

Package leaflet: Information for the user

EDURANT 25 mg film-coated tablets rilpivirine

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
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1. What EDURANT is and what it is used for

EDURANT contains rilpivirine that is 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.

EDURANT is used in combination with other HIV medicines to treat adults, adolescents and children weighing at least 25 kg who are infected with HIV.

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 to rilpivirine or any of the other ingredients of this medicine (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.

Warnings and precautions

Talk to your doctor or pharmacist before taking EDURANT.

EDURANT is not a cure for HIV infection. It is part of a treatment reducing the amount of virus in the blood.

EDURANT has only been used in a limited number of patients of 65 years or older. If you belong to this age group, please discuss the use of EDURANT with your doctor.

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, and/or **problems with your kidneys**. Your doctor may evaluate how severe your liver or kidney disease is before deciding if you can take EDURANT.
- Tell your doctor immediately if you notice any **symptoms of infections** (for example, fever, chills, sweats). In some patients with advanced HIV infection and a history of opportunistic infection, 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.
- 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 you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.
- Tell your doctor if you are taking any medicines that may cause a life-threatening irregular heartbeat (Torsade de Pointes).

Children

EDURANT is not for use in children less than 2 years of age or weighing less than 14 kg, because it has not been evaluated in these patients.

Other medicines and EDURANT

You must take EDURANT together with other HIV medicines. Your doctor will advise on which HIV medicines can be combined with EDURANT and together you will decide which combination fits your needs best. Follow your doctor's instruction carefully.

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

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 take EDURANT in section 3 "Instructions for proper use in adults and adolescents (12 to less than 18 years of age)".
- clarithromycin, erythromycin (antibiotics)
- cimetidine, famotidine, nizatidine, ranitidine (H₂-receptor antagonists used to treat stomach or intestinal ulcers or used to relieve heartburn due to acid reflux). If you take these medicines, please carefully read how to take them in section 3 "Instructions for proper use in adults and adolescents (12 to less than 18 years of age)".
- antacids (used to treat diseases related to the acid in the stomach; for example, aluminium/magnesium hydroxide, calcium carbonate). If you take these medicines, please

carefully read how to take them in section 3 “Instructions for proper use in adults and adolescents (12 to less than 18 years of age)”.

- methadone (used to treat narcotic withdrawal and dependence)
- dabigatran etexilate (anticoagulant).

Tell your doctor if you take any of the medicines listed above.

Pregnancy and breast-feeding

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.

Breast-feeding is not recommended in women living with HIV because HIV infection can be passed on to the baby in breast milk.

If you are breast-feeding, or thinking about breast-feeding, you should discuss it with your doctor as soon as possible.

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

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.

EDURANT contains lactose

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

EDURANT contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take EDURANT

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Instructions for proper use in adults, adolescents and children (weighing at least 25 kg)

EDURANT is also available as dispersible tablets for paediatric patients 2 to less than 18 years of age weighing at least 14 kg and less than 25 kg (**see the separate instructions for use**). Film-coated tablets and dispersible tablets are not the same. Do not replace the 25 mg film-coated tablet with ten 2.5 mg dispersible tablets.

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

EDURANT **must be taken with a meal**. A meal is important to get the right levels of active substance in your body. A nutritional drink (e.g. protein-rich) alone does not replace a meal.

There are four 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 “Other medicines and EDURANT”).
3. **If you take an H₂-receptor antagonist** (medicines used to treat stomach or intestinal ulcers or used to relieve heartburn due to acid reflux (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 section 2 “Other medicines and EDURANT”). H₂-receptor antagonists should not be taken in a twice a day regimen. Talk to your doctor about an alternative regimen.

4. **If you take didanosine** (a medicine to treat HIV infection), no dose adjustment is required. Didanosine should be administered on an empty stomach at least two hours before or at least four hours after EDURANT (which must be taken with a meal).

Removing the child resistant cap



The bottle comes with a child resistant cap. It can be opened by pushing the screw cap down while turning it anti-clockwise.

If you take more EDURANT than you should

Contact your doctor or pharmacist immediately. In case of overdose, you may have a headache, nausea, dizziness, and/or abnormal dreams.

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. The EDURANT tablet must be taken with a meal. Then take the next dose as usual. If you notice **after 12 hours**, then skip that dose and take the next doses as usual. Do not take a double dose to make up for a forgotten dose.

If you vomit less than 4 hours after taking EDURANT, take another tablet with a meal. If you vomit more than 4 hours after taking EDURANT you do not need to take another tablet until your next regularly scheduled tablet.

Contact your doctor if uncertain about what to do if you miss a dose or vomit.

Do not stop using EDURANT

HIV treatment does not cure HIV infection! Do not stop using EDURANT without talking to your doctor first. 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Very common (**may affect more than 1 in 10 people**):

- headache
- nausea
- difficulty falling asleep (insomnia)
- feeling dizzy
- changes in one of your routine liver tests (transaminase)
- increase in cholesterol and/or pancreatic amylase in your blood

Common (**may affect up to 1 in 10 people**):

- abnormal dreams
- rash
- stomach pain
- depression
- feeling very tired
- vomiting

- feeling sleepy
- decreased appetite
- sleep disorders
- stomach discomfort
- feeling depressed
- dry mouth
- low white blood cell and/or platelet count, decrease in haemoglobin in your blood, increase in triglycerides, lipase and/or bilirubin in your blood

Uncommon (may affect up to 1 in 100 people):

- signs or symptoms of inflammation or infection, for example fever, chills, sweats (immune reactivation syndrome)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store EDURANT

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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.

Store in the original bottle in order to protect from light. This medicinal product does not require any special temperature storage conditions.

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.

6. Contents 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 of the film-coated tablet core are lactose monohydrate, croscarmellose sodium (E468), povidone K30 (E1201), polysorbate 20, silicified microcrystalline cellulose (E460) and magnesium stearate (E470b). The film-coating contains lactose monohydrate, hypromellose 2910 6 mPa.s (E464), titanium dioxide (E171), macrogol 3000 and triacetin (E1518).

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 bottle with child resistant closure containing 30 film-coated tablets.

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