SCHEDULING STATUS: S4

RILOVIA 100/25 (film-coated tablet)

RILOVIA 200/50 (film-coated tablet)

Lopinavir/Ritonavir

Sugar free

Read all of this leaflet carefully before you start taking RILOVIA 100/25 and RILOVIA 200/50.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- RILOVIA 100/25 and RILOVIA 200/50 have 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 RILOVIA 100/25 AND RILOVIA 200/50 is and what it is used for.

2. What you need to know before you take RILOVIA 100/25 AND RILOVIA 200/50.

3. How to take RILOVIA 100/25 AND RILOVIA 200/50.

4. Possible side effects.

5. How to store RILOVIA 100/25 AND RILOVIA 200/50.

6. Contents of the pack and other information.

1. What RILOVIA 100/25 and RILOVIA 200/50 is and what it is used for

RILOVIA 100/25 and RILOVIA 200/50 are used by adults who are infected with HIV, the virus which causes AIDS. RILOVIA 100/25 or RILOVIA 200/50 should not be administered to children younger than 2 years of age unless specifically directed by their doctor.

RILOVIA 100/25 and RILOVIA 200/50 are antiretroviral medicines. They belong to a group of medicines called protease inhibitors.

RILOVIA 100/25 or RILOVIA 200/50 are prescribed for use in combination with other antiviral medicines. Your doctor will determine which medicines are best for you.

2. What you need to know before you take RILOVIA 100/25 and RILOVIA 200/50

Do not take RILOVIA 100/25 and RILOVIA 200/50 if:

- You are hypersensitive (allergic) to lopinavir or ritonavir or any of the other ingredients of RILOVIA 100/25 and RILOVIA 200/50 (listed in section 6).
- You have severe liver problems.
- You are taking any of the following medicines:

- Alfuzosin (used in men to treat symptoms of enlarged prostate);
- Apalutamide (used for prostate cancer);
- Blonanserin (used to treat psychosis);
- Colchicine (medicine used to treat gout) - if you have kidney and/or liver problems;
- Amiodarone or dronedarone (used to treat abnormal heart beat);
- Any medicines for treating HIV infection unless your doctor, pharmacist or healthcare professional has approved it, as some of the HIV medicines may influence the way the other HIV medicines work;
- Astemizole or terfenadine (commonly used to treat allergy symptoms – these medicines may be available without prescription);
- Cisapride (used to relieve certain stomach problems);

- Ergotamine, dihydroergotamine, ergonovine, methylergonovine (used to treat headaches);

- Elbasvir/grazoprevir (used to treat chronic hepatitis C virus [HCV]);

- Fusidic acid (used to treat bacterial infection);

- Lovastatin, simvastatin, lomitapide - (used to lower blood cholesterol);

- Lurasidone (used to treat depression);

- Midazolam taken orally (taken by mouth), triazolam (used to relieve anxiety and/or trouble sleeping);

- Neratinib (used to treat breast cancer);

- Pimozide (used to treat schizophrenia);

- Quetiapine (used to treat schizophrenia, bipolar disorder and major depressive disorder);

- Salmeterol (used to treat asthma);

- Ranolazine (used to treat chronic chest pain [angina]);

- Sildenafil (used to treat pulmonary arterial hypertension). Sildenafil used to treat erectile dysfunction may be taken under doctor's supervision (see Take special care with RILOVIA 100/25 and RILOVIA 200/50);

- Vardenafil or avanafil (used to treat erectile dysfunction);

- Medicines that contain St John's Wort (*Hypericum perforatum*).

If you are currently taking any of these medicines, ask your doctor about switching to another medicine while you are taking RILOVIA 100/25 and RILOVIA 200/50.

Warnings and precautions

Take special care with RILOVIA 100/25 AND RILOVIA 200/50:

Important information:

- RILOVIA 100/25 and RILOVIA 200/50 are not a cure for HIV infection or AIDS.

