

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Edurant® , Film-coated Tablets, 25 mg

Active ingredient and its quantity per dosage unit:
Rilpivirine (as hydrochloride) 25 mg per tablet

Inactive and allergenic ingredients in the medicine – see section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

The medicine is intended for adults (above the age of 18 years).

1. WHAT IS THE MEDICINE INTENDED FOR?

Edurant is a medicine intended for the treatment of HIV infection in adults. Edurant works by reducing the amount of HIV in your body. This reduction will lead to an improved immune system and to a reduction in the risk of developing diseases that are associated with HIV.

Edurant is intended for adults who were not treated in the past with other HIV medicines and whose viral load does not exceed 100,000 copies per ml. The doctor will measure your viral load.

Edurant is always given in combination with other HIV medicines. Your doctor will explain to you which combination of medicines is best for you.

Therapeutic group: HIV treatment from the non-nucleoside reverse transcriptase inhibitors (NNRTIs) group.

2. BEFORE USING THE MEDICINE:

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient rilpivirine or to any of the other ingredients contained in Edurant. For a list of the additional ingredients, see section 6 "Further information".
- **Do not take Edurant in combination with any of the following medicines**, as they may affect the activity of Edurant or alternatively, Edurant may affect the activity of the medicines:
 - carbamazepine, oxcarbazepine, phenobarbital, phenytoin (medicines to treat epilepsy and prevent seizures).
 - rifampicin and rifapentine (medicines to treat bacterial infections, such as tuberculosis).
 - omeprazole, esomeprazole, lansoprazole, pantoprazole, rabeprazole (medicines from the proton pump inhibitors group for prevention and treatment of stomach ulcers, heartburn or acid reflux disease).
 - dexamethasone (a corticosteroid used in a variety of conditions, such as inflammations and allergic reactions), when taken orally or by injection, except when administered as a single-dose treatment.
 - preparations that contain St. John's wort (*Hypericum perforatum*) (a herbal preparation to treat depression).

If you are taking any of the above-mentioned medicines, consult with the doctor about alternatives.

Special warnings regarding use of the medicine

- Before treatment with Edurant, speak to your doctor or pharmacist.
- Edurant does not cure HIV infection. This medicine is part of a treatment to reduce the amount of virus in the blood.
- Edurant has only been used by a limited number of patients 65 years of age and older. If you belong to this age group, consult the doctor about taking this medicine.

Tell the doctor about your condition

Tell the doctor if any of the following relate to you:

- Tell your doctor if you suffer, or have suffered in the past, from **liver problems**, including hepatitis B and/or C, and/or **kidney problems**. Your doctor may evaluate the severity of your liver or kidney disease before deciding if you can take Edurant.
- Tell your doctor immediately if you notice any **symptoms of an infection** (e.g., fever, chills, sweating). In some patients with advanced HIV infection and a history of opportunistic infections, signs and symptoms of inflammation from previous infections may occur soon after treatment with HIV medicines is started. It is assumed that these symptoms occur due to an improvement in the body's immune response, which allows the body to fight infections that may have been present with no obvious symptoms.
- In addition to opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after initiation of treatment with HIV medicines. Autoimmune problems may even 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 that moves up towards the trunk of the body, palpitations, tremor or hyperactivity, inform your doctor immediately to get essential treatment.
- Tell your doctor if you are taking medicines that may cause life-threatening heart rhythm disturbances (torsade de pointes).

Children and adolescents

Edurant is not intended for use in children and adolescents under 18 years of age.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

- Edurant must be taken together with other HIV medicines. The doctor will advise regarding which other HIV medicines can be taken together with Edurant. Together with the doctor, you will decide which combination of medicines is optimal for you. Follow the doctor's instructions.
- Some medicines may affect the levels of Edurant in the blood when they are taken at the same time as Edurant.
- **It is not recommended to take Edurant together with other non-nucleoside reverse transcriptase inhibitors (NNRTIs)**, such as: delavirdine, efavirenz, etravirine and nevirapine.
- **The effect of Edurant or of other medicines might change** if you take Edurant together with any of the following medicines. Tell the doctor if you are taking:
 - Rifabutin (a medicine for the treatment of certain bacterial infections). If you take this medicine during the course of treatment with Edurant, please carefully read how to take Edurant, in section 3 "How should the medicine be used".
 - Clarithromycin, erythromycin (antibiotics).
 - Cimetidine, famotidine, nizatidine, ranitidine (H₂-receptor antagonists, to treat stomach or intestinal ulcers or to relieve heartburn due to acid reflux). If you take these medicines, please carefully read how to take them, in section 3 "How should the medicine be used".
 - Antacids (for treatment of diseases related to stomach acidity, such as aluminum/magnesium hydroxide, calcium carbonate). If you take these medicines, please carefully read how to take them, in section 3 "How should the medicine be used".
 - Methadone (to treat narcotic withdrawal or dependence).
 - Dabigatran etexilate (anticoagulant).

Use of the medicine and food

Edurant must be taken with a meal. A meal is important in order to receive the right levels of active ingredient in your body. A nutritional drink alone (e.g., a protein-rich drink) is not a substitute for a meal. See section 3 "How should the medicine be used".

