PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ISENTRESS® Tablets

Raltegravir 400 mg

ISENTRESS® CHEWABLE 25 mg and 100 mg Tablets

Raltegravir 25 mg or 100 mg

Read all of this leaflet carefully before you start taking ISENTRESS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ISENTRESS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. What ISENTRESS is and what is it 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 viruses.

ISENTRESS is used in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection in patients 2 years of age and older.

ISENTRESS does not cure HIV infection or AIDS.

Your doctor has prescribed ISENTRESS to help control your HIV infection.

It is very important that you stay under the care of your doctor during treatment of your HIV infection.

2. What you need to know before you take ISENTRESS

Do not take ISENTRESS

Do not take ISENTRESS if you are allergic to any of the ingredients in ISENTRESS Tablets.

Tell your doctor if you have or have had any allergies.

Tell your doctor if you are planning to become pregnant.

Do not breastfeed your baby if you are taking ISENTRESS.

Patients with phenylketonuria (PKU): ISENTRESS CHEWABLE Tablets contain phenylalanine as part of the artificial sweetener, aspartame. The artificial sweetener may be harmful to people with PKU.

Take special care

Use in children

ISENTRESS 400 mg should not be used in children less than 25 kg.

ISENTRESS CHEWABLE should not be used in children less than 2 years of age.

Use in pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or healthcare professional immediately for advice, before taking ISENTRESS.

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

If you are taking ISENTRESS you should not breastfeed your baby.

If you are HIV-infected you should not breastfeed your baby, because of the possibility that your baby can be infected with HIV through your breast milk. Talk to your doctor about the best way to feed your baby.

Driving and use of machinery

ISENTRESS causes fatigue (tiredness) which may affect your ability to drive or operate machinery.

Important information about some of the ingredients of ISENTRESS

ISENTRESS Tablets 400 mg contain sugar (lactose monohydrate). Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take ISENTRESS.

ISENTRESS contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by your doctor that you have intolerance to some kinds of sugar, contact your doctor before taking ISENTRESS.

ISENTRESS CHEWABLE contains aspartame, a source of phenylalanine which may be harmful for patients with phenylalanine intolerance.

Contains sugar (mannitol, sorbitol, and fructose).

ISENTRESS CHEWABLE contains fructose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take ISENTRESS CHEWABLE.

Contains fructose which may have an effect on the control of your child's blood sugar if they have diabetes mellitus.

Contains mannitol and sorbitol. Contains sucralose, saccharin sodium.

If you have been told by your doctor that your child is intolerant to some kinds of sugars, contact your doctor before giving them ISENTRESS CHEWABLE tablets.

Taking other medicines with ISENTRESS

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

ISENTRESS may be taken with most medicines. Tell your doctor about all medicines you take. This includes prescription medicines:

- rifampicin (a medicine used to treat infections such as tuberculosis)
- antacids, as it is not recommended to take ISENTRESS with certain antacids (those containing aluminium and/or magnesium) and
- non-prescription medicines, herbal supplements or traditional medicines.

3. How to take ISENTRESS

Always take ISENTRESS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The recommended dose is to take:

Adults: One 400 mg tablet twice daily, orally.

Give your child ISENTRESS CHEWABLE Tablets twice a day, by mouth, with or without food.

ISENTRESS must be used with other anti-HIV medicines.

If you have the impression that the effect of ISENTRESS is too strong or too weak for you, tell your doctor or pharmacist.

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 correct times of day.

Do not change your child's dose, switch between the 400 mg tablet and the chewable tablets or stop giving ISENTRESS CHEWABLE