, ceritinib, encorafenib, dasatinib, ibrutinib, nilotinib, venetoclax, vincristine, vinblastine);
- medicines used to treat low blood platelet count (e.g. fostamatinib);
- anticoagulants (e.g. rivaroxaban, vorapaxar, warfarin);
- antidepressants (e.g. amitriptyline, desipramine, fluoxetine, imipramine, nefazodone, nortriptyline, paroxetine, sertraline, trazodone);
- antifungals (e.g. ketoconazole, itraconazole);
- antihistamines (e.g. loratadine, fexofenadine);
- 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);
- antiviral medicine used to treat chronic hepatitis C virus (HCV) infection in adults (e.g. glecaprevir/pibrentasvir and simeprevir);
- anxiety medicine, buspirone;
- asthma medicine, theophylline, salmeterol;

- atovaquone, a medicine used to treat a certain type of pneumonia and malaria;
- buprenorphine, a medicine used for the treatment of chronic pain;
- bupropion, a medicine used to help you stop smoking;
- epilepsy medicines (e.g. carbamazepine, divalproex, lamotrigine, phenytoin);
- heart medicines (e.g. disopyramide, mexiletine and calcium channel antagonists such as amlodipine, diltiazem and nifedipine);
- immune system medicines (e.g. cyclosporine, tacrolimus, everolimus);
- levothyroxine (used to treat thyroid problems);
- morphine and morphine-like medicines used to treat severe pain (e.g. methadone, fentanyl);
- sleeping pills (e.g. alprazolam, zolpidem) and also midazolam administered by injection;
- tranquillisers (e.g. haloperidol, risperidone, thioridazine);
- colchicine, a treatment for gout.

There are some medicines you cannot take at all with Norvir. These are listed earlier in section 2, under '**Do not take Norvir**'.

Taking Norvir with food and drink

See section 3.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, it is very important that you ask your doctor for advice before taking this medicine.

There is a large amount of information on the use of ritonavir (the active ingredient in Norvir) during pregnancy. In general, pregnant mothers received ritonavir after the first three months of pregnancy at a lower dose (booster) along with other protease inhibitors. Norvir did not appear to increase the chance of developing birth defects compared to the general population.

Norvir can pass into breast milk. To avoid transmitting the infection, mothers with HIV must not breast feed their babies.

Driving and using machines

Norvir can cause dizziness. If you are affected do not drive or use machinery.

3. How to take Norvir

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Take this medicine one or two times a day every day with food.

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.

For administration using a feeding tube follow the instructions in section 'How do I take the correct dose of Norvir powder for oral suspension mixed with liquid?' **Use water to mix the medicine** and follow the feeding tube instructions to administer the medicine.

Recommended doses of Norvir are:

- if Norvir is used to boost the effects of other anti-HIV medicines, the typical dose for adults is 1 or 2 sachets once or twice daily. For more detailed dose recommendations, including those for children, see the Package Leaflet of the anti-HIV medicines Norvir is given in combination with.
- if your doctor prescribes a full dose, adults may be started on a dose of 3 sachets in the morning and 3 sachets 12 hours later, gradually increasing over a period of up to 14 days to the full dose of 6 sachets twice daily. Children (2 – 12 years of age) will start with a dose smaller than this and continue up to the maximum allowed for their size.

Your doctor will advise you on the dosage to be taken.

Norvir should be taken every day to help control your HIV, no matter how much better you feel. If a side effect is preventing you from taking Norvir, tell your doctor straight away. During episodes of diarrhoea your doctor may decide that extra monitoring is needed.

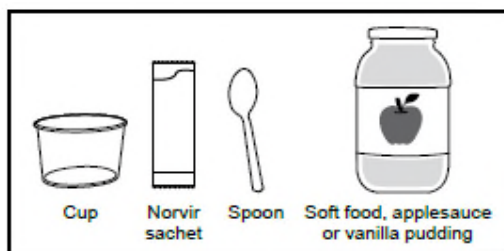
Always keep enough Norvir on hand so you don't run out. When you travel or need to stay in the hospital, make sure you have enough Norvir to last until you can get a new supply.

Norvir powder for oral suspension has a lingering aftertaste. Eating peanut butter, hazelnut chocolate spread, or black currant syrup immediately after taking the medication may help clear the aftertaste from your mouth.

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.

How do I take the correct dose of Norvir powder for oral suspension mixed with food (full sachet)?

Follow the instructions below:



Step 1. Before mixing dose of Norvir, collect the following supplies: (see Figure 1).

