

Package leaflet: Information for the user

Ritonavir Mylan 100 mg film-coated tablets

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. 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 Ritonavir Mylan is and what it is used for
2. What you need to know before you or your child takes Ritonavir Mylan
3. How to take Ritonavir Mylan
4. Possible side effects
5. How to store Ritonavir Mylan
6. Contents of the pack and other information

1. What Ritonavir Mylan is and what it is used for

Ritonavir Mylan contains the active substance ritonavir. Ritonavir is a protease inhibitor used to control HIV infection. Ritonavir 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.

Ritonavir Mylan 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 Ritonavir Mylan

Do not take Ritonavir Mylan

- if you are allergic to ritonavir or any of the other ingredients of this medicine (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 [anginal]);
 - pethidine, 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 Ritonavir Mylan**);
 - 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 Ritonavir Mylan**);
 - products containing St John's wort (*Hypericum perforatum*) as this may stop ritonavir 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 ritonavir but a full dose of ritonavir 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 Ritonavir Mylan.

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

Warnings and precautions

Talk to your doctor before taking Ritonavir Mylan.

Important information

- If Ritonavir Mylan 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 ritonavir should be avoided. If you have any further questions about Ritonavir Mylan (ritonavir) or the other medicines prescribed, please ask your doctor or pharmacist.
- Ritonavir is not a cure for HIV infection or AIDS.
- People taking ritonavir 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 Mylan.

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 ritonavir 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 ritonavir 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

Ritonavir Mylan is not recommended in children below 2 years of age.

Other medicines and Ritonavir Mylan

Tell your doctor or pharmacist if you are taking or 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 ritonavir. These are listed earlier in section 2, under 'Do not take Ritonavir Mylan'. There are some other medicines that can only be used under certain circumstances as described below.

The following warnings apply when Ritonavir Mylan is taken as a full dose. However, these warnings may also apply when Ritonavir Mylan 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 Ritonavir Mylan with sildenafil if you suffer from pulmonary arterial hypertension (see also section 2. **What you need to know before you or your child takes Ritonavir Mylan**). Tell your doctor if you are taking tadalafil for pulmonary arterial hypertension.

- **Colchicine** (for gout) as ritonavir may raise the blood levels of this medicine. You must not take ritonavir with colchicine if you have kidney and/or liver problems (see also '**Do not take Ritonavir Mylan**' above).
- **Digoxin** (heart medicine). Your doctor may need to adjust the dose of digoxin and monitor you while you are taking digoxin and Ritonavir Mylan in order to avoid heart problems.
- **Hormonal contraceptives** containing ethinylestradiol as ritonavir 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.
- **Atorvastatin or rosuvastatin** (for high cholesterol) as ritonavir may raise the blood levels of these medicines. Talk to your doctor before you take any cholesterol-reducing medicines with ritonavir (see also '**Do not take Ritonavir Mylan**' above).
- **Steroids** (e.g. dexamethasone, fluticasone propionate, prednisolone, triamcinolone) as ritonavir 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.
- **Rifampicin and saquinavir** (used for tuberculosis and HIV, respectively) as serious liver damage can occur when taken with ritonavir.
- **Bosentan, riociguat** (used for pulmonary arterial hypertension) as ritonavir may increase the blood levels of this medicine.

There are medicines that may not mix with ritonavir 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. dabigatran etexilate, edoxaban, 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 (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 ritonavir. These are listed earlier in section 2, under 'Do not take Ritonavir Mylan'.

Taking Ritonavir Mylan with food and drink

Ritonavir Mylan tablets should be taken with food.

Pregnancy and breast-feeding

If you are pregnant, 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 Ritonavir Mylan) 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. Ritonavir did not appear to increase the chance of developing birth defects compared to the general population.

Breast-feeding is not recommended in women living with HIV because HIV infection can be passed on to the baby in breast milk.

If you are breast-feeding, or thinking about breast-feeding, you should discuss it with your doctor as soon as possible.

Driving and using machines

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

Ritonavir Mylan contains sodium

This medicine contains 87.75 mg of sodium in each tablet. This is equivalent to 4.4% of the recommended maximum daily dietary intake of sodium for an adult. Talk to your doctor or pharmacist if you need five or more tablets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How to take Ritonavir Mylan

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.

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

Recommended doses of Ritonavir Mylan are:

- if Ritonavir Mylan is 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 Leaflet of the anti-HIV medicines Ritonavir Mylan is given in combination with.
- if your doctor prescribes a full dose, adults may be started on a dose of 3 tablets in the morning and 3 tablets 12 hours later, gradually increasing over a period of up to 14 days to the full dose of 6 tablets twice daily (totalling 1,200 mg per day). 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.

Other forms of this medicine may be more appropriate for children who have difficulty swallowing tablets.

Ritonavir Mylan 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 Mylan as directed, tell your doctor straight away. During episodes of diarrhoea your doctor may decide that extra monitoring is needed.

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

If you take more Ritonavir Mylan than you should

Numbness, tingling, or a “pins and needles” sensation may occur if you take too much ritonavir. If you realise you have taken more Ritonavir Mylan 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 Ritonavir Mylan

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 Mylan

Even if you feel better, do not stop taking Ritonavir Mylan without talking to your doctor. Taking Ritonavir Mylan 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 lifestyle, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Like all medicines, this medicine can cause side effects, although not everybody gets them. Also, the side effects of ritonavir 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

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

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 Ritonavir Mylan.**

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.

Abnormal liver function tests, hepatitis (inflammation of the liver), and rarely jaundice, have been reported in patients taking ritonavir. 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 Ritonavir Mylan 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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ritonavir Mylan

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

Do not use this medicine after the expiry date on the carton or bottle label after 'EXP'. The expiry date refers to the last day of that month.

For HDPE bottle: After first opening, use within 45 days.

Do not store above 30°C. Store in the original packaging in order to protect from moisture.

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

6. Contents of the pack and other information

What Ritonavir Mylan contains

- The active substance is ritonavir. Each film-coated tablet contains 100 mg ritonavir.
- The other tablet ingredients are: copovidone, sorbitan laurate, colloidal anhydrous silica, sodium chloride, sodium stearyl fumarate see section 2 'Ritonavir Mylan contains sodium'.
- The tablet coating is composed of: hypromellose, titanium dioxide (E171), macrogols, hydroxypropylcellulose, talc, iron oxide yellow (E172), colloidal anhydrous silica, polysorbate 80.

What Ritonavir Mylan looks like and contents of the pack

Ritonavir Mylan film coated tablets are yellow, capsule shaped, biconvex, beveled edge and marked with 'M163' on one side and blank on the other.

Ritonavir Mylan film coated tablets are available in plastic bottles with screw caps and aluminium sealing liner wads, containing 30, 90 or 100 tablets and in multipacks of 90 tablets comprising 3 bottles, each containing 30 tablets. The bottles also contain a desiccant. Do not eat the desiccant.

Also available in blister pack containing 30 and 90 tablets and in perforated unit dose blister packs containing, 30 x 1 and 90 x 1 tablets.

Not all pack sizes may be marketed.

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