

Applicant: JANSSEN PHARMACEUTICA (PTY) LTD
Product Proprietary Name: EDURANT
Dosage Form: FILM COATED TABLETS
Strength(s): Rilpivirine 25 mg per tablet



PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

Schedule 4

EDURANT

Film-coated tablet

contains 25 mg of rilpivirine as rilpivirine hydrochloride

Contains sugar: Each film-coated tablet contains 56,113 mg lactose monohydrate.

Read all of this leaflet carefully before you are given EDURANT Film-coated tablet

- Keep this leaflet. You may need to read it again.
- EDURANT has 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.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What EDURANT is and what it is used for
2. What you need to know before you take EDURANT
3. How to take EDURANT
4. Possible side effects

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5. How to store EDURANT
6. Contents of the pack and other information

1. What EDURANT is and what it is used for

EDURANT is a medicine used for the treatment of Human Immunodeficiency Virus (HIV) infection. It belongs to a group of HIV medicines called non-nucleoside reverse transcriptase inhibitors (NNRTIs). EDURANT works by reducing the amount of HIV in your body. This will improve your immune system and reduces the risk of developing illnesses linked to HIV infection.

EDURANT is always used in combination with other HIV medicines to treat patients 12 years of age and older who are infected by HIV and who have never been treated before with HIV medicines.

Your doctor will discuss with you which combination of medicines is best for you.

2. What you need to know before you take EDURANT

Do not take EDURANT

- If you are **allergic** (hypersensitive) to rilpivirine or any of the other ingredients of EDURANT.
- EDURANT is not for use in children aged less than 12 years because safety and efficacy have not been proven in this age group.

Do not take EDURANT with any of the following medicines as they may affect the way EDURANT or the other medicine works. Some of these medicines may be obtained without a

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prescription and some of these may be available under other names. It is important that you carefully read the package leaflets that are provided with these medicines:

- Non-nucleoside reverse transcriptase inhibitors (NNRTIs) (HIV medicines)
- rifampicin and rifapentine (medicines to treat some bacterial infections such as tuberculosis)
- carbamazepine, oxcarbazepine, phenobarbital, phenytoin (medicines to treat epilepsy and prevent seizures)
- dexamethasone (a corticosteroid used in a variety of conditions such as inflammation and allergic reactions) when taken by mouth or injected, except as a single dose
- products that contain St John's Wort (*Hypericum perforatum*) (an herbal product used for depression)
- omeprazole, lansoprazole, rabeprazole, pantoprazole, esomeprazole (medicines to prevent and treat stomach ulcers, heartburn or acid reflux disease)

If you are taking any of these, ask your doctor about alternatives.

Warnings and precautions

EDURANT must be taken together with other antiretrovirals as prescribed by your doctor and with a meal. EDURANT is not a cure for HIV infection. It is part of a treatment reducing the amount of virus in the blood. EDURANT does not reduce the risk of passing HIV to others through sexual contact or contamination with blood or other bodily secretions. Therefore, you must continue to use appropriate precautions (e.g. a condom) to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions or blood.

People taking EDURANT may still develop infections or other illnesses associated with HIV

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infection. You must keep in regular contact with your doctor.

Make sure that you check the following points and tell your doctor if any of these apply to you.

- Tell your doctor if you have or have had problems with your liver, including hepatitis B and/or C. Your doctor may evaluate how severe your liver disease is before deciding if you can take EDURANT.
- Tell your doctor if you notice changes in body shape or fat. A gain, loss or redistribution of body fat may occur if you take a combination of HIV medicines. These changes can happen in patients taking HIV medicine. The changes may include an increased amount of fat in the upper back and neck, breast and around the back, chest and stomach area. Loss of fat from the legs, arms and face may also happen. The exact cause and long-term health effects of these conditions are not known.
- Tell your doctor immediately if you notice any symptoms of infections. A condition called Immune Reconstitution Inflammatory Syndrome can happen in some patients with advanced HIV infection (AIDS) when HIV treatment is started. In some patients with advanced HIV-infection and a history of opportunistic infections, signs and symptoms of inflammation from previous infections may occur soon after HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms.

Children and adolescents

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EDURANT is not for use in children less than 12 years of age, because it has not been sufficiently studied in these patients.

Other medicines and EDURANT

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of EDURANT with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare provider, for advice.

EDURANT can be combined with most HIV medicines while some are not recommended. Your doctor will advise on which HIV medicines can be combined with EDURANT. Follow your doctor's instruction carefully.

Some medicines may affect the blood levels of EDURANT in the body when they are taken at the same time as EDURANT.

The effects of EDURANT or other medicines might be influenced if you take EDURANT together with any of the following medicines. Tell your doctor if you take:

- rifabutin (a medicine to treat some bacterial infections). If you take this medicine while taking EDURANT, please carefully read section 3 '*How to take EDURANT*'
- clarithromycin, erythromycin
- cimetidine, famotidine, nizatidine, ranitidine (antihistamines used to treat stomach or intestinal ulcers or used to relieve heartburn from acid reflux)
- antacids (for example, aluminium/magnesium hydroxide, calcium carbonate)
- methadone

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EDURANT with food and drink

It is important that you take EDURANT with a meal. A meal is important to get the right medicine levels in your body. A protein drink alone does not replace a meal.

