

ISENTRESS[®] and ISENTRESS HD[®]

raltegravir

The following information is applicable to ISENTRESS (400 mg tablet) and ISENTRESS HD (600 mg tablet)

What is in this leaflet

This leaflet answers some common questions about the ISENTRESS product range. 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 to treat HIV infection.

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.

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 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

Tell your doctor about all the medicines you take, including prescription and non-prescription medicine, vitamins, and herbal supplements. Some medicines are not recommended with ISENTRESS.

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 pregnancy

Be sure to tell your doctor immediately if you are or may be pregnant or if you are breast-feeding.

The use of ISENTRESS 400 mg twice daily may be considered during pregnancy, if necessary. Talk to your doctor.

There are no data on the use of ISENTRESS HD 1200 mg (2 x 600 mg) once daily in pregnant women.

Use in children

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

Taking other medicines

Tell your doctor about all the medicines you take including prescription and non-prescription medicines (including antacids), vitamins, and herbal supplements. Some medicines are not recommended with ISENTRESS.

Tell your doctor especially if you take:

- antacids
- atazanavir
- rifampin
- tipranavir/ritonavir

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.

Keep a list of all your medicines to show your doctor and pharmacist.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with ISENTRESS.
- Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take ISENTRESS with other medicines.

How to take ISENTRESS

How much to take

Take ISENTRESS exactly as your doctor has prescribed by mouth, with or without food.

The recommended dose is to take:

- One ISENTRESS 400 mg tablet twice daily or two ISENTRESS HD 600 mg tablets once daily as directed by your doctor or pharmacist. Swallow whole.

ISENTRESS must be used with other anti-HIV medicines.

Do not switch between the ISENTRESS 400 mg or ISENTRESS HD 600 mg tablet. Do not change your dose or stop taking ISENTRESS without first talking with your doctor.

It is very important to take each of 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.

Side Effects

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

Like all medicines, ISENTRESS can cause side effects, although not everybody gets them. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

In studies, side effects usually were mild and did not cause patients to stop taking ISENTRESS. The side effects reported in patients were similar to side effects in patients

treated with a tablet containing no medication (a placebo). The most common side effects are nausea, headache, diarrhoea, tiredness, inflammation of the nasal passages and throat, trouble sleeping, upper respiratory tract infection, cough, fever, bronchitis, back pain and depression.

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
- headache
- diarrhoea
- tiredness
- inflammation of the nasal passages and throat
- trouble sleeping
- cough
- fever or high temperature
- bronchitis
- upper respiratory tract infection
- back pain
- depression

These are the more common side effects of ISENTRESS.

Also, tell your doctor if you notice:

- abdominal pain
- unusual tiredness or weakness

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

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

Severe life-threatening skin reactions and allergic reactions have been reported in some patients taking ISENTRESS

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 side effects. You may need urgent medical attention or hospitalisation.

All of these side effects are rare.

Additionally, while the medicine has been on the market, the following have been reported: depression, suicidal thoughts and actions, low blood platelet count, clumsiness and lack of coordination, rash with or without increase in some white blood cells, severe skin reactions, liver failure.

Other side 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 side 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 available as a 400 mg tablet and ISENTRESS HD is available as a 600 mg tablet

- 400 mg - pink, oval shaped tablet with "227" on one side and plain on the other. Available in bottles containing 60 tablets
- 600 mg - yellow, oval shaped tablet with MSD logo and "242" on one side and plain on the other. Available in bottles containing 60 tablets.

Ingredients

Active ingredient:

- ISENTRESS HD 600mg contains 600mg of raltegravir
- ISENTRESS 400mg contains 400mg of raltegravir

Inactive ingredients:

ISENTRESS HD 600 mg Tablets

- hypromellose 2910
- croscarmellose sodium
- microcrystalline cellulose
- magnesium stearate
- carnauba wax

Film coating contains: lactose monohydrate, hypromellose 2910, titanium dioxide, triacetin, iron oxide yellow, iron oxide black

ISENTRESS 400 mg Tablets

- 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

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