

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Ritonavir Tablets 100 mg<sup>1</sup>

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Ritonavir Tablets 100 mg are and what they are used for
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## **1. WHAT RITONAVIR TABLETS 100 MG ARE AND WHAT THEY ARE USED FOR**

Ritonavir Tablets 100 mg are a protease inhibitor used to control HIV infection. Ritonavir Tablets 100 mg are 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.

## **2. BEFORE YOU TAKE RITONAVIR TABLETS 100 MG**

### **Do not take Ritonavir Tablets 100 mg**

- if you are allergic (hypersensitive) to Ritonavir Tablets 100 mg or any of the other ingredients of Ritonavir Tablets 100 mg (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, 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);
  - 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);
  - alfuzosin (used to treat enlarged prostate gland);
  - fusidic acid (used to treat bacterial infections);

<sup>1</sup>Trade names are not prequalified by WHO. This is the national medicines regulatory agency's (NMRA) responsibility. Throughout this WHOPAR, the proprietary name is given as an example only.

- 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 "Taking other medicines");
- products containing St John's wort (*Hypericum perforatum*) as this may stop Ritonavir Tablets 100 mg from working properly. St John's wort is often used in herbal medicines that you can buy yourself.

\* Your doctor will decide whether you can take rifabutin and/or voriconazole with Ritonavir Tablets 100 mg

If you are currently taking any of the above medicines, ask your doctor about switching to a different medicine while you are taking Ritonavir Tablets 100 mg. Often, there are other medicines you can take instead.

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

### Take special care with Ritonavir Tablets 100 mg

#### Important information

- If Ritonavir Tablets 100 mg are 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 Ritonavir Tablets 100 mg should be avoided. If you have any further questions about Ritonavir Tablets 100 mg or the other medicines prescribed, please ask your doctor or pharmacist.
- Ritonavir Tablets 100 mg are not a cure for HIV infection or AIDS.
- People taking Ritonavir Tablets 100 mg 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 Ritonavir Tablets 100 mg.
- Ritonavir Tablets 100 mg as part of antiretroviral therapy may lower the risk of passing HIV to others, but it does not eliminate the risk. Appropriate precautions should still be taken to prevent passing the disease through sexual contact (e.g. use of a condom) or blood contamination. (You should not give blood or share needles.)

#### 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:**

- **Changes in the distribution of the fat** on your body, or a build up or loss of body fat (see section 4. **Possible side effects**).
- **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 Ritonavir Tablets 100 mg 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.
- **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 Ritonavir Tablets 100 mg 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.

Ritonavir Tablets 100 mg are not recommended in children below 2 years of age.

**Taking other medicines**

There are some medicines you cannot take at all with Ritonavir Tablets 100 mg. These are listed earlier in Section 2, under 'Do not take Ritonavir Tablets 100 mg'. There are some other medicines that can only be used under certain circumstances, as described below. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

- **Sildenafil, tadalafil, vardenafil** 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 Ritonavir Tablets 100 mg with sildenafil for the treatment of pulmonary arterial hypertension (see also section 2.)
- **Digoxin** (heart medicine). Your doctor may need to adjust the dose of digoxin and monitor you while you are taking digoxin and Ritonavir Tablets 100 mg in order to avoid heart problems.
- **Hormonal contraceptives** containing ethinyl oestradiol as Ritonavir Tablets 100 mg 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 Ritonavir Tablets 100 mg.
- **Atorvastatin or rosuvastatin** (for high cholesterol) as Ritonavir Tablets 100 mg may raise the blood levels of these medicines. Talk to your doctor before you take any cholesterol-reducing

- medicines with Ritonavir Tablets 100 mg (see also ‘**Do not take Ritonavir Tablets 100 mg**’ above).
- **Steroids** (eg dexamethasone, fluticasone propionate, prednisolone) as Ritonavir Tablets 100 mg 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 Ritonavir Tablets 100 mg.
  - **Rifampicin and saquinavir** (used for tuberculosis and HIV, respectively) as serious liver damage can occur when taken with Ritonavir Tablets 100 mg.

