

**Applicant:** Mylan (Pty) Ltd

**Proprietary Name:** Rilovia 100/25 & Rilovia 200/50

Each film-coated tablet contains 100 mg lopinavir and 25 mg ritonavir or 200 mg lopinavir and 50 mg ritonavir

## **PROPOSED PATIENT INFORMATION LEAFLET – December 2021**

**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 or your pharmacist.
- **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.

### **SCHEDULING STATUS:**

Schedule 4

### **PROPRIETARY NAME AND DOSAGE FORM:**

**RILOVIA 100/25** (film-coated tablet)

**RILOVIA 200/50** (film-coated tablet)

Lopinavir/Ritonavir

### **1. WHAT RILOVIA 100/25 AND RILOVIA 200/50 CONTAIN:**

**RILOVIA 200/25:** 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.

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**Inactive 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}

**2. WHAT RILOVIA 100/25 AND RILOVIA 200/50 ARE 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.

**3. BEFORE YOU TAKE RILOVIA 100/25 AND RILOVIA 200/50:**

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

- You are allergic to lopinavir or ritonavir or any of the other ingredients contained in the tablets.
- You have severe liver problems.

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- You are taking any of the following medicines:

- Amiodarone (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);

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

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

- Pimozide (used to treat schizophrenia);

- Salmeterol

- 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 (used to treat erectile dysfunction);

- Products 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**.

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

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***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.

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- 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.

**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 and breast-feeding:**

**If you are pregnant or breast-feeding your baby while taking RILOVIA 100/25 and RILOVIA 200/50, please consult your doctor, pharmacist or other health care professional for advice.**

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

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breast-feeding.

- Pregnant or breast-feeding mothers should not take **RILOVIA 100/25** and **RILOVIA 200/50**.

- It is recommended that HIV-infected women do not breast-feed 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 machinery:**

Make sure you know how you react to this medicine before you drive, use machines, or do anything else that could be dangerous.

**Taking other medicines with RILOVIA 100/25 and RILOVIA 200/50:**

**If you are taking medicines on a regular basis, concomitant use of RILOVIA 100/25 and RILOVIA 200/50 may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional, for advice.**

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

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then be taken:

- Acid reducing medicines (omeprazole, ranitidine)
- Anticancer medicines (e.g. vincristine and vinblastine)
- Anticoagulants (e.g. warfarin)
- Anticonvulsants (phenobarbital, phenytoin, carbamazepine)
- Antidepressants (e.g. bupropion; trazodone, midazolam)
- Anti-epilepsy medicines (e.g. phenytoin)
- Antifungals (e.g. ketoconazole, itraconazole, voriconazole)
- Anti-infectives (e.g. clarithromycin; erythromycin; methadone)
- Antimycobacterials (e.g. rifabutin, rifampicin)
- Chlorpheniramine (heart rate may be influenced)
- Contraceptives containing ethinyl oestradiol
- Erectile dysfunction medicines (e.g. sildenafil and tadalafil)
- Heart medicines:
  - calcium channel blockers (e.g. felodipine, nifedipine, nicardipine)
  - medicines used to correct heart rhythm (e.g. amiodarone, bepridil, systemic lidocaine, quinidine)
  - congestive heart failure (digoxin)
- Herbal preparations (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. atorvastatin, lovastatin or simvastatin)
- Non-nucleoside reverse transcriptase inhibitors (NNRTIs) (e.g. efavirenz, nevirapine)
- Protease inhibitors (e.g. amprenavir, fosamprenavir, indinavir, nelfinavir, ritonavir,

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saquinavir)

- Sedatives (e.g. midazolam administered by injection)
- Steroids (e.g. dexamethasone, fluticasone propionate, ethinyl oestradiol)

#### **4. HOW TO TAKE RILOVIA 100/25 AND RILOVIA 200/50:**

##### **Method of administration:**

Consult with your doctor as to the appropriate dosage in relation to your age and weight.

Always take **RILOVIA 100/25** and **RILOVIA 200/50** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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

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

Do not suddenly stop taking **RILOVIA 100/25** and **RILOVIA 200/50** without consulting with your doctor first.

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

##### **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, rush the patient to the nearest hospital or poison control centre.

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

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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.

