

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

Pr **EDURANT**[®]
rilpivirine tablets
25 mg rilpivirine as rilpivirine hydrochloride

Read this carefully before you start taking **EDURANT**[®] and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **EDURANT**[®].

What is EDURANT[®] used for?

- **EDURANT**[®] is an anti-HIV (Human Immunodeficiency Virus) medicine that helps to control HIV infection in adults and children (12 years to less than 18 years of age and weighing at least 35 kg). HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

How does EDURANT[®] work?

- **EDURANT**[®] blocks an enzyme which the virus (HIV) needs in order to make more virus. The enzyme that **EDURANT**[®] blocks is called HIV reverse transcriptase.
- When used with other anti-HIV medicines, **EDURANT**[®] may help:
 - reduce the amount of HIV in your blood. This is called “viral load.”
 - increase the number of white blood cells called CD4+ (T) cells that help fight off other infections.
- Reducing the amount of HIV and increasing the CD4+ (T) cell count may improve your immune system and, as a result, reduce the risk of death or infections that can happen when your immune system is weak (opportunistic infections).

What are the ingredients in EDURANT[®]

Medicinal ingredients: rilpivirine in the form of rilpivirine hydrochloride

Non-medicinal ingredients: croscarmellose sodium, hypromellose 2910 6 mPa.s, lactose monohydrate, magnesium stearate, polyethylene glycol 3000, polysorbate 20, povidone K30, silicified microcrystalline cellulose, titanium dioxide and triacetin.

EDURANT[®] comes in the following dosage forms:

Tablets: 25 mg

Do not use EDURANT[®] if:

- you are allergic to rilpivirine or any of the other ingredients in **EDURANT**[®]
- you take the following drugs:

<u>Type of Drug</u>	<u>Examples of Generic Names</u>
Anticonvulsants (to treat epilepsy and prevent seizures)	carbamazepine, oxcarbazepine, phenytoin, phenobarbital

<u>Type of Drug</u>	<u>Examples of Generic Names</u>
Antimycobacterials	rifapentine, rifampin
Glucocorticoids	Systemic dexamethasone (more than a single dose)
Herbal products	St. John's wort (<i>Hypericum perforatum</i>)
Proton Pump Inhibitors (to prevent or treat stomach ulcers, heartburn or acid reflux disease)	omeprazole, lansoprazole, rabeprazole, pantoprazole, esomeprazole

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take EDURANT®. Talk about any health conditions or problems you may have, including if you:

- have an eating disorder or are following a strict diet.
- have any drug allergies.
- have heart disease or a heart condition, including a heart rhythm disorder (QT prolongation) or family history of heart rhythm disorders (QT prolongation) or sudden (heart) death under 50 years of age.
- have electrolyte disturbances (e.g., low blood magnesium or potassium levels) or other conditions that could lead to electrolyte disturbances such as dehydration, diarrhea, vomiting.
- have depression or develop depression while taking EDURANT®.
- have had or currently have liver problems, including hepatitis B or C.
- have severe kidney disease.
- are pregnant or planning to become pregnant.
 - It is not known if EDURANT® can harm your unborn baby. You and your doctor will need to decide if taking EDURANT® is right for you.
 - If you take EDURANT® while you are pregnant, talk to your doctor about how you can be included in the Antiretroviral Pregnancy Registry.
- are breast-feeding or plan to breast-feed.
 - Do not breast-feed if you are taking EDURANT®.
 - It is recommended that HIV-infected women not breast-feed their infants because their babies could become infected with HIV through their breast milk. Talk with your doctor about the best way to feed your baby.
- are 65 years of age or older. If you belong to this age group, please discuss the use of EDURANT® with your doctor
- you have a rare hereditary problem of galactose intolerance (severe lactase deficiency or glucose/galactose malabsorption) as this product contains lactose.

Other warnings that you should know about:

Blood Tests:

Your blood sugar levels (glucose) or levels of fats (lipids) in your blood may increase with HIV treatment. Your doctor may order blood tests for you.

HIV / AIDS:

EDURANT® does not cure HIV infection or AIDS. Right now, there is no cure for HIV infection. People taking EDURANT® may still develop opportunistic infections or other conditions that happen with HIV infection.

Opportunistic infections are infections that develop because the immune system is weak. Some of the other conditions that can happen with HIV are: pneumonia, herpes virus infection, and *Mycobacterium avium* complex (MAC) infections.

EDURANT® does **not** reduce the risk of passing HIV to others through sexual contact, sharing needles, or being exposed to your blood.

- Always practice safer sex.
- Use latex or polyurethane condoms to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions, or blood.
- Never re-use or share needles.

Ask your doctor if you have any questions on how to prevent passing HIV to other people.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine. Your doctor and your pharmacist can tell you if you can take these medicines with EDURANT®.