There are medicines that may not mix with Ritonavir Tablets 100 mg 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 (eg erythromycin, clarithromycin);
- anticancer treatments (eg vincristine, vinblastine);
- antidepressants (eg amitriptyline, desipramine, fluoxetine, imipramine, nortriptyline, paroxetine, sertraline, trazodone);
- antifungals (eg ketoconazole, itraconazole);
- antihistamines (eg loratidine, fexofenadine);
- antiretroviral medicines including HIV-protease inhibitors and non-nucleoside reverse transcriptase inhibitors( NNRTI);
- 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 (eg carbamazepine, divalproex, lamotrigine, phenytoin);
- heart medicines (eg digoxin, disopyramide, mexiletine and calcium channel antagonists such as amlodipine, diltiazem and nifedipine);
- immune system (eg cyclosporine, tacrolimus, everolimus);
- morphine and morphine-like medicines used to treat severe pain (eg methadone, fentanyl);
- sleeping pills (eg alprazolam, zolpidem) and also midazolam administered by injection;
- tranquillisers (eg haloperidol, risperidone, thioridazine);
- warfarin, a blood thinner.

### **Taking Ritonavir Tablets 100 mg with food and drink**

Ritonavir Tablets 100 mg tablets should be taken with food.

### **Pregnancy**

**If you think you are pregnant or you are planning to become pregnant, it is very important that you discuss this with your doctor, so that the benefits and risks of your treatment are clear**

### **Breast feeding**

If you are interested in breast-feeding your baby, you should discuss the risks and benefits with your doctor or healthcare provider.

### **Driving and using machines**

Ritonavir Tablets 100 mg can cause sleepiness and dizziness. If you are affected do not drive or use machinery.

### **3. HOW TO TAKE RITONAVIR TABLETS 100 MG**

Always take Ritonavir Tablets 100 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. It is taken by mouth usually once or twice every day. Ritonavir Tablets 100 mg tablets should be taken with food as this can affect the way in which Ritonavir Tablets 100 mg are absorbed into your body.

It is important that Ritonavir Tablets 100 mg tablets are swallowed whole and not chewed, broken or crushed.

Recommended dose of Ritonavir Tablets 100 mg:

- Ritonavir Tablets 100 mg are used to boost the effects of certain other anti-HIV medicines. The typical dose for adults is 1 to 2 tablets once or twice daily. For more detailed dose recommendations, including those for children, see the Package Leaflets of the other anti-HIV medicines that are being given in the combination.

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

Like all anti-HIV medicines, Ritonavir Tablets 100 mg 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 Ritonavir Tablets 100 mg as directed, tell your doctor straight away. During episodes of diarrhoea your doctor may decide that extra monitoring is needed.

Always keep enough Ritonavir Tablets 100 mg on hand so you don't run out. When you travel or need to stay in the hospital, make sure you have enough Ritonavir Tablets 100 mg to last until you can get a new supply.

#### **If you take more Ritonavir Tablets 100 mg than you should**

Numbness, tingling, or a "pins and needles" sensation may occur if you take too much Ritonavir Tablets 100 mg. If you realise you have taken more Ritonavir Tablets 100 mg than you were supposed to, contact your doctor or the Emergency Department of your nearest hospital straight away.

#### **If you forget to take Ritonavir Tablets 100 mg**

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 Ritonavir Tablets 100 mg**

Even if you feel better, do not stop taking Ritonavir Tablets 100 mg without talking to your doctor. Taking Ritonavir Tablets 100 mg as recommended should give you the best chance of delaying resistance to the medicines.

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Ritonavir Tablets 100 mg can cause side effects, although not everybody gets them. Also, the side effects of Ritonavir Tablets 100 mg when used with other antiretroviral medicines are dependent on the other medicines. It is important that you carefully read the side effects section of the leaflets that are provided with these other medicines.

The frequency of possible side effects listed below is defined using the following convention:

very common	affects more than 1 user in 10
common	affects 1 to 10 users in 100
uncommon	affects 1 to 10 users in 1,000
rare	affects 1 to 10 users in 10,000
very rare	affects less than 1 user in 10,000
not known	frequency cannot be estimated from the available data.

