PART III: CONSUMER INFORMATION

PrEDURANT®
rilpivirine tablets
25 mg rilpivirine as rilpivirine hydrochloride

This leaflet is Part III of a three-part “Product Monograph” published when EDURANT® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about EDURANT®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What is EDURANT®?

- EDURANT® is a prescription anti-HIV medicine that helps to control HIV (Human Immunodeficiency Virus) infection in adults and children (12 years to less 18 years of age and weighing at least 35 kg). HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).
- EDURANT® is a type of anti-HIV drug called a non-nucleoside reverse transcriptase inhibitor (NNRTI).
- EDURANT® is used in adults and children (12 years to less than 18 years of age and weighing at least 35 kg) who have not taken anti-HIV medicines before.
- EDURANT® must be taken in combination with other anti-HIV medicines.
- It is very important for you to remain under the care of your doctor during treatment with EDURANT®.
- The safety and effectiveness of EDURANT® in children less than 12 years of age has not been determined.

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).

Does EDURANT® cure HIV or AIDS?

No. 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.

Does EDURANT® reduce the risk of passing HIV to others?

No. 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.

When it should not be used:

Do not take EDURANT® if you are allergic to rilpivirine or any of the other ingredients in EDURANT® (See “What the nonmedicinal ingredients are”).

Do not take EDURANT® with the following drugs:

<table>
<thead>
<tr>
<th>Type of Drug</th>
<th>Examples of Generic Names</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticonvulsants</td>
<td>carbamazepine, oxcarbazepine, phenytoin, phenobarbital</td>
</tr>
<tr>
<td>Antimycobacterials</td>
<td>rifapentine, rifampin</td>
</tr>
<tr>
<td>Glucocorticoids</td>
<td>Systemic dexamethasone (more than a single dose)</td>
</tr>
<tr>
<td>Herbal products</td>
<td>St. John’s wort (Hypericum perforatum)</td>
</tr>
<tr>
<td>Proton Pump Inhibitors</td>
<td>omeprazole, lansoprazole, rabeprazole, pantoprazole, esomeprazole</td>
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</tbody>
</table>

What the medicinal ingredient is:

Each tablet contains 25 mg of rilpivirine in the form of rilpivirine hydrochloride.

What the nonmedicinal ingredients are:

Each EDURANT® tablet contains the inactive ingredients croscarmellose sodium, magnesium...
stearate, lactose monohydrate, povidone K30, polysorbate 20 and silicified microcrystalline cellulose.
The tablet coating contains hypromellose 2910 6mPa.s, lactose monohydrate, polyethylene glycol 3000, titanium dioxide and triacetin.

**What dosage forms it comes in:**
25 mg tablets

### WARNINGS AND PRECAUTIONS

**What should I tell my doctor before I take EDURANT®?**
Together with your doctor, you need to decide whether taking EDURANT® is right for you.

**Tell your doctor about all of your medical conditions, 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.

Serious skin and allergic reactions have been reported with the use of drug treatments including EDURANT®. Contact your doctor immediately if you develop a severe rash or rash accompanied by fever, blisters, blisters of the mouth and throat, swollen face or limbs, red spots on the skin or liver problems with symptoms such as abdominal pain, nausea, vomiting, dark urine, or yellowing of the skin and eyes.

### INTERACTIONS WITH THIS MEDICATION

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®.

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.

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.

