

ISENTRESS[®] and ISENTRESS HD[®]

raltegravir

Consumer Medicine Information

The following information is applicable to ISENTRESS (400 mg tablet, 25 mg and 100 mg chewable 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, pharmacist or treatments officer at your local AIDS Council.

Keep this leaflet with the medicine.

You may need to read it again.

What ISENTRESS is used for

ISENTRESS is used in combination with other anti-HIV medicines to treat adults, adolescents and children 2 years of age and older who are infected with HIV. The children and adolescents (2 - 18 years of age) who participated in the ISENTRESS studies had previously taken HIV medicines.

ISENTRESS belongs to a group of medicines called integrase inhibitors. It works by blocking HIV integrase, one of the enzymes that is needed

during the replication process for HIV to make more virus. When integrase is blocked by ISENTRESS, the virus is not able to reproduce normally. This helps reduce the amount of virus in the blood.

When used with other anti-HIV medicines, ISENTRESS helps reduce the amount of HIV virus in your blood (called "viral load") and increase the number of CD4 (T) cells.

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.

Before you take ISENTRESS

When you must not take it

Do not take ISENTRESS if you have an allergy to:

- any medicine containing raltegravir
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

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

You should not take ISENTRESS when you are pregnant unless your doctor says you should. Your doctor will discuss the risks and benefits of using ISENTRESS 400 mg twice daily if you are pregnant.

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

Do not breast-feed if you are taking this medicine.

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.

Do not give this medicine to a child under the age of 2 years.

ISENTRESS has not been studied in children under 2 years.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

ISENTRESS is not recommended for use during breast-feeding.

Tell your doctor if you have phenylketonuria.

ISENTRESS chewable tablets contain aspartame, a source of phenylalanine, which may be harmful to people with phenylketonuria.

If you have not told your doctor about any of the above, tell him/her before you start taking ISENTRESS.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop, including antacids.

ISENTRESS can be taken with most medicines, however some medicines are not recommended with ISENTRESS. Tell your doctor if you take:

- antacids
- atazanavir, for treatment of HIV
- tipranavir/ritonavir, for treatment of HIV
- rifampin, a medicine used to treat tuberculosis
- medicines used to treat seizures known as phenytoin and phenobarbitone

These medicines may affect how well ISENTRESS works. You may need different amounts of your

medicines, or you may need to take different medicines.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Do not start taking a new medicine without telling your doctor or pharmacist. Your doctor or pharmacist can tell you if it is safe to take ISENTRESS with other medicines.

How to take ISENTRESS

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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

How much to take

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

Adults: Take one ISENTRESS 400 mg tablet twice daily or two ISENTRESS HD 600mg tablets once daily as directed by your doctor or pharmacist. Swallow whole.

Children and adolescents:

- Your child's doctor will tell you how many tablets your child should take and the type of ISENTRESS (ISENTRESS or ISENTRESS HD tablet or ISENTRESS chewable tablet), based on your child's age and weight.
- The 100 mg chewable tablet is scored and can be split into equal halves.

Do not take more than 300 mg of the chewable tablet twice a day.

Chewable tablets are to be chewed, not swallowed whole.

Do not switch between the 400 mg or 600 mg tablet and the chewable tablet.

How to take it

Take ISENTRESS as directed by mouth, with or without food.

ISENTRESS must be used with other anti-HIV medicines.

When to take it

Take your medicine at about the same time each day.

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

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).

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

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

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.

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 to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice.

You may need urgent medical attention.

While you are using ISENTRESS

Things you must do

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. 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.

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

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

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

Things you must not do

Do not stop taking your medicine or lower the dosage without checking with your doctor.

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.

Things to be careful of

Be careful driving or operating machinery until you know how ISENTRESS affects you.

There have been side effects reported with ISENTRESS that may affect your ability to drive or operate machinery. Individual responses to ISENTRESS may vary.

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.

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 and upper respiratory tract infection, cough, fever, bronchitis, back pain and depression.

Additionally, since the medicine has been on the market, the following side effects have been reported: depression, suicidal thoughts and actions, low blood platelet count, muscle tenderness or weakness, clumsiness and lack of coordination, rash with or without increase in some

white blood cells, severe skin reactions, liver failure.

In some patients with advanced HIV infection (AIDS), signs and symptoms of inflammation from opportunistic infections (eg: pneumonia, tuberculosis or a painful blistering rash known as shingles) may occur when combination antiretroviral treatment is started. Tell your doctor immediately if you notice any symptoms of infection.