- People taking RILOVIA 100/25 and RILOVIA 200/50 may still develop infections or other illnesses associated with HIV disease and AIDS. It is therefore important that you remain under the supervision of your doctor while taking RILOVIA 100/25 and RILOVIA 200/50.

- RILOVIA 100/25 and RILOVIA 200/50 do not reduce the risk of passing HIV to others. Appropriate precautions should be taken to prevent passing the disease through sexual contact (e.g. use of a condom) or blood contamination.

Use with caution in patients with:

Tell your doctor if you experience or have/had:

- A history of liver problems as patients with a history of liver disease, including chronic hepatitis B or C is at increased risk of severe and potentially fatal liver side effects.
- Haemophilia type A and B as RILOVIA 100/25 and RILOVIA 200/50 might increase the risk of bleeding.
- Problems when your cholesterol and triglyceride testing was done.
- Nausea, vomiting, abdominal pain as large increases in the amount of triglycerides (fats in the blood) have been considered a risk factor for pancreatitis (inflammation of the pancreas) and these symptoms may suggest this condition.
- Diabetes as increased blood sugar has been reported in patients receiving RILOVIA 100/25 and RILOVIA 200/50.
- Thirst, frequent urination, blurred vision or weight loss as this may indicate raised sugar levels in the blood.
- 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 other 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 at this time.
- Worsening of signs and symptoms of previous infections soon after anti-HIV treatment is started.
- Joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement as some patients taking these medicines may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe

immunosuppression (reduction in the activity of the immune system), higher body mass index, among others, may be some of the many risk factors for developing this disease.

Other medicines and RILOVIA 100/25 and RILOVIA 200/50

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

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

- Anticancer medicines (e.g. abemaciclib, apalutamide, dasatinib, encorafenib, ibrutinib, ivosidenib, neratinib, nilotinib, venetoclax, vincristine and vinblastine)
- Anticoagulants (e.g. warfarin, rivaroxaban)
- Anticonvulsants (e.g. phenobarbital, phenytoin, carbamazepine)
- Antidepressants (e.g. bupropion; trazodone, midazolam)
- Anti-epilepsy medicines (e.g. phenytoin, lamotrigine and valproate)
- Antifungals (e.g. ketoconazole, itraconazole, voriconazole)
- Anti-infectives (e.g. clarithromycin, erythromycin)
- Anti-mycobacterials (e.g. rifabutin, rifampicin, bedaquiline, delamanid) and antiparasitics (e.g. atovaquone)
- Antipsychotics (e.g. quetiapine)
- Bosentan a vasodilating medicine used to treat pulmonary arterial hypertension
- Chlorpheniramine (heart rate may be influenced)
- Colchicine used to treat gout
- Contraceptives containing ethinyl oestradiol
- Elagolix used in the treatment of pain associated with endometriosis in women
- Erectile dysfunction medicines (e.g. avanafil, vardenafil, sildenafil and tadalafil)
- Fentanyl used to treat pain
- Fostamatinib used to chronic immune thrombocytopenia (a blood disorder)
- Heart medicines:

calcium channel blockers (e.g. felodipine, nifedipine, nicardipine)

medicines used to correct heart rhythm (e.g. amiodarone, dronedarone, bepridil, systemic lidocaine, quinidine)

congestive heart failure (digoxin)

- Herbal medicines (e.g. St John's Wort)
- Medicines affecting the immune system (e.g. cyclosporin, sirolimus (rapamycin)), tacrolimus)
- Medicines used to lower blood cholesterol (e.g. lomitapide, atorvastatin, lovastatin or simvastatin)
- Medicines used to treat hepatitis (e.g. boceprevir)
- Methadone used to treat pain and also for opioid use disorder
- Non-nucleoside reverse transcriptase inhibitors (NNRTIs) (e.g. efavirenz, nevirapine, delavirdine, etravirine, rilpivirine)
- Protease inhibitors (e.g. amprenavir, fosamprenavir, indinavir, nelfinavir, ritonavir, saquinavir)
- Sedatives (e.g. midazolam administered by injection)
- Steroids (e.g. dexamethasone, fluticasone propionate, ethinyl oestradiol)

These examples are a guide and not considered a comprehensive list of all possible medicines that may interact with RILOVIA 100/25 and RILOVIA 200/50. Your healthcare provider should consult appropriate references for comprehensive information.