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

### Type of Drug

**Antacids**
(to treat heartburn from acid reflux)
- Aluminum, magnesium hydroxide, calcium carbonate

**Antimycobacterials:**
(to treat some bacterial infections)
- rifabutin
<table>
<thead>
<tr>
<th>Type of Drug</th>
<th>Examples of Generic Names (Brand Names)</th>
<th>Notation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Azole Antifungal Agents</td>
<td>ketoconazole, fluconazole, itraconazole, posaconazole, voriconazole</td>
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<tr>
<td>Corticosteroids (to treat</td>
<td>dexamethasone (Decadron®)</td>
<td></td>
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<tr>
<td>inflammation or asthma)</td>
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<td></td>
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<tr>
<td>$H_2$-Receptor Antagonists (to</td>
<td>cimetidine (Tagamet®), famotidine (Pepcid®), nizatidine (Axd AR®), ranitidine (Zantac®)</td>
<td></td>
</tr>
<tr>
<td>treat stomach ulcers or used to</td>
<td></td>
<td></td>
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<tr>
<td>relieve heartburn from acid</td>
<td></td>
<td></td>
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<tr>
<td>reflux)</td>
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<tr>
<td>Macrolide Antibiotics (to treat</td>
<td>clarithromycin (Biaxin®), erythromycin (Benzamycin®, AK Mycin®, EES*-200/400, EES-600, ERYC®, Erythro-S®, Erythro-ES®, Erybid®, PCE®)</td>
<td></td>
</tr>
<tr>
<td>bacterial infections)</td>
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<tr>
<td>Narcotic Analgesic</td>
<td>methadone (Methadol®, Metadol-D®, Cophylac® drops)</td>
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This is not a complete list of medicines that you should tell your doctor about.

**PROPER USE OF THIS MEDICATION**

- **Take EDURANT® tablets every day exactly as prescribed by your doctor.** The recommended dose is one tablet of EDURANT® one time each day.

- **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. **If you take an antacid** (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®. **If you take an $H_2$-receptor antagonist** (medicines used to treat stomach ulcers, heartburn or acid reflux disease such as cimetidine, famotidine, nizatidine or ranitidine), take the $H_2$-receptor antagonist at least 12 hours before or at least 4 hours after EDURANT®.

  - Importantly, proton pump inhibitors (such as omeprazole, lansoprazole, rabeprazole, pantoprazole, esomeprazole) should not be taken with EDURANT®.

**Overdose:**

In case of drug overdose, contact a health care practitioner (doctor), 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.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all medicines, EDURANT® may cause side effects including:

- **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
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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.

- Feeling depressed, and thoughts of self-harm or suicide while taking EDURANT®. If you experience any of these symptoms, contact your doctor.

- Changes in body shape or body fat. These changes can happen in patients taking anti-HIV medicines. 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.

- Changes in your immune system (Immune Reconstitution Inflammatory Syndrome) can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time, or you could develop an autoimmune disease in which your immune system reacts against your own body (e.g. Grave's disease (which affects the thyroid gland), Guillain-Barré syndrome (which affects the nervous system) or polymyositis (which affects the muscles) and it may develop at any time, sometimes months later after the start of HIV therapy). Sometimes symptoms can be severe, so if you develop high temperature (fever), joint or muscle pain, redness, rash, swelling, or fatigue or any new symptoms contact your doctor straight away.

- Liver problems can happen in people who take EDURANT®. People with a history of hepatitis B or C virus infection or who have certain liver function test changes may have an increased risk of developing new or worsening liver problems during treatment with EDURANT®. Liver problems have also been reported during treatment with EDURANT® in people without history of liver disease. Your doctor may need to do tests to check liver function before and during treatment with EDURANT®. If you suffer symptoms such as abdominal pain, vomiting, nausea, yellowing of the eyes or skin or fatigue, contact your doctor.

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

This is not a complete list of side effects. For any unexpected effects while taking EDURANT®, contact your doctor or pharmacist.

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

**HOW TO STORE IT**

- 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 EDURANT® and all medications out of reach and sight of children.

**General advice about EDURANT®:**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use EDURANT® for a condition for which it was not prescribed. Do not give EDURANT® to other people even if they have the same condition you have. It may harm them.

This leaflet provides a summary of the most important information about EDURANT®. If you would like more information, talk to your doctor. You can ask your doctor or pharmacist for information about EDURANT® that is written for health professionals.

**REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
  Health Canada
  Postal Locator 1908C
  Ottawa, Ontario
  K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect® Canada Web site at www.healthcanada.gc.ca/medeffect.

**NOTE:** Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.
MORE INFORMATION

For questions, concerns, or the full product monograph go to:
http://www.janssen.com/canada
or contact the manufacturer, Janssen Inc., at:
1-800-567-3331 or 1-800-387-8781.

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