Tell your doctor or pharmacist if you develop any unusual side effect or if any known side effect does not go away or gets worse.

ISENTRESS helps most people with HIV infection, but it may have unwanted side effects. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

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

- headache
- nausea
- diarrhoea
- tiredness
- upper respiratory tract infection (inflammation of the nasal passages and throat)
- trouble sleeping
- cough
- fever

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- frequent infections such as fever, severe chills, sore throat or mouth ulcers

- abdominal pain, nausea, vomiting, vomiting blood, and blood in the bowel motions
- loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine.
- that you are bleeding or bruising more easily than normal
- aching muscles, muscle tenderness or weakness, not caused by exercise

On rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- any severe skin reaction
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- fainting
- fast or irregular heart beat
- wheeziness due to tightness in the chest

Because these side effects are serious, you may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients.

The long-term effects of ISENTRESS are unknown at this time. Tell your doctor if you notice any other effects.

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the pack/bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store ISENTRESS or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ISENTRESS is available as a 400mg tablet and as a chewable tablet formulation in 100 mg (scored) and 25mg strengths. ISENTRESS HD is available as a 600 mg tablet.

- 600 mg tablet - yellow, oval shaped tablet with the MSD logo and "242" on one side and plain on the other. Available in bottles containing 60 tablets.
- 400mg tablet - pink, oval shaped tablet with "227" on one side and plain on the other. Available in bottles containing 60 tablets.
- 100 mg chewable tablet - pale orange oval tablet scored on both sides; one side is plain, and the other side is imprinted with the MSD logo and "477" on either side of the score. Available in bottles containing 60 chewable tablets.
- 25 mg chewable tablet - pale yellow round tablet with the MSD logo on one side and "473" on the other side. Available in bottles containing 60 chewable tablets.

ISENTRESS 25 mg and 100mg chewable tablets are banana-orange flavoured.

Ingredients

Active ingredient:

- ISENTRESS HD 600mg contains 600mg of raltegravir
- ISENTRESS 400 mg contains 400 mg of raltegravir
- ISENTRESS 100 mg contains 100 mg raltegravir
- ISENTRESS 25 mg contains 25 mg raltegravir.

Inactive ingredients:

ISENTRESS HD 600mg Tablets

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

The yellow film coating contains the following inactive ingredients:

- lactose monohydrate
- hypromellose 2910
- titanium dioxide
- glycerol triacetate
- iron oxide yellow
- iron oxide black

The tablets do not contain sucrose, gluten, tartrazine or any other azo dyes.

ISENTRESS 400mg Tablets

- microcrystalline cellulose
- lactose monohydrate
- calcium phosphate dibasic anhydrous
- hypromellose 2208
- poloxamer 407 (contains 0.01% butylated hydroxytoluene as antioxidant)
- sodium stearyl fumarate
- magnesium stearate.

The pink film coating contains the following inactive ingredients:

- polyvinyl alcohol
- titanium dioxide

- polyethylene glycol 3350
- talc
- iron oxide red
- iron oxide black

The tablets do not contain sucrose, gluten, tartrazine or any other azo dyes.

ISENTRESS Chewable Tablets

- hydroxypropylcellulose
- sucralose
- saccharin sodium
- sodium citrate
- mannitol
- iron oxide red CI77411 (100 mg tablet only)
- iron oxide yellow CI77492
- ammonium glycyrrhizinate
- sorbitol
- fructose
- natural and artificial flavours (orange, banana and masking that contains aspartame)
- crospovidone
- magnesium stearate
- sodium stearyl fumarate
- ethylcellulose 20cP
- ammonium hydroxide
- medium chain triglycerides
- oleic acid
- hypromellose 2910/6cp
- macrogol 400

ISENTRESS chewable tablets contain phenylalanine as part of the artificial sweetener, aspartame. The artificial sweetener may be harmful to people with phenylketonuria.

The chewable tablets do not contain sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer

ISENTRESS is supplied in Australia by:

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road, Macquarie Park, NSW 2113

Australian Register Numbers:

Tablet

600 mg bottle - AUST R 280294

400 mg bottle - AUST R 140238

Chewable Tablet

100 mg bottle - AUST R 193388

25 mg bottle - AUST R 193383

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