Step 2. Check prescription for number of sachets or call your doctor or pharmacist.

Figure 1

Step 3. Before first using the mixing cup, wash the cup in warm water and dish soap. Rinse and allow to air dry.



Figure 2

Step 4. Put a small serving of soft food (applesauce or vanilla pudding) in a cup (see Figure 2).

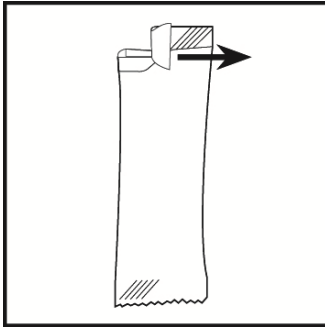


Figure 3

Step 5. Tear open sachet (see Figure 3).

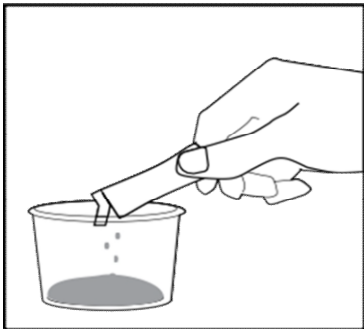


Figure 4

Step 6. Pour ALL powder from sachet onto food (see Figure 4).

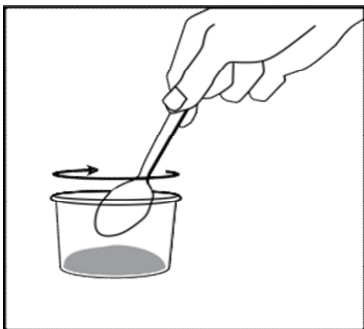


Figure 5

Step 7. Mix thoroughly (see Figure 5).

Step 8. Feed serving to patient.

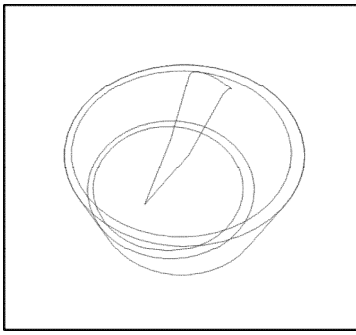


Figure 6

Step 9. ENTIRE serving must be eaten (see Figure 6). If **powder residue** is left, add more spoonfuls of food and serve to patient. *Use within 2 hours.*

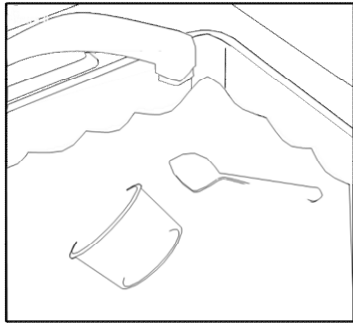


Figure 7

Step 10. Place empty sachet in rubbish. Wash and dry preparation area. Immediately wash the spoon and cup in warm water and dish soap (see Figure 7). Rinse and allow to air dry.

How do I take the correct dose of Norvir powder for oral suspension mixed with liquid?

Follow the instructions below:

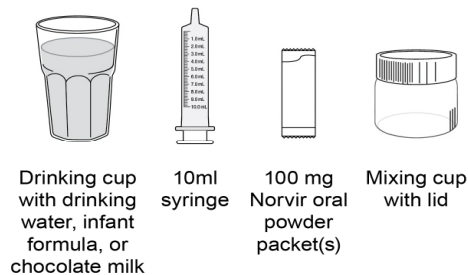


Figure 1

What you need

Before mixing a dose of Norvir, collect the items shown in Figure 1.

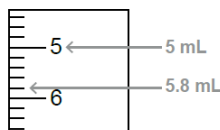
You may need more than 1 sachet for each dose. Check the prescription label on the carton or call your doctor or pharmacist if you are not sure. If you do need more than 1 sachet, repeat all the steps with each sachet.

Using the syringe

Before first using the dosing syringe, wash the syringe in warm water and dish soap. Rinse and allow to air dry.

Reading the scale

- a. Each millilitre (ml) is shown as a number with a big line.
- b. Each 0.2 ml is shown as a smaller line between the numbers.



Check the syringe before each use

You will need to use a new syringe if:

- you cannot clean the syringe
- you cannot read the scale

- you cannot move the plunger
- the syringe is damaged or leaking.

Step 1. Fill the syringe

- Push the plunger all the way into syringe.
- Place the syringe tip into the liquid.
- Slowly pull the plunger back to the 10 ml mark on the syringe (see Figure 2).

