

EDURANT[®] FILM-COATED TABLET

Rilpivirine (25 mg)

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What EDURANT[®] 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 is always used in combination with other HIV medicines. Your doctor will discuss with you which combination of medicines is best for you.

EDURANT in combination with other HIV medicines is used to treat adults who are infected by HIV and who have never been treated before with HIV medicines.

How EDURANT[®] works

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.

Before you use EDURANT[®]

- When you must not use it

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 "Product Description".

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.

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 breast-feed, as there is a possibility of infecting the baby with HIV via breastmilk.

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

- Before you start to use it
Take special care with EDURANT
EDURANT is not a cure for HIV infection. It is part of a treatment reducing the amount of virus in the 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 or adolescents, because it has not been sufficiently studied in patients under 18 years of age.

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.

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- Taking other medicines

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 'How to use EDURANT'.
- clarithromycin, erythromycin (antibiotics)
- cimetidine, famotidine, nizatidine, ranitidine (H₂-receptor antagonists used to

treat stomach or intestinal ulcers or used to relieve heartburn from acid reflux)

- antacids (for example, aluminium / 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.

How to use EDURANT[®]

- How much to use

The recommended dose of EDURANT 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 "Taking other medicines").
3. If you take an H₂-receptor antagonist (a medicine 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 (see "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.

- When to use it

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

- How long to use it

Continue taking EDURANT for as long as your doctor recommends.

- If you forget to use it

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.

- If you use too much (overdose)

Contact your doctor or pharmacist immediately.

While you are using it

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- Things you must do

Be sure to keep all your doctor's appointments so your progress can be checked. Your doctor will want to do some blood and other tests from time to time to check on your progress.

Be sure to follow up your doctor's instructions about other medicines you should take, and other things you should do. Ask your doctor or pharmacist if you have any questions.

Tell any other doctors and pharmacists who are treating you that you are taking EDURANT. If you are undergoing anaesthesia, tell your anaesthetist that you are taking EDURANT.

If you are about to be started on any new medicines, tell your doctor or pharmacist that you are taking EDURANT.

If you become pregnant while taking EDURANT, tell your doctor immediately.

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

- Things you must not do

Do not stop taking 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 anti-HIV medicines. Doing so could increase the risk of the virus developing resistance. Talk to your doctor first.

- Things to be careful of

Driving and using machines

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

Side effects

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

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
- rash
- tiredness
- changes in your routine liver tests

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

- depressed mood
- drowsiness
- stomach discomfort

Some side effects are typical for anti-HIV medicines. These include immune reconstitution inflammatory syndrome. 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 that 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of EDURANT[®]

- Storage

Do not store above 30°C.

Keep out of the reach and sight 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.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

White to off-white, film-coated, round, biconvex tablet, with

EDURANT[®] FILM-COATED TABLET

Rilpivirine (25 mg)

“TMC” on one side and “25” on the other side.

A plastic bottle containing 30 tablets.

- Ingredients

- Active ingredient

Rilpivirine hydrochloride.

- Inactive ingredients

Lactose monohydrate,
croscarmellose sodium, povidone
K30, polysorbate 20, silicified
microcrystalline cellulose,
magnesium stearate, hypromellose
2910 6 mPa.s, titanium dioxide
E171, macrogol 3000 and triacetin.

- MAL number:

MAL13035067AZ

Manufacturer

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

Product Registration Holder

Johnson & Johnson Sdn Bhd
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Malaysia

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