

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking EDURANT?

EDURANT contains the active ingredient rilpivirine. EDURANT in combination with other HIV medicines is used to treat adults who are infected by HIV and who have not used other anti-HIV medicines before.

For more information, see Section [1. Why am I using EDURANT?](#) in the full CMI.

2. What should I know before I take EDURANT?

Do not use if you have ever had an allergic reaction to EDURANT or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you are 65 years or older, or have problems with your liver, or symptoms of infection or inflammation. Tell your doctor if you take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use EDURANT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EDURANT and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take EDURANT?

- The usual dose of EDURANT is one tablet taken once daily with a meal.

More instructions can be found in Section [4. How do I use EDURANT?](#) in the full CMI.

5. What should I know while taking EDURANT?

Things you should do	<ul style="list-style-type: none">• Call your doctor straight away if you become pregnant while taking EDURANT• Remind any doctor, dentist or pharmacist you visit that you are taking EDURANT.• If you are undergoing anaesthesia, tell your anaesthetist that you are taking EDURANT.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine without talking to your doctor first.
Looking after your medicine	<ul style="list-style-type: none">• Store EDURANT tablets below 30°C.• Store EDURANT tablets in the original bottle. Keep the bottle tightly closed in order to protect from moisture and light.

For more information, see Section [5. What should I know while using EDURANT?](#) in the full CMI.

6. Are there any side effects?

The side effects you may experience include: skin rash, stomach pain, nausea, depression, sleep disorders, decreased appetite, tiredness, changes in your routine liver tests, and headache.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

EDURANT®

Active ingredient(s): *rilpivirine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using EDURANT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking EDURANT.**

Where to find information in this leaflet:

- [1. Why am I using EDURANT?](#)
- [2. What should I know before I take EDURANT?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take EDURANT?](#)
- [5. What should I know while using EDURANT?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking EDURANT?

EDURANT contains the active ingredient rilpivirine. EDURANT is a medicine used for the treatment of Human Immunodeficiency Virus (HIV) infection. It belongs to a group of anti-HIV medicines called non-nucleoside reverse transcriptase inhibitors (NNRTIs).

EDURANT in combination with other HIV medicines is used to treat adults who are infected by HIV and who have not used other anti-HIV medicines before.

EDURANT must be taken in combination with other anti-HIV medicines. Your doctor will discuss with you which combination of medicines is best for you.

EDURANT works by reducing the amount of HIV in your body. This will improve your immune system and reduce the risk of developing illnesses linked to HIV infection.

2. What should I know before I take EDURANT?

Warnings

Do not take EDURANT if:

- you are allergic to rilpivirine, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can take this medicine.

Do not combine EDURANT with any of the following medicines:

- carbamazepine, oxcarbazepine, phenobarbital, phenytoin (to treat epilepsy or prevent seizures)
- non-nucleoside reverse transcriptase inhibitors (NNRTIs) (HIV medicines)

- rifampicin, rifapentine (to treat some infections such as tuberculosis)
- products that contain St John's wort (*Hypericum perforatum*) (a herbal product used for depression)
- omeprazole, esomeprazole, lansoprazole, rabeprazole, pantoprazole (to treat gastrointestinal ulcers, heartburn or acid reflux disease)
- dexamethasone (a corticosteroid used in a variety of conditions such as inflammation and allergic reactions)

If you are taking any of these, ask your doctor for advice.

There are other medicines that you need to be careful of when taking EDURANT (see Section [3. What if I am taking other medicines?](#)).

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.
- EDURANT does not reduce the risk of passing HIV to others through sexual contact or blood contamination. Therefore, you must continue to use appropriate precautions (a condom or other barrier method) 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 to monitor your health while taking EDURANT.
- EDURANT is not for use in children or adolescents.
- EDURANT has only been used in a limited number of patients aged 65 years or older. If you belong to this age group, discuss the use of EDURANT with your doctor.

Check with your doctor if you:

- have or have had any medical conditions, especially the following:
 - Problems with your liver.**
Including hepatitis B and/or C. Your doctor may need to evaluate how severe your liver disease is before deciding if you can take EDURANT.
 - 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

During pregnancy you should not take EDURANT, unless it is specifically approved by your doctor.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

HIV infected mothers must not breast-feed, as there is a possibility of infecting the baby with HIV.

