

Package leaflet: Information for the user

EDURANT 2.5 mg dispersible tablets rilpivirine

Read all of this leaflet carefully before you (or your child) 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 (or your child) only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours (or your child).
- If you (or your child) get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- The information in this leaflet is for you or your child – but in this leaflet we usually just say ‘you’.

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 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 the body.

EDURANT is used in combination with other HIV medicines to treat children and adolescents 2 to less than 18 years of age weighing at least 14 kg and less than 25 kg who are infected with HIV.

Your doctor will talk to you about 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 (a herbal product used for depression).

Do not take EDURANT if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking EDURANT. Ask your doctor about alternatives to the medicines listed above.

Warnings and precautions

Talk to your doctor or pharmacist before you start taking EDURANT.

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

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

Do not use EDURANT for children less than 2 years old 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 tell you which HIV medicines can be taken with EDURANT and together you will decide which combination fits your needs best. You must 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:

- antibiotics such as clarithromycin, erythromycin
- 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.
- 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.
- 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, cycling, and using tools or machines

Some patients may feel tired, dizzy or drowsy during treatment with EDURANT.

- Do not drive, cycle or use tools or machines if you feel tired, dizzy or drowsy while taking EDURANT.

EDURANT contains lactose and sodium

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

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. Your doctor or pharmacist will tell you how many EDURANT dispersible tablets you should take. EDURANT dispersible **tablets must be dispersed in water and must be taken with a meal.**

- EDURANT is also available as film-coated tablets for paediatric and adult patients weighing at least 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.

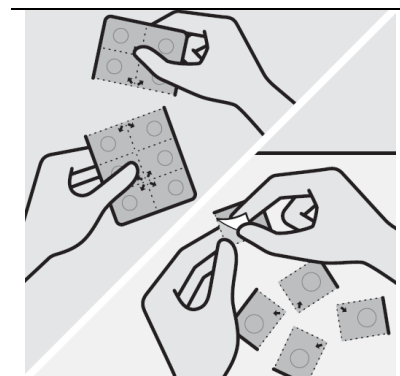
Instructions for use

EDURANT dispersible tablets **must be taken with a meal.** A meal is important to get the right levels of medicine in your body. A nutritional drink (such as a-protein shake) or yogurt alone does not replace a meal.

Prepare and take EDURANT dispersible tablets every day exactly as your doctor tells you. Read these instructions carefully before you take EDURANT dispersible tablets. Your doctor will tell you how many EDURANT dispersible tablets you need to take, based on your weight. EDURANT dispersible tablets must be dispersed in water. You must not chew or swallow the tablets whole.

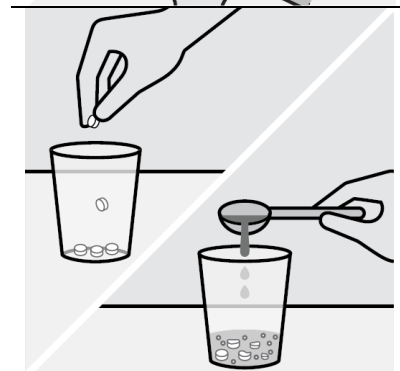
Step 1: Prepare the medicine

- Count the number of tablets you need and tear each unit from the blister pack along the dotted line.
- Do not push the tablets out of the foil as they may break.
- For each unit, peel back the foil gently in the direction of the arrow.



Step 2: Place the tablets in a cup

- Gently place the tablets in a cup. Do not crush the tablets.
- Add 5 ml (1 teaspoon) of water at room temperature to the cup.
- Swirl the cup carefully to disperse the tablets. The mixture will start to look cloudy.



If you spill any medicine, clean up the spill. Throw away the rest of the prepared medicine and make a new dose

You must take the dose of medicine immediately. If you do not take the medicine immediately, throw away the mixture, and prepare a new dose of medicine.

Step 3: Taking the medicine

- Take all the prepared medicine immediately or add another 5 ml (1 teaspoon) of either water or any of the following to aid in administration: milk, orange juice or applesauce which has acclimated to room temperature before use.
- Swirl and take all medicine immediately. A spoon can be used if needed.
- Make sure the entire dose is taken and no medicine is left in the cup, if required add another 5 ml (1 teaspoon) of water or same beverage (milk, orange juice) or applesauce, swirl and drink immediately

There are three situations that require special attention. If you take:

1. **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”).
2. **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 either:
 - 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.

3. **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 EDURANT or,
 - at least four hours after EDURANT (which must be taken with a meal).

If you take more EDURANT than you should

Contact your doctor or pharmacist immediately. In case of overdose, you may have a headache, nausea, feel dizzy, and/or have 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 dose as soon as possible. The EDURANT tablets 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 dose as usual. Do not take a double dose to make up for a forgotten dose.

Contact your doctor if you are not sure about what to do if you miss a dose.

If you vomit after taking EDURANT

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

Contact your doctor if uncertain about what to do if you vomit after taking this medicine.

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 EDURANT or other HIV medicines. If you do, it could increase the risk of the virus developing resistance. Talk to your doctor before stopping taking this medicine.

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 blister after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light and moisture. 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 dispersible tablet of EDURANT contains rilpivirine hydrochloride equivalent to 2.5 mg rilpivirine.
- The other ingredients of the dispersible tablet are croscarmellose sodium (E468), lactose monohydrate, mannitol (E421), microcrystalline cellulose (E460), polysorbate 20, povidone K30 (E1201), sodium lauryl sulfate (E487) and sodium stearyl fumarate.

What EDURANT looks like and contents of the pack

White to almost white, round 6.5 mm, debossed with "TMC" on one side and "PED" on the other side.

EDURANT 2.5 mg dispersible tablets come in perforated Alu-Alu unit dose blisters with integrated desiccant and an aluminium peelable lidding foil. Each child-resistant blister contains 10 x 1 dispersible tablets. Each carton contains 90 x 1 dispersible tablets.

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