

ISENTRESS and ISENTRESS HD®

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 Isentress?

ISENTRESS contains the active ingredient raltegravir. 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. For more information, see Section [1. Why am I taking ISENTRESS?](#) in the full CMI.

2. What should I know before I take Isentress?

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

Talk to your doctor if you have any other medical conditions, 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 take ISENTRESS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ISENTRESS 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 ISENTRESS?

Adults: Take one ISENTRESS 400mg tablet twice daily or two ISENTRESS HD 600mg 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 table) based on your child's age and weight.

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

5. What should I know while taking ISENTRESS?

Things you should do	
	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using ISENTRESS.

	<ul style="list-style-type: none"> • Do not change your dose or stop taking ISENTRESS or your other HIV medicines without first talking with your doctor
<p>Things you should not do</p>	<ul style="list-style-type: none"> • 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
<p>Driving or using machines</p>	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools 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.

Looking after your medicine

- Keep your tablets in a cool dry place where the temperature stays below 30°C and where children cannot reach them
- Keep your tablets in the bottle until it is time to take them, if you take the tablets out of the bottle they may not keep well

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

6. Are there any side effects?

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.

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: any severe skin reaction, hives or nettlerash, fainting, fast or irregular heart beat or tightness in the chest.

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.

ISENTRESS and ISENTRESS HD®

Active ingredient: *raltegravir*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking ISENTRESS?

ISENTRESS contains the active ingredient raltegravir.

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 (Immune Cells that help fight infection). 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.

2. What should I know before I take ISENTRESS?

Warnings

Do not use ISENTRESS if:

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

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

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

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have or have had any allergies to any other medicines, foods, preservatives or dyes
- are not sure whether you should start taking this medicine.

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?](#)

Phenylketonuria

Tell your doctor if you have phenylketonuria.

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

Pregnancy

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

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 limited data on the use of ISENTRESS HD 1200 mg (2 x 600 mg) once daily in pregnant women

Breastfeeding

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.

Child under the age of 2 years

Do not give this medicine to a child under the age of 2 years. ISENTRESS has not been studied in children under the age of 2.

3. What if I am taking 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.

ISENTRESS can be taken with most medicines, however some medicines are not recommended with ISENTRESS. Some medicines may interfere with ISENTRESS and affect how it works.

Medicines that may increase the effect of ISENTRESS include:

- Atazanavir, for treatment of HIV

Medicines that may reduce the effect of ISENTRESS include:

- Antacids
- Rifampin, a medicine used to treat tuberculosis
- Tipranavir/Ritonavir, for treatment of HIV
- Phenytoin and Phenobarbitone, medicines used to treat seizures

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 and to show your doctor or pharmacist.

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

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

4. How do I 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

Adults

- Take one ISENTRESS 400mg tablet twice daily or two ISENTRESS HD 600mg 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 table) based on your child's age and weight
- The 100mg chewable tablet is scored and can be split into equal halves.

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

Chewable tablets are to be chewed, not swallowed whole.

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

When to take ISENTRESS

- ISENTRESS should be used 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).

How to take ISENTRESS

- Take ISENTRESS as directed by mouth, with or without food.
- ISENTRESS must be used with other anti-HIV medicines
- If taking iron salts (to treat and prevent iron deficiency or anaemia): You should wait at least two hours between taking iron salts and taking ISENTRESS, as these medicines may reduce ISENTRESS efficacy.

How long to take ISENTRESS

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 ISENTRESS

If you miss your dose at the usual time, take it as soon as you remember.

If it is almost time for your next dose, 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 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 ISENTRESS

If you think that you have used too much ISENTRESS, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- 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 ISENTRESS?

Things you should do

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.

Starting antiretroviral treatment

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.

Call your doctor straight away if you:

- notice any symptoms of infection

Tell and remind any doctor, dentist, pharmacist or other health professional you visit that you are using ISENTRESS.

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Looking after your medicine

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

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

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.

Follow the instructions on the bottle on how to take care of your medicine properly.