##### Very common side effects:

- stomach ache
- vomiting
- diarrhoea
- feeling sick (nausea)
- headache
- a tingling sensation or numbness in the hands, feet or around the lips and mouth
- feeling weak/tired
- bad taste in the mouth

##### Common side effects:

- allergic reactions including skin rashes (may be red, raised, itchy), severe swelling of the skin and other tissues
- difficulty in breathing
- flushing of the skin (vasodilation)
- changes in fat distribution (see **Side effects associated with combination antiretroviral therapy** below)
- dizziness
- inability to sleep (insomnia)
- anxiety
- sleepiness
- numbness
- unusual sensitivity of the skin
- heartburn
- sore throat
- increased cough
- wind (flatulence)
- loss of appetite
- dry mouth
- belching
- mouth ulcer
- sweating
- muscle aches
- fever
- pain
- weight loss
- laboratory test results: changes in blood test results (such as blood chemistry and blood count)

##### Uncommon side effects:

- dehydration (thirst)
- diabetes
- jaundice (yellowing of the skin or whites of eyes)
- muscle pain, tenderness or weakness
- hepatitis (inflammation of the liver)
- laboratory test results: changes in blood test results (such as blood chemistry and blood count)

##### Rare side effects:

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

Other side effects that have been reported with Ritonavir Tablets 100 mg: low levels of bloodplatelets, kidney failure, seizures (fits), fainting and feeling faint when getting up, abnormally heavy periods. It is not known how frequently these effects may occur.

Tell your doctor if you feel sick (nauseated), 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 **Before you take Ritonavir Tablets 100 mg**.

**Side effects associated with combination antiretroviral therapy** may cause changes in body shape due to changes in fat distribution. These may include loss of fat from legs, arms and face, increased fat in the abdomen (belly) and internal organs, breast enlargement and fatty lumps on the back of the neck ("buffalo hump"). The cause and long-term health effects of these conditions are not known. Combination antiretroviral therapy may also cause raised lactic acid and sugar in the blood, increased fats in the blood and resistance to insulin (insulin will not work as effectively).

In patients with haemophilia type 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.

Cases of diabetes mellitus or increased blood sugars have been reported in patients receiving Ritonavir Tablets 100 mg or other protease inhibitors.

Abnormal liver function tests, hepatitis (inflammation of the liver), and rarely jaundice, have been reported in patients taking Ritonavir Tablets 100 mg. 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 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 Ritonavir Tablets 100 mg 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, or Emergency department.**

## 5. HOW TO STORE RITONAVIR TABLETS 100 MG

Keep out of the reach and sight of children.

Do not use Ritonavir Tablets 100 mg after the expiry date on the label. The expiry date refers to the last day of that month.

**THIS MEDICINAL PRODUCT SHOULD BE STORED BELOW 30 DEGREES C. STORE IN ORIGINAL CONTAINER.**

## **6. FURTHER INFORMATION**

### **What Ritonavir Tablets 100 mg contains**

- The active substance is ritonavir. Each film-coated tablet contains 100 mg ritonavir.
- Sodium (oral): This medicinal product contains 3.82 mmol (or 87.76 mg) sodium per tablet. Discuss with your doctor if you are on a controlled sodium diet.
- Core tablet: Colloidal silicon dioxide, copovidone, sodium chloride, sodium stearyl fumarate, sorbitan monolaurate.
- Film coating: Colloidal anhydrous silica, hypromellose, hydroxypropyl cellulose, iron oxide yellow, polyethylene glycol, polysorbate 80, talc and titanium dioxide.

### **What Ritonavir Tablets 100 mg look like and contents of the bottle**

Ritonavir Tablets 100 mg tablets are yellow and film-coated with “M163” written on one side. There is no score-line. They are supplied in:

- white opaque bottle with white opaque cap with inbuilt drying agent. Pack size: 120 tablets.
- white HDPE bottle with white opaque polypropylene screw closure with aluminium induction sealing liner and 2g silica gel desiccant canister. Pack size: 30 and 120 tablets.
- Alu-Alu cold form blister of 10 tablets. 1 such blister packed in a carton box.

### **Supplier**

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Detailed information on this medicine is available on the World Health Organization (WHO) web site:  
<https://extranet.who.int/prequal/>