Pregnancy and Breastfeeding

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby, while taking EDURANT please consult your healthcare provider for advice.

Tell your doctor immediately if you are pregnant. Pregnant women should not take EDURANT unless specifically directed by the doctor.

HIV infected mothers must not breast feed, because there is a possibility of infecting the baby with HIV via breast milk.

Driving and using machines

Some patients may experience tiredness, dizziness or drowsiness during treatment with EDURANT. Do not drive or operate machinery if you feel tired, dizzy or drowsy while taking EDURANT.

Important information about some of the ingredients in EDURANT

EDURANT contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take EDURANT.

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If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take EDURANT

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

Always use EDURANT exactly as your doctor has told you. You must check with your doctor or pharmacist if you are not sure.

Instructions for proper use in adults and children (12 to less than 18 years of age):

The usual dose of EDURANT is one tablet once a day.

Always take EDURANT with a meal.

A meal is important to get the right medicine blood levels in your body.

A protein drink alone does not replace a meal.

Do not change your dose of EDURANT without first talking to your doctor. See your doctor regularly while taking EDURANT.

- When your supply of EDURANT starts to run low, get more from your doctor or pharmacy. It is important not to run out of EDURANT. The amount of HIV in your blood may increase if the medicine is stopped even for a short time.
- If you take an antacid (a medicine to treat heartburn from acid reflux such as

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aluminium/magnesium hydroxide, calcium carbonate), take the antacid either at least 12 hours before or at least 4 hours after EDURANT. If you take an H₂-receptor antagonist (medicines used to treat stomach ulcers, heartburn or acid reflux disease such as cimetidine, famotidine, nizatidine or ranitidine), take the H₂-receptor antagonist at least 12 hours before or at least 4 hours after EDURANT.

- If you take rifabutin (a medicine to treat some bacterial infections), take two tablets of EDURANT once a day. When you stop taking rifabutin, take one tablet of EDURANT once a day. Talk to your doctor or pharmacist if you are not sure.

Do not stop using EDURANT without talking to your doctor first.

HIV therapy may increase your sense of well-being. Even if you feel better, do not stop taking EDURANT or your other HIV medicines. Doing so could increase the risk of the virus developing resistance. Talk to your doctor first.

Removing the child-resistant cap



The plastic bottle comes with a child-resistant cap and should be opened as follows:

- Push the plastic screw cap down while turning it counter clockwise.
- Remove the unscrewed cap.

If you take more EDURANT than you should

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

If you forget to take / missed a dose of EDURANT

- If you notice within 12 hours of the time you usually take EDURANT, you must take the tablet as soon as possible. Always take the tablet with a meal. Then take the next dose as usual.
- If you notice after 12 hours, then skip the dose and take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

EDURANT can have side effects.

Frequent side effects:

- decreased appetite
- depression
- difficulty falling asleep (insomnia), abnormal dreams, sleep disorders
- headache
- stomach pain, nausea
- rash
- tiredness
- changes in your routine liver tests

Less frequent side effects:

- depressed mood
- dizziness, drowsiness

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- vomiting, stomach discomfort

Tell your doctor right away if any of the side effects gets serious, or if you notice any side effects not listed in this leaflet. If the any of the side effects do not go away or worsen, get medical help.

Tell your doctor right away about these or any other unusual symptoms. If the condition does not go away or worsens, get medical help.

Not all side effects reported for EDURANT are included in this leaflet. Should your general health worsen while taking EDURANT, please consult your healthcare provider for advice.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via “6.04 Adverse Drug Reaction Reporting Form” found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/index/8>.

By reporting side effects, you can help provide more information on the safety of EDURANT.

5 How to store EDURANT

Store at or below 30 °C in the original bottle in order to protect from light.

Keep the bottle tightly closed.

Keep in original packaging until required for use.

Do not use EDURANT after the expiry date which is stated on the label.

Do not store in a bathroom.

Return all unused medicine to your pharmacist.

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

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STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.

6 Contents of the pack and other information

What EDURANT contains:

Each film-coated tablet of EDURANT contains 25 mg of rilpivirine as rilpivirine hydrochloride.

Contains sugar: Each film-coated tablet contains 56,113 mg lactose monohydrate.

The other ingredients are:

Croscarmellose sodium, hypromellose, magnesium stearate, povidone, polyethylene glycol, polysorbate, silicified microcrystalline cellulose, titanium dioxide, triacetin

What EDURANT looks like and contents of the pack

White to off-white, film-coated, round, biconvex tablet, debossed with “TMC” on one side and “25” on the other side.

30 tablets are packed into white, high density polyethylene bottle sealed with a polypropylene child-resistant closure with an induction seal liner. The bottle is packed into an outer cardboard carton together with a leaflet.

Holder of certificate of registration



JANSSEN PHARMACEUTICA (PTY) LTD

2 Medical Street, Halfway House

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This leaflet was revised in

19 June 2023

Registration number

46/20.2.8/0793

Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.