Keep your tablets in a cool dry place away from moisture, heat or sunlight where the temperature stays below 30°C; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines

Getting rid of any unwanted medicine

If your doctor tells you to stop taking 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. Your doctor will discuss these with you and will explain the risks and benefits of your treatment. Less serious side effects

Less serious side effects	What to do
<p>The most common side effects are:</p> <ul style="list-style-type: none">• Nausea• Headache• Diarrhoea• Tiredness• Inflammation of the nasal passages and throat• Trouble sleeping	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Upper respiratory tract infection ● Cough ● Fever ● Bronchitis ● Back pain ● Depression 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● Hypersensitivity reaction ● Severe skin reactions ● Pinkish, itchy swellings on the skin, also called hives or nettlerash ● 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 	<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>

Serious side effects	What to do
<p>and blood in the bowel motions</p> <ul style="list-style-type: none"> ● 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.) ● Fainting ● Fast or irregular heartbeat ● Wheeziness due to tightness in the chest <p>Since the medicine has been on the market the following side effects have been reported:</p>	

Serious side effects	What to do
<ul style="list-style-type: none"> • 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 • Liver Failure 	

Serious side effects are rare.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell, or if any known side effect does not go away or gets worse.

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

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

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 ISENTRESS 400 mg Tablet contains

Active ingredient (main ingredient)	Raltegravir 400 mg
Other ingredients (inactive ingredients)	Microcrystalline cellulose Lactose monohydrate Calcium phosphate dibasic anhydrous Hypromellose 2208 Poloxamer 407 (contains 0.01% butylated hydroxytoluene as antioxidant) Sodium stearyl fumarate Magnesium stearate.

	<p>The pink film coating contains the following inactive ingredients:</p> <p>Polyvinyl alcohol</p> <p>Titanium dioxide</p> <p>Polyethylene glycol 3350</p> <p>Talc</p> <p>Iron oxide red</p> <p>Iron oxide black</p>
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What ISENTRESS HD 600 mg Tablet contains

Active ingredient (main ingredient)	Raltegravir 600 mg
Other ingredients (inactive ingredients)	<p>Hypromellose 2910</p> <p>Croscarmellose sodium</p> <p>Microcrystalline cellulose</p> <p>Magnesium stearate</p> <p>Carnauba wax</p> <p>The yellow film coating contains the following inactive ingredients:</p> <p>Lactose monohydrate</p>

	Hypromellose 2910 Titanium dioxide Glycerol triacetate Iron oxide yellow Iron oxide black
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What ISENTRESS 25 mg and 100 mg Chewable Tablets contains

Active ingredient (main ingredient)	Raltegravir 25 mg and 100 mg
Other ingredients (inactive ingredients)	Hydroxypropylcellulose Sucralose Saccharin sodium Sodium citrate Mannitol Iron oxide red CI77411 (100 mg tablet only) Iron oxide yellow CI77492 Ammonium glycyrrhizinate Sorbitol Fructose

	<p>Natural and artificial flavours (orange, banana and masking that contains aspartame)</p> <p>Crospovidone</p> <p>Magnesium stearate</p> <p>Sodium stearyl fumarate</p> <p>Ethylcellulose 20cP</p> <p>Ammonium hydroxide</p> <p>Medium chain triglycerides</p> <p>Oleic acid</p> <p>Hypromellose 2910/6cp</p> <p>Macrogol 400</p>
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Do not take this medicine if you are allergic to any of these ingredients.

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

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

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.

What ISENTRESS 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.

ISENTRESS HD 600 mg (AUST R 280294) is yellow, oval shaped tablet with the corporate logo and "242" on one side and plain on the other. Available in bottles containing 60 tablets

ISENTRESS 400 mg (AUST R 140238) is pink, oval shaped tablet with "227" on one side and plain on the other. Available in bottles containing 60 tablets

ISENTRESS Chewable tablet 25 mg (AUST R 193383) is pale yellow round tablet with the corporate logo on one side and "473" on the other side. Available in bottles containing 60 chewable tablets

ISENTRESS Chewable tablet 100 mg (AUST R 193388) is pale orange oval tablet scored on both sides; one side is plain, and the other side is imprinted with the corporate logo and "477" on either side of the score. Available in bottles containing 60 chewable tablets.

Who distributes ISENTRESS

ISENTRESS is supplied in Australia by:

Merck Sharp & Dohme (Australia) Pty Limited

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

NSW 2113, Australia

This leaflet was prepared in November 2023.

WRM-WPPI-MK0518-MF-042023WPPI-MK0518-
MF-032023

RCN000025612, 000025862

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