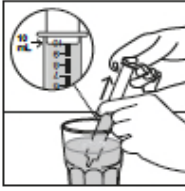


Figure 2

Step 2. Move any bubbles to the tip of the syringe

- Hold the syringe with the tip pointing up.
- Tap the syringe with your other hand. This will move any bubbles to the tip.
- Pull the plunger down. Be careful not to pull the plunger out.
- Tap the syringe again. This will help to break up the bubbles and make sure they are all at the tip (see Figure 3).

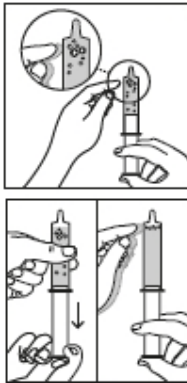


Figure 3

Step 3. Measure the liquid

- Keep the syringe pointed up.
- Slowly push the plunger up until the top of the plunger is at 9.4 ml - this will remove any bubbles from the syringe (see Figure 4).

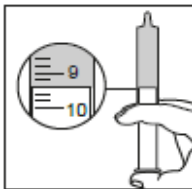


Figure 4

Step 4. Empty the syringe

- Slowly push the plunger to empty the liquid from the syringe into the mixing cup (see Figure 5).

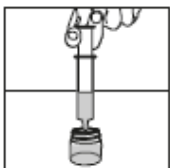


Figure 5

Step 5. Pour the powder into the cup

- Tear open the sachet.
- Pour all of the powder into the mixing cup.
- Check if the sachet is empty.



Figure 6

Be careful not to spill any powder outside of the mixing cup (see Figure 6).



Figure 7

Step 6. Mix the powder and liquid

- Tightly screw on the lid and keep shaking the mixing cup hard for at least 90 seconds until all the lumps have gone.
- Check for any lumps of powder. If there are still lumps, keep shaking until they have all gone.
- The liquid may look cloudy - this is okay.
- Let the liquid stand for 10 minutes and most of the bubbles will disappear.
- You may see some small bubbles on top of the liquid - this is also okay (see Figure 7).

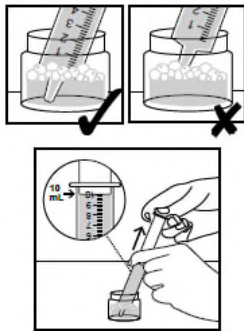


Figure 8

Step 7. Fill the syringe

- Push the plunger completely into the syringe.
- Place the syringe tip at the bottom of the mixing cup.
- Slowly pull the plunger back to the 10 ml mark - try not to pull any bubbles into the syringe (see Figure 8).

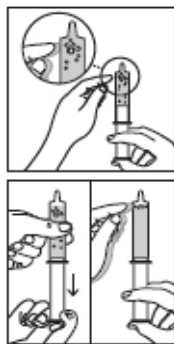


Figure 9

Step 8. Remove any bubbles

- Hold the syringe with the tip pointing up.
- Tap the syringe with your other hand. This will move any bubbles to the tip.
- Pull the plunger down. Be careful not to pull the plunger out.
- Tap the syringe again to break up the bubbles so they are all at the tip (see Figure 9).
- Slowly push the plunger until you see a small amount of liquid at the tip of the syringe.
- If there are any large air bubbles, empty the liquid from the syringe into the mixing cup and start again from Step 7.

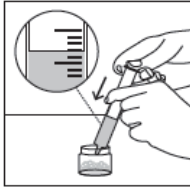


Figure 10

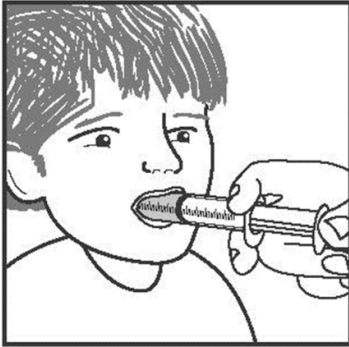


Figure 11

Step 9. Measure the dose

- Check the prescription label on the carton for the dose in ml. If you are not sure, call your doctor or pharmacist.
- Point the syringe into the mixing cup and slowly push the plunger to the correct ml for the dose (see Figure 10).
- If you push out too much liquid, start again from Step 7. Be careful not to spill the liquid outside of the mixing cup.

Step 10. Give the medicine to the patient

- Place the syringe tip against the inside of the patient's cheek.
- Slowly push the plunger to give all of the dose (see Figure 11).
- Give the patient the full dose within 2 hours of opening the sachet.

Step 11. (If required)

If you need to use more than one sachet, repeat the process from the beginning.

