

## PATIENT INFORMATION LEAFLET

### EDURANT™ 25 mg film-coated tablets Active substance: rilpivirine

Scheduling Status:

POM

R<sub>x</sub> only

Botswana Schedule: S2

Namibia Schedule: NS2

Zimbabwe Schedule: PP

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- 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 only. 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 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
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 used in combination with other HIV medicines to treat adults and children 12 to 17 years who are infected by HIV and who have never been treated before with HIV medicines. EDURANT is not for use in children less than 12 years of age, because it has not been sufficiently studied in these patients.

### 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. These other ingredients are listed in section 6.

**Do not take EDURANT in combination with any of the following medicines** as they may affect the

way EDURANT or the other medicine works:

- carbamazepine, oxcarbazepine, phenobarbital, phenytoin (medicines to treat epilepsy and prevent seizures)
- rifampicin, rifapentine (medicines to treat some bacterial infections such as tuberculosis)
- omeprazole, esomeprazole, lansoprazole, pantoprazole, rabeprazole (proton pump inhibitors that are medicines to prevent and treat stomach ulcers, heartburn or acid reflux disease)
- 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 treatment
- products that contain St John's wort (*Hypericum perforatum*) (a herbal product used for depression)

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

### **Take special care with EDURANT**

Talk to your doctor or pharmacist before using EDURANT.

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. Therefore, you must continue to use appropriate precautions (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 infection. You must keep in regular contact with your doctor.

EDURANT is not for use in children less than 12 years

.

### **Tell your doctor about your situation**

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 immediately if you notice any **symptoms of infection or inflammation**. In some patients with advanced HIV infection, signs and symptoms of infection or inflammation may occur after HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response.

### **Other medicines and EDURANT**

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription (e.g., over-the-counter herbal products).

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

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.

**It is not recommended to combine EDURANT with** other non-nucleoside reverse transcriptase inhibitors (NNRTIs, which are HIV medicines) such as delavirdine, efavirenz, etravirine, and nevirapine.

If you are taking any of these, ask your doctor for advice.

**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, (antibiotics)
- cimetidine, famotidine, nizatidine, ranitidine (H<sub>2</sub>-receptor antagonists used to treat stomach or intestinal ulcers or used to relieve heartburn from acid reflux)
- antacids (for example, aluminum / magnesium hydroxide, calcium carbonate)
- methadone

### **Taking EDURANT with food and drink**

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

### **Pregnancy and breastfeeding**

Tell your doctor immediately if you are pregnant or if you plan to become pregnant. Pregnant women should discuss the use of EDURANT with their doctor.

HIV infected mothers must not breastfeed, as there is a possibility of infecting the baby with HIV via breastmilk.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

EDURANT has no or negligible influence on the ability to drive and use machines.

### **EDURANT contains lactose**

EDURANT tablets contain lactose. 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**

Always take EDURANT exactly as your doctor has told you. You should check with your doctor if you are not sure.

### **Instructions for proper use**

The recommended dose of EDURANT in adults and children (12 to 17 years) is one tablet once a day. It is important that you always take EDURANT with a meal.

There are three situations that require special attention:

1. **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.
2. **If you take an antacid** (a medicine to treat diseases related to the acid in the stomach, such as aluminium/magnesium hydroxide, calcium carbonate), take the antacid either at least 2 hours before or at least 4 hours after EDURANT (see section 2 “Taking other medicines”).
3. **If you take an H<sub>2</sub>-receptor antagonist** (a medicine to treat stomach ulcers, heartburn, or acid reflux disease, such as cimetidine, famotidine, nizatidine or ranitidine), take the H<sub>2</sub>-receptor

antagonist at least 12 hours before or at least 4 hours after EDURANT (see section 2 “Taking other medicines”).

### 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

Contact your doctor or pharmacist immediately.

### If you forget to take 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 intake and take the next doses as usual. Do not take a double dose to make up for a forgotten dose.

### 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.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## 4. POSSIBLE SIDE-EFFECTS

Like all medicines, EDURANT can cause side-effects, although not everybody gets them.

Common side-effects (affects less than one in ten people)

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

Uncommon side-effects (affects less than one in 100 people)

- depressed mood
- drowsiness
- stomach discomfort

Some side-effects are typical for anti-HIV medicines. These include immune reconstitution inflammatory syndrome and autoimmune hepatitis. In some patients with advanced HIV infection (AIDS) and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti HIV treatment is started, including EDURANT. 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 any of the side-effects gets serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor.

#### Reporting of side-effects

If you get any side-effects, talk to your doctor. This includes any possible side-effects not listed in this leaflet. You can also report side-effects directly to [www.janssen.com](http://www.janssen.com). By reporting side-effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE EDURANT**

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

### **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**

Do not use EDURANT after the expiry date, which is stated on the carton and on the bottle after EXP. The expiry date refers to the last day of that month.

EDURANT tablets should be stored in the original bottle in order to protect from light.

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

Shelf-life: 36 months

## **6. CONTENT OF THE PACK AND OTHER INFORMATION**

### **What EDURANT contains**

- The active substance is rilpivirine in the form of rilpivirine hydrochloride. Each tablet of EDURANT contains rilpivirine hydrochloride equivalent to 25 mg rilpivirine.
- The other ingredients are lactose monohydrate, croscarmellose sodium, povidone K30, polysorbate 20, silicified microcrystalline cellulose, magnesium stearate, hypromellose 2910 6 mPa.s, titanium dioxide, polyethylene glycol 3000 and triacetin.

### **What EDURANT looks like and contents of the pack**

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

A plastic bottle containing 30 tablets.

### **MARKETING AUTHORISATION NUMBERS**

<b>COUNTRY</b>	<b>NUMBER</b>
Botswana	BOT 1703212
Ethiopia	4006/NMR/2017
Malawi	PMPB/PL437/1

Mozambique	
NAFDAC	B4-4149
Namibia	14/20.2.8/0025
Tanzania	TZ14H0270
Uganda	NDA/MAL/HDP/6257
Zambia	8942/14
Zimbabwe	2014/7.13/4960

**MARKETING AUTHORIZATION HOLDER**

Janssen Cilag International NV  
Turnhoutseweg 30  
B-2340 Beerse  
Belgium  
Tel: +27 11 518 7000 (South Africa)  
[www.janssen.com](http://www.janssen.com)

**MANUFACTURED AND PACKED BY**

Janssen-Cilag S.p.A  
Via C.Janssen  
Borgo S. Michele  
04100 Latina  
Italy

**THIS LEAFLET WAS LAST REVISED IN**

April 2022

**FOR DISTRIBUTION IN ACCESS COUNTRIES ONLY**