Do not start any new medicines while you are taking EDURANT® without first talking with your doctor or pharmacist. You can ask your doctor or pharmacist for a list of medicines that can interact with 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.

Avoid grapefruit juice as this may increase the blood levels of EDURANT®.

The following may interact with EDURANT®

Tell your doctor if you are taking any of the following medicines. Some of these medicines may be obtained without a 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.

<u>Type of Drug</u>	<u>Examples of Generic Names (Brand Names)</u>	<u>Type of Drug</u>	<u>Examples of Generic Names (Brand Names)</u>
Antacids (to treat heartburn from acid reflux)	Aluminum, magnesium hydroxide, calcium carbonate	H₂-Receptor Antagonists (to treat stomach ulcers or used to relieve heartburn from acid reflux)	cimetidine (Tagamet®), famotidine (Pepcid®), nizatidine (Axid AR®), ranitidine (Zantac®)

<u>Type of Drug</u>	<u>Examples of Generic Names (Brand Names)</u>	<u>Type of Drug</u>	<u>Examples of Generic Names (Brand Names)</u>
Antimycobacterials: (to treat some bacterial infections)	rifabutin	Macrolide Antibiotics (to treat bacterial infections)	clarithromycin (Biaxin®), erythromycin (Benzamycin®, AK Mycin®, EES®-200/400, EES-600, ERYC®, Erythro-S®, Erythro-ES®, Erybid®, PCE®)
Azole Antifungal Agents	ketoconazole, fluconazole, itraconazole, posaconazole, voriconazole	Narcotic Analgesic	methadone (Methadol®, Metadol-D®, Cophylac® drops)
Corticosteroids (to treat inflammation or asthma)	dexamethasone (Decadron®)		

This is **not** a complete list of medicines that you should tell your doctor about.

How to take EDURANT®:

- **Take EDURANT® tablets every day exactly as prescribed by your doctor.**
- **Always 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.
- Swallow EDURANT® tablets whole with water.
- Do not change your dose or stop taking EDURANT® without first talking with 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:**
 - **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.
 - **antacids** (a medicine to treat heartburn from acid reflux such as aluminum/magnesium hydroxide, calcium carbonate), take the antacid either at least 2 hours before or at least 4 hours after EDURANT®.
 - **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®.

Usual dose:

The recommended dose is one tablet of EDURANT® one time each day.

Overdose:

If you think you have taken too much EDURANT[®], contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of EDURANT[®] within 12 hours of the time you usually take it, take your dose of EDURANT[®] with a meal as soon as possible. Then, take your next dose of EDURANT[®] at the regularly scheduled time.

If you miss a dose of EDURANT[®] by more than 12 hours of the time you usually take it, wait and then take the next dose of EDURANT[®] at the regularly scheduled time.

Do not double the next dose to make up for a missed dose. Do not take more or less than your prescribed dose of EDURANT[®] at any one time. Always take EDURANT[®] with a meal.

What are possible side effects from using EDURANT[®]?

These are not all the possible side effects you may feel when taking EDURANT[®]. If you experience any side effects not listed here, contact your healthcare professional.

Common side effects (affects less than 1 in 10 people)

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

Uncommon side effects (affects less than 1 in 100 people)

- depressed mood
- drowsiness
- stomach discomfort

Other side effects include:

- Possible heart rhythm disturbance, such as dizziness, palpitations (feeling rapid heartbeat) fainting or seizures. If you experience any of these symptoms, seek medical help immediately.

Call your doctor right away if you notice any signs or symptoms of an infection after starting EDURANT[®] with other HIV medicines.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<u>COMMON</u> Effect: Depression or mood changes Symptoms: feelings of deep sadness, thoughts of self-harm or suicide.		x	
<u>RARE</u> Effect: Liver problems Symptoms: abdominal pain, vomiting, nausea, yellowing of the eyes or skin, dark urine or fatigue.		x	
<u>VERY RARE</u> Effect: Severe and potentially life-threatening rash Symptoms: fever, blisters, blisters of the mouth and throat, swollen face or limbs, red spots on the skin, abdominal pain, nausea, vomiting, dark urine, or yellowing of the skin and eyes.		x	
<u>VERY RARE</u> Effect: Changes to your immune system Symptoms: fever, joint or muscle pain, redness, rash, swelling, or fatigue.		x	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store EDURANT® tablets at room temperature between 15–30°C.
- Keep EDURANT® in the bottle given to you by your pharmacist and protect the bottle from light.

Keep out of reach and sight of children.

If you want more information about EDURANT®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>) .
- For questions, concerns and the full product monograph go to <http://www.janssen.com/canada> or contact the manufacturer, Janssen Inc. by calling 1-800-567-3331 or 1-800-387-8781.

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