Step 12. After you have finished

- Place the empty sachet and any left over medicine from the mixing cup into a rubbish bag.
- Remove the plunger from the syringe.
- Hand wash the syringe, plunger, and mixing cup and lid in warm water and dish soap. Rinse with water and allow to air dry. Do not wash these in the dishwasher.
- Wash and dry the area used to mix the medicine.

If you take more Norvir than you should

Numbness, tingling, or a “pins and needles” sensation may occur if you take too much Norvir. If you realise you have taken more Norvir than you were supposed to, contact your doctor or the Accident and Emergency Department of your nearest hospital straight away.

If you forget to take Norvir

If you miss a dose, take the missed dose as soon as possible. If it is nearly time for the next dose, just take that one. Do not take a double dose to make up for a forgotten dose.

If you stop taking Norvir

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.

4. Possible side effects

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Like all medicines, Norvir can cause side effects, although not everybody gets them. Also, the side effects of Norvir when used with other antiretroviral medicines are dependent on the other medicines. So it is important that you carefully read the side effects section of the leaflets that are provided with these other medicines.

Very common: may affect more than 1 in 10 people

- upper or lower stomach ache
- vomiting
- diarrhoea (may be severe)
- feeling sick (nausea)
- flushing, feeling hot
- headache
- dizziness
- pain in the throat
- cough
- upset stomach or indigestion
- a tingling sensation or numbness in the hands, feet or around the lips and mouth
- feeling weak/tired
- bad taste in the mouth
- damage to the nerves that can cause weakness and pain
- itching
- rash
- joint pain and back pain

Common: may affect up to 1 in 10 people

- allergic reactions including skin rashes (may be red, raised, itchy), severe swelling of the skin and other tissues
- inability to sleep (insomnia)
- anxiety
- increase in cholesterol
- increase in triglycerides
- gout
- stomach bleeding
- inflammation of the liver and yellowing of skin or whites of the eyes
- increase in urination
- reduced kidney function
- seizures (fits)
- low levels of blood platelets
- thirst (dehydration)
- abnormally heavy periods
- wind (flatulence)
- loss of appetite
- mouth ulcer
- muscle aches (pain), tenderness or weakness
- fever
- weight loss
- laboratory test results: changes in blood test results (such as blood chemistry and blood count)
- confusion
- difficulty paying attention
- fainting
- blurred vision
- swelling of the hands and feet
- high blood pressure
- low blood pressure and feeling faint when getting up
- coldness in the hands and feet
- acne

Uncommon: may affect up to 1 in 100 people

- heart attack
- diabetes
- kidney failure

Rare: may affect up to 1 in 1,000 people

- severe or life threatening skin reaction including blisters (Stevens Johnson syndrome, toxic epidermal necrolysis)
- serious allergic reaction (anaphylaxis)
- high levels of sugar in the blood

Not known: frequency cannot be estimated from the available data

- kidney stones

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. See also section 2. **What you need to know before you or your child takes Norvir.**

In patients with haemophilia types A and B, there have been reports of increased bleeding while taking this treatment or another protease inhibitor. Should this happen to you, seek immediate advice from your doctor.

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 of 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 Accident and Emergency Department of your nearest hospital.

Inform your doctor as soon as possible if you experience any symptoms that suggest an allergic reaction after taking Norvir such as rash, hives or breathing difficulties.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, contact your doctor, pharmacist, Accident and Emergency department or if it is urgent get immediate medical help.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Norvir

Keep this medicine out of the sight and reach of children.

Do not use Norvir powder for oral suspension after the expiry date on the sachet and carton. The expiry date refers to the last day of the month.

Norvir powder for oral suspension should be stored below 30°C.

Do not use this medicine if you notice the powder is not beige/pale yellow to yellow.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Norvir contains

- The active substance is ritonavir. Each sachet of Norvir contains 100 mg ritonavir.
- The other ingredients are copovidone; sorbitan laurate; silica, colloidal anhydrous.

What Norvir looks like and contents of the pack

Norvir powder for oral suspension comes in individual sachets containing 100 mg ritonavir. 30 sachets are packed in a carton together with 1 mixing cup and 2 oral dosing syringes.

Not all pack sizes may be marketed.

Norvir is also supplied as a film-coated tablet containing 100 mg ritonavir.

Marketing Authorisation Holder

AbbVie Ltd, Maidenhead, SL6 4UB, UK

Manufacturers

AbbVie Deutschland GmbH & Co. KG, Knollstrasse, 67061 Ludwigshafen, Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom

AbbVie Ltd

Tel: +44 (0)1628 561090

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