3. What if I am taking other medicines?

EDURANT might interact with other medicines. Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

EDURANT can be combined with most other anti-HIV medicines belonging to another class. However, some combinations are not recommended. In other cases, increased monitoring and/or a change in the dose of the medicine may be needed. Therefore, always tell your doctor which other anti-HIV medicines you take. Carefully follow your doctor's instructions, on which medicines can be combined.

EDURANT may interfere with and affect how some medicines work.

- methadone (strong pain killer also used in drug dependence programs)

Medicines that may increase the effect of EDURANT include:

- clarithromycin, erythromycin, troleandomycin (antibiotics)

Medicines that may reduce the effect of EDURANT include:

- rifabutin (a medicine to treat some bacterial infections). If you take this medicine while taking EDURANT, please carefully read Section [4. How do I take EDURANT?](#)
- cimetidine, famotidine, nizatidine, ranitidine (antihistamines used to treat stomach or intestinal ulcers or used to relieve heartburn from acid reflux)
- antacids (for example, aluminium / magnesium hydroxide, calcium carbonate)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect EDURANT.

4. How do I take EDURANT?

How much to take

- The usual dose of EDURANT is one tablet taken once daily with a meal.

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

When to take EDURANT

- 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.

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 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.

If you take an H₂-receptor antagonist (medicines used for 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. Importantly, proton pump inhibitors (such as omeprazole, lansoprazole, rabeprazole, pantoprazole, esomeprazole) also available for these conditions should not be taken with EDURANT.

Make sure that you always have enough EDURANT available so that you don't run out. For example in case you cannot return home, need to travel or stay in a hospital.

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.



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. Always take the tablet with a meal. Then take the next dose as usual.

If you notice after 12 hours, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you take too much EDURANT

If you think that you have taken too much EDURANT, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre:
 - Australia: **13 11 26**
 - New Zealand: **0800 POISON or 0800 764 766**
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking EDURANT?

Things you should do

- 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.
- Follow 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.

Call your doctor straight away if you:

- Become pregnant while taking EDURANT

Remind any doctor, dentist or pharmacist you visit that you are using 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.

Things you should 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.

Driving or using machines

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

Looking after your medicine

- Store EDURANT tablets below 30°C.
- Store EDURANT tablets in the original bottle. Keep the bottle tightly closed in order to protect from moisture and light. Do not store it:
 - in the bathroom or near a sink, or
 - in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

When treating HIV infection, it is not always easy to identify what side effects are caused by EDURANT, which are caused by other medicines you are taking, or which are caused by the HIV infection itself.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • stomach pain • nausea • vomiting • depression • difficulty falling asleep (insomnia) • abnormal dreams • sleep disorders • decreased appetite • tiredness • changes in your routine liver tests • headache • dizziness <p>Some side effects are typical for combination anti-HIV therapy. These are:</p> <ul style="list-style-type: none"> • immune reconstitution 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 the start of treatment. 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. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• skin rash <p>The rash is usually mild to moderate. In rare instances, rash can be potentially life-threatening. It is therefore important to contact your doctor immediately if you develop a rash.</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>Your doctor will advise you how to deal with your symptoms or whether EDURANT must be stopped.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What EDURANT contains

Active ingredient (main ingredient)	rilpivirine (as hydrochloride)
Other ingredients (inactive ingredients)	glycerol triacetate silicified microcrystalline cellulose magnesium stearate hypromellose croscarmellose sodium lactose monohydrate povidone polysorbate 20

	titanium dioxide macrogol 3000
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Do not take this medicine if you are allergic to any of these ingredients.

What EDURANT looks like

EDURANT (AUST R 176666) tablets are white to off-white, film-coated, round, biconvex, with "TMC" on one side and "25" on the other side.

Each plastic bottle contains 30 tablets.

Who distributes EDURANT

Janssen-Cilag Pty Ltd
1-5 Khartoum Road Macquarie Park NSW 2113
Telephone: 1800 226 334
NZ Office: Auckland New Zealand
Telephone: 0800 800 806

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