Pregnancy and breastfeeding

Tell your doctor immediately if you are pregnant or plan to become pregnant. Pregnant women should discuss the use of Edurant with their doctor.

Breastfeeding is not recommended in women living with HIV, due to the fear that the HIV infection can pass to the baby through breast milk.

If you are breastfeeding, or are planning to breastfeed, consult a doctor or pharmacist as soon as possible.

Driving and using machines

Some patients may experience tiredness, dizziness or drowsiness during treatment with Edurant. Do not drive or operate dangerous machinery if you feel tired, dizzy or drowsy while taking Edurant.

Important information about some of the ingredients of the medicine

Edurant contains lactose

If you have been told by the doctor that you suffer from an intolerance to certain sugars, consult with the doctor before taking Edurant.

Edurant contains sodium

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

3. HOW SHOULD THE MEDICINE BE USED?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about how to use it.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is one tablet, once a day.

Do not exceed the recommended dosage.

Edurant must be taken with a meal. A meal is important in order to receive the right levels of active ingredient in your body. A nutritional drink alone (e.g., a protein-rich drink) is not a substitute for a meal.

There are four situations that require special attention:

1. **If you take rifabutin** (a medicine for the treatment of certain bacterial infections), take two Edurant tablets once a day. When you stop taking rifabutin, take one Edurant tablet once a day. Speak to the doctor or pharmacist if you are uncertain.
2. **If you take antacids** (to treat diseases related to stomach acidity, such as: aluminum/magnesium hydroxide, calcium carbonate). Take the antacid at least two hours before or at least four hours after taking Edurant (see section 2 "Before using the medicine", subsection "Drug interactions").
3. **If you take H₂-receptor antagonists** (to treat stomach or intestinal ulcers or 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 taking Edurant (see section 2 "Before using the medicine", subsection "Drug interactions"). H₂-receptor antagonists should not be taken in a twice-a-day regimen. Refer to the doctor about an alternative regimen.
4. **If you take didanosine** (a medicine to treat HIV infection), a dosage adjustment is not required. Take didanosine on an empty stomach at least two hours before or at least 4 hours after taking Edurant (which must be taken with food).

Opening instructions for a child-resistant cap:

The plastic bottle comes with a child-resistant cap. Open the cap by pressing down on the plastic cap while turning counterclockwise.



There is no information regarding crushing/halving/chewing the tablets. However, it is recommended not to crush them since it can lead to loss of material and thereby to administration of a less accurate dosage.

If you have accidentally taken a higher dosage, if you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you. In case of an overdose, you may suffer from a headache, nausea, dizziness and/or unusual dreams.

If you forget to take Edurant

If you notice that you forgot to take Edurant **within 12 hours of the time you usually take it** – take Edurant as soon as you remember. Always take Edurant with a meal. Afterwards, continue taking Edurant as usual, at the regular time.

If you notice that you forgot to take Edurant **after 12 hours from the time you usually take it**, skip the present dose and continue taking the rest of the doses at their usual times. Do not take a double dose to compensate for a forgotten dose.

If you vomit within less than 4 hours after taking Edurant, take another tablet with a meal. If you vomited more than 4 hours after taking Edurant, there is no need to take another tablet until the next scheduled administration time.

Contact the doctor if you are uncertain about what to do if you forgot to take Edurant or vomited.

Adhere to the treatment regimen as recommended by the doctor.

Do not stop treatment with Edurant

Treatment of HIV does not cure HIV infection! Do not stop treatment with Edurant without consulting a doctor. Even if there is an improvement in your health, do not stop treatment with Edurant or with the other HIV medicines you are taking. **If you stop taking the medicine**, you may increase the risk of the HIV developing resistance. Before stopping treatment with the medicine, consult the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Edurant may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Very common side effects:

- headache
- nausea
- difficulty falling asleep (insomnia)
- dizziness
- changes in liver function test results (transaminase)
- increase in cholesterol and/or a pancreatic enzyme called amylase in the blood

Common side effects:

- abnormal dreams
- rash
- stomach pain
- depression
- tiredness
- vomiting
- drowsiness
- decreased appetite
- sleep disorders
- stomach discomfort
- depressed mood
- dry mouth
- low white blood cell and/or platelet count, decrease in hemoglobin in your blood, increase in triglycerides, lipase and/or bilirubin in your blood

Uncommon side effects:

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

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Do not store the medicine at a temperature that exceeds 30°C.
- After first opening the package, use within 8 weeks, but no later than the expiry date.
- Store the Edurant tablets in their original bottle in order to protect the medicine from light.

6. FURTHER INFORMATION

• In addition to the active ingredient, the medicine also contains:

Tablet core:

Lactose monohydrate, Silicified microcrystalline cellulose, Croscarmellose sodium, Povidone K30, Magnesium stearate, Polysorbate 20.

Tablet coating:

Hypromellose 2910 6mPa.s, Titanium dioxide, Lactose monohydrate, Macrogol 3000, Triacetin.

- What the medicine looks like and the contents of the package: white to off-white, film-coated, round, biconvex tablet, with "TMC" imprinted on one side and "25" imprinted on the other side.
- The package – a plastic bottle **with a child-resistant cap** that contains 30 tablets.

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

Registration Holder: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Revised in March 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 148-57-33585-00