## 5. SIDE EFFECTS

**RILOVIA 100/25** and **RILOVIA 200/50** can cause side effects. 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.

### ***Frequent:***

- Abdominal (stomach) pain and other discomforts
- Asthenia, pain
- Diarrhoea; nausea; vomiting
- Difficulty in sleeping
- Fever
- Headache
- Increased cholesterol levels in your blood, increased triglycerides (a form of fat) levels in your blood, high blood pressure
- Inflammation of the liver including increased liver enzymes
- Paraesthesia
- Rash, acne

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*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:***

- Abnormal vision, eye disorders
- Abnormal dreams
- Abnormal thinking
- Abnormally high level of bilirubin (a pigment produced from the breakdown of red blood cells) in the blood (low number of red blood cells, low number of white blood cells which are usually used to fight infection)
- Agitation
- Anaemia and other blood disorders
- Anorexia
- Anxiety
- Bacterial infection

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- Bronchitis
- Cholesterol disorders
- Confusion
- Constipation
- Decreased sexual desire and other disorders such as menstrual
- Depression and emotional problems
- Diabetes mellitus
- Dizziness
- Dry mouth
- Enlarged abdomen
- Feeling tired, lack of strength and energy
- Forgetfulness
- Hair loss
- Heart disorders – various such as abnormal heart beat, heart attack
- High blood pressure
- Inability to control your bowels
- Increased appetite
- Inflammation of blood vessels and capillaries; deep vein inflammation related to a blood clot
- Kidney disorders (kidney failure; Inflammation of the kidney)
- Lactic acidosis
- Liver disorders
- Lower respiratory tract infection (rhinitis, increased cough)
- Lung disorders

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- Migraine
- Mouth sores or ulcerations, inflammation of the stomach and intestine
- Muscle disorders such as weakness and spasms, pain in the joints, muscles and back
- Otitis media (middle ear problems)
- Sinusitis
- Skin (various disorders such as dry skin, skin discolouration, eczema, 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)
- Tremor (uncontrollable shaking of the body)
- Viral infection
- Weight gain (also changes in body shape or face shape due to changes in fat distribution)

*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.

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**Not all side effects reported for RILOVIA 100/25 and RILOVIA 200/50 are included in this leaflet. Should your general health worsen while taking RILOVIA 100/25 or RILOVIA 200/50, please consult your doctor, pharmacist or other health care professional for advice.**

#### **6. STORAGE AND DISPOSAL OF 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.

KEEP THIS MEDICINE OUT OF THE REACH AND SIGHT OF CHILDREN.

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 (eg. toilets)

#### **7. PRESENTATION OF RILOVIA 100/25 AND RILOVIA 200/50:**

**RILOVIA 100/25** film-coated tablets will be packed in High Density Polyethylene (HDPE) bottle (Pill jar) pack (marketable pack) with white opaque polypropylene (PP) tamper evident closure with inbuilt desiccant packed into a carton in pack size of 120's.

**RILOVIA 100/25** film-coated tablets will be packed in High Density Polyethylene (HDPE) bottle (Pill jar) pack (marketable pack) with white opaque polypropylene (PP) tamper evident closure with inbuilt desiccant packed in pack size of 120's

High density polyethylene (HDPE) bottle pack (marketable pack) comprises of round, wide mouth white HDP bottle with white opaque polypropylene (PP) screw closure containing

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desiccant packed into a carton in pack size of 60's and 120's.

High density polyethylene (HDPE) bottle pack (marketable pack) comprises of round, wide mouth white HDP bottle with white opaque polypropylene (PP) screw closure containing desiccant packed in pack size of 60's and 120's.

**RILOVIA 200/50** film-coated tablets will be packed in high density polyethylene (HDPE) bottle (Pill jar) pack (marketable pack) with white opaque polypropylene (PP) tamper evident closure with inbuilt desiccant packed into a carton in pack size of 120's.

**RILOVIA 200/50** film-coated tablets will be packed in high density polyethylene (HDPE) bottle (Pill jar) pack (marketable pack) with white opaque polypropylene (PP) tamper evident closure with inbuilt desiccant packed in pack size of 120's.

High density polyethylene (HDPE) bottle pack (marketable pack) with white opaque polypropylene (PP) child resistant closure with aluminium induction sealing wad packed into a carton in pack size of 120's. Separate desiccant is included in the final pack.

High density polyethylene (HDPE) bottle pack (marketable pack) with white opaque polypropylene (PP) child resistant closure with aluminium induction sealing wad packed i in pack size of 120's.

## **8. IDENTIFICATION OF RILOVIA 100/25 AND RILOVIA 200/50**

**RILOVIA 100/25:** Light yellow to yellow coloured, round, biconvex, film-coated tablets,

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debossed with "M172" on one side and plain on 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.

**9. REGISTRATION NUMBERS:**

**RILOVIA 100/25:** 45/20.2.8/0336

**RILOVIA 200/50:** 45/20.2.8/0111

**10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE:**

Mylan (Pty) Ltd

4 Brewery Street

Isando

Johannesburg

Republic of South Africa

**11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:**

20 April 2012