Taking RILOVIA 100/25 and RILOVIA 200/50 with food and drink:

RILOVIA 100/25 and RILOVIA 200/50 should be swallowed whole and not chewed, broken or crushed and may be taken with food or on an empty stomach.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before taking this medicine.

- Tell you doctor immediately if you are pregnant, think you may be pregnant or if you are breastfeeding.

- Pregnant or breastfeeding mothers should not take RILOVIA 100/25 and RILOVIA 200/50.

- It is recommended that HIV-infected women do not breastfeed their infants because there is a possibility that the baby can be infected with HIV through your breast milk.

Contraceptives:

- If you are currently using an oral contraceptive or using a patch contraceptive to prevent pregnancy, you should use an additional or different type of contraception (e.g. condom) as RILOVIA 100/25 and RILOVIA 200/50 may reduce the effectiveness of oral and patch contraceptives.

- RILOVIA 100/25 and RILOVIA 200/50 do not reduce the risk of passing HIV to others. Appropriate precautions (e.g. use of a condom) should be taken to prevent passing on the disease through sexual contact.

Driving and using machines:

It is not always possible to predict to what extent RILOVIA 100/25 and RILOVIA 200/50 may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which RILOVIA 100/25 and RILOVIA 200/50 affects them.

Do not drive a car or operate machinery if you experience any side effects (e.g. nausea or dizziness) that impact your ability to do so safely. Instead, contact your doctor.

RILOVIA 100/25 AND RILOVIA 200/50 contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium free’.

3. How to take RILOVIA 100/25 AND RILOVIA 200/50

Do not share medicines prescribed for you with any other person.

Always take RILOVIA 100/25 and RILOVIA 200/50 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

It is important that you take RILOVIA 100/25 and RILOVIA 200/50 every day exactly as your doctor prescribed it. Even if you feel better, do not stop taking RILOVIA 100/25 and RILOVIA 200/50 without talking to your doctor. Using RILOVIA 100/25 and RILOVIA 200/50 as recommended should give you the best chance to delay the development of resistance to the medicine.

The recommended dose is:

RILOVIA (200 mg/50 mg)

Adult and adolescent use: The recommended dosage of RILOVIA is two 200/50 mg tablets twice daily taken with or without food.

Use in children (2 years of age and above):

For children, your doctor will decide the right dose (number of tablets) based on the child's height and weight.

RILOVIA 100/25 and RILOVIA 200/50 may be taken with or without meals.

The tablets should be swallowed whole and not chewed, broken or crushed.

If you take more RILOVIA 100/25 and RILOVIA 200/50 than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take RILOVIA 100/25 and RILOVIA 200/50:

It is important to take the total daily dose prescribed to ensure you get maximum benefit. If you miss a dose of RILOVIA 100/25 or RILOVIA 200/50, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double dose.

If you stop taking RILOVIA 100/25 and RILOVIA 200/50

RILOVIA 100/25 and RILOVIA 200/50 should be taken every day exactly as prescribed by your doctor to help control your HIV, no matter how much better you feel. If a side effect is preventing you from taking RILOVIA 100/25 and RILOVIA 200/50 as directed, tell your doctor right away. Always keep enough medicine on hand so you don't run out. When you travel or need to stay in the hospital make sure you will have enough medicine to last until you can get a new supply. Continue to take RILOVIA 100/25 and RILOVIA 200/50 until your doctor tells you otherwise.

