



400 mg tablet

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about ISENTRESS. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ISENTRESS against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

WHAT ISENTRESS IS USED FOR

ISENTRESS works against the Human Immunodeficiency Virus (HIV), the virus that causes AIDS (Acquired Immune Deficiency Syndrome). ISENTRESS blocks HIV integrase, an enzyme that is needed for HIV to make more virus.

ISENTRESS is used in combination with other antiretroviral medicinal products by persons who are infected with HIV.

Your doctor has prescribed ISENTRESS to help control your HIV infection. ISENTRESS is not a cure for HIV infection.

When used with other anti-HIV medicines, ISENTRESS may reduce the amount of HIV in your blood (called "viral load") and increase the number of CD4 (T) cells. Reducing the amount of HIV in the blood may keep your immune system healthy, so it can help fight infection. ISENTRESS may not have these effects in all patients.

ISENTRESS does not cure HIV infection or AIDS. It is very important that you stay under the care of your doctor during treatment with ISENTRESS.

HIV

HIV is a blood-borne disease spread by contact with blood or sexual contact with an infected individual.

Does ISENTRESS lower the chance of passing HIV to other people?

ISENTRESS does not reduce the chance of passing HIV to others through sexual contact, sharing needles, or being exposed to your blood. Continue to practice safer sex. Use latex or polyurethane condoms or other barrier methods to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions or blood. Never re-use or share needles.

Ask your doctor if you have any questions about safer sex or how to prevent passing HIV to other people.

BEFORE YOU TAKE ISENTRESS

When you must not take it

Do not take ISENTRESS if:

- you are allergic to any of the ingredients in ISENTRESS
- you are pregnant or intend to become pregnant. ISENTRESS is not recommended for use during pregnancy. ISENTRESS has not been studied in pregnant women.
- you are breast-feeding or plan to breast-feed. ISENTRESS is not recommended for use when breast-feeding. It is recommended that HIV-infected women should not breast-feed their infants because of the possibility that your baby can be infected with HIV through your breast milk. Talk with your doctor about the best way to feed your baby.

- the packaging is torn or shows signs of tampering
- the expiry date on the pack has passed. If you take this medicine after the expiry date has passed, it may not work.

Before you start to take it

Tell your doctor if:

- you have or have had any allergies to any other medicines or any other substances, such as foods, preservatives or dyes
- you have any past or present medical problems

If you have not told your doctor about any of the above, tell them before you take any ISENTRESS.

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

Use in children

ISENTRESS has not been studied in children less than 16 years of age.

Taking other medicines

ISENTRESS may be taken with most medicines. Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines and ISENTRESS may interfere with each other. This includes rifampin (a medicine used to treat some infections such as tuberculosis).

These medicines may be affected by ISENTRESS, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with while taking ISENTRESS.

HOW TO TAKE ISENTRESS

How much to take

Your doctor will tell you how many tablets you need to take each day. This depends on your condition and whether you are taking other medicines. Take ISENTRESS only when prescribed by your doctor.

The recommended dose is to take:

- one 400 mg tablet
- twice a day
- by mouth, without regard to food or drink

ISENTRESS must be used with other anti-HIV medicines.

Do not change your dose or stop taking ISENTRESS without first talking with your doctor.

It is very important to take all your anti-HIV medicines as prescribed and at the right times of day. This can help your medicines work better. It also lowers the chance that your medicines will stop working to fight HIV (drug resistance).

When your supply of ISENTRESS starts to run low, get more from your doctor or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short period of time. HIV may develop resistance to ISENTRESS and become harder to treat.

You should not stop taking ISENTRESS or your other HIV medicines without talking with your doctor.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to take it

ISENTRESS comes as tablets. It does not matter if you take ISENTRESS with or without food or drink.

When to take it

Take your ISENTRESS at about the same time each day as prescribed by your doctor.

Taking ISENTRESS at the same time each day will have the best effect. It will also help you remember when to take the dose.

If you forget to take it

If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not take a double dose of ISENTRESS.

If you take too much (overdose)

Immediately telephone your doctor or National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much ISENTRESS. Do this even if there are no signs of discomfort or poisoning.

WHILE YOU ARE USING ISENTRESS

Things you must do

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

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking ISENTRESS.

Things you must not do

Do not give ISENTRESS to anyone else, even if they have the same condition as you.

Things to be careful of

There have been side effects reported with ISENTRESS that may affect your ability to drive or operate machinery. Individual responses to ISENTRESS may vary. Be careful driving or operating machinery until you know how ISENTRESS affects you.

ADVERSE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ISENTRESS.

All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nausea
- vomiting
- headache
- diarrhoea
- inflammation of the nasal passages and throat
- trouble sleeping
- fever or high temperature
- cough

These are the more common adverse effects of ISENTRESS.

Also, tell your doctor if you notice:

- abdominal pain
- unusual tiredness or weakness
- upper respiratory tract infection
- dizziness

Tell your doctor immediately if you notice any of the following:

- signs and symptoms of inflammation from infections
- unexplained muscle pain, tenderness, or weakness

If any of the following happen, stop taking ISENTRESS and tell your doctor immediately or go to accident and emergency at your nearest hospital:

- swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing
- wheeziness due to chest tightness
- collapse, numbness or weakness of arms and legs

These are serious adverse effects. You may need urgent medical attention or hospitalisation.

All of these adverse effects are rare.

Additionally, while the medicine has been on the market, the following have been reported: depression, suicidal thoughts and actions.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

AFTER USING ISENTRESS

Storage

Keep your tablets in the original container until it is time to take them. If you take the tablets out of the container they may not keep well, (as they are affected by moisture).

Keep ISENTRESS in a cool dry place where the temperature stays below 30°C. Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking ISENTRESS, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

PRODUCT DESCRIPTION

What it looks like

ISENTRESS is a film-coated pink tablet that contains 400 mg of raltegravir.

Ingredients

Active ingredient:

- raltegravir

Inactive ingredients:

- microcrystalline cellulose
- lactose monohydrate
- calcium phosphate dibasic anhydrous
- hypromellose 2208
- poloxamer 407
- Sodium stearyl fumarate
- Magnesium stearate

Film coating contains: polyvinyl alcohol, titanium dioxide, polyethylene, glycol 3350, talc, red iron oxide and black iron oxide.

Supplier

ISENTRESS is supplied in New Zealand by:
Merck Sharp & Dohme (New Zealand) Limited
P O Box 99 851
Newmarket
Auckland
NEW ZEALAND
Tel: 0800 500 673

This leaflet was prepared in February 2009

CP-ISE-0109(060209)

™ Trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Whitehouse Station, NJ, USA Copyright © 2009 Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Whitehouse Station, NJ, USA. All rights reserved.