4. Possible side effects

RILOVIA 100/25 and RILOVIA 200/50 can cause side effects.
Not all side effects reported for RILOVIA 100/25 and RILOVIA 200/50 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RILOVIA 100/25 or RILOVIA 200/50, please consult your healthcare provider for advice.

It may be difficult to tell which side effects have been caused by RILOVIA 100/25 and RILOVIA 200/50 and which may occur due to other medicines you take at the same time or by the complications of the HIV infection.
You should tell your doctor promptly about these or any other symptoms. If the condition persists or worsens, seek medical attention.

If any of the following happens, stop taking RILOVIA 100/25 and RILOVIA 200/50 and tell your doctor immediately or go to casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to RILOVIA 100/25 and RILOVIA 200/50. You may need urgent medical attention or hospitalisation.
Tell your doctor if you notice any of the following:

Frequent side effects:

- Anaemia (low number of red blood cells), low number of white blood cells (which are usually used to fight infection)
- Hypersensitivity (including hives and swelling)
- Diabetes mellitus
- Anxiety
- Abdominal (stomach) pain and other discomforts (e.g. abnormal stools, indigestion, reflux, flatulence), haemorrhoids
- Asthenia (feeling weak), pain
- Feeling tired, lack of strength and energy
- Muscle disorders such as weakness and spasms, pain in the joints, muscles and back
- Diarrhoea, nausea, vomiting, decreased appetite
- Difficulty in sleeping, night sweats
- Fever, chills, flu syndrome, malaise (feeling unwell)
- Headache (including migraine), dizziness
- Increased cholesterol levels in your blood, increased triglycerides (a form of fat) levels in your blood, increased glucose levels in your blood, high blood pressure
- Inflammation of the liver including increased liver enzymes
- Pancreatitis (swelling (inflammation) of the pancreas)
- Lactic acidosis (a medical condition characterised by a build-up of lactate in the body)
- Paraesthesia (tingling or prickling sensation)
- Peripheral neuropathy (weakness, numbness and pain from nerve damage, usually in the hands and feet)
- Rash, itching, acne, eczema
- Lipodystrophy (weight gain including changes in body shape or face shape due to changes in fat distribution)
- Erectile dysfunction, menstrual disorders (e.g. the absence of monthly menstrual periods or heavy/prolonged vaginal bleeding with menstrual cycle.)

Further information about nausea, vomiting or abdominal pain:

Tell your doctor if you experience nausea, vomiting or abdominal pain as these may be suggestive of pancreatitis (inflammation of the pancreas).

Further information about increased cholesterol and triglycerides:

- The long-term risks for complications such as heart attacks or stroke due to increased triglycerides and cholesterol are not known at this time.
- Your doctor will monitor you and may prescribe other medicines if needed.
- Large increases in the amount of triglycerides (fats in the blood) have been considered a risk factor for pancreatitis (inflammation of the pancreas).

Less frequent side effects:

- Abnormal vision, eye disorders
- Abnormal dreams
- Abnormal thinking
- Abnormally high level of bilirubin (causing yellow discoloration of the eyes and skin, called jaundice) in the blood
- Agitation, nervousness
- Anorexia
- Bacterial infection, skin infections
- Immune reactivation syndrome (a flare-up of symptoms related to an inactive infection in your body)
- Bronchitis
- Cholesterol disorders
- Confusion
- Constipation
- Decreased sexual desire
- Depression and emotional problems
- Dry mouth, dehydration

- Enlarged abdomen
- Forgetfulness
- Hair loss
- Heart disorders – various such as abnormal heart beat, heart attack
- Inability to control your bowels
- Increased appetite
- Inflammation of blood vessels and capillaries; deep vein inflammation related to a blood clot
- Dyspnoea (shortness of breath), chest pain
- Kidney disorders (kidney failure; Inflammation of the kidney)
- Liver disorders
- Lower respiratory tract infection (rhinitis, increased cough)
- Lung disorders
- Mouth sores or ulcerations
- Otitis media (middle ear problems)
- Sinusitis
- Skin (various disorders such as dry skin, skin discolouration, accumulation of scales of greasy skin)
- Swelling or inflammation of the stomach, intestines and colon
- Taste: Loss or changed sense of taste
- Thyroid problems
- Tinnitus (a sound in one ear or both ears, such as buzzing, ringing or whistling), vertigo (sensation of motion or spinning that is often described as dizziness)
- Tremor (uncontrollable shaking of the body)
- Viral infection

Changes in body shape due to changes in fat distribution:

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 other 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 at this time.

Tell your doctor if you notice any changes in your body shape due to changes in fat distribution.

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 or pharmacist. 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 RILOVIA 100/25 AND RILOVIA 200/50.

5. How to store RILOVIA 100/25 AND RILOVIA 200/50

Store at or below 30 °C. Store in the original container. Do not remove from the carton until required for use. Bottles must be kept tightly closed.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What RILOVIA 100/25 AND RILOVIA 200/50 contains

RILOVIA 100/25: Each film-coated tablet contains the active substances: Lopinavir 100 mg and ritonavir 25 mg.

RILOVIA 200/50: Each film-coated tablet contains the active substances: Lopinavir 200 mg and ritonavir 50 mg.

The other ingredients are:

Sodium stearyl fumarate, colloidal silicon dioxide, copovidone, sorbitan monolaurate, film-coat (hypromellose, titanium dioxide, polyethylene glycol 400, hydroxypropyl cellulose, iron oxide yellow, talc, polyethylene glycol 3350, polysorbate 80, colloidal anhydrous silica).

What RILOVIA 100/25 AND RILOVIA 200/50 looks like and contents of the pack

RILOVIA 100/25: Light yellow to yellow coloured, round, biconvex, film-coated tablets, debossed with “M172” on one side and plain on the other side.

RILOVIA 200/50: Light yellow to yellow coloured, film-coated ovaloid tablets, debossed with “M124” on one side and plain on the other side.

RILOVIA 100/25 film-coated tablets will be packed in a round, white and opaque 250 ml HDPE container (Pill jar) (marketable pack) with a white, opaque, tamper-evident polypropylene (PP) closure containing an inbuilt desiccant packed with or without a carton in pack sizes of 56’s, 60’s 112’s and 120’s*.

RILOVIA 100/25 film-coated tablets will be packed in an HDPE bottle pack (marketable pack) comprises of round, wide mouth white HDPE bottle with white opaque polypropylene (PP) screw closure containing desiccant packed in pack sizes of 56’s, 60’s, 112’s and 120’s.

RILOVIA 100/25 film-coated tablets will be packed in a blue HDPE bottle pack comprising of blue opaque HDPE bottle with blue opaque polypropylene (PP) screw closure with aluminium inductions sealing wad with or without desiccant in pack sizes of 60’s and 120’s.

RILOVIA 200/50 film-coated tablets will be packed in white opaque HDPE bottle with white opaque polypropylene (PP) tamper evident closure with inbuilt desiccant packed with or without a carton in pack sizes of 112’s and 120’s*.

1.3.2 Patient Information leaflet

RILOVIA 200/50 film-coated tablets will be packed in white opaque HDPE bottle with white opaque polypropylene (PP) child resistant closure with aluminium induction sealing wad. Separate desiccant is included in the final pack. Packed into a carton in pack size of 112's and 120's*.

RILOVIA 200/50 film-coated tablets will be packed in blue opaque HDPE bottle with blue opaque polypropylene (PP) screw closure with aluminium induction sealing wad without desiccant in pack sizes of 120's.

*Not all packs may be marketed.

Holder of Certificate of Registration

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This leaflet was last revised in

27 January 2025

REGISTRATION NUMBERS:

RILOVIA 100/25: 45/20.2.8/0336

RILOVIA 200/50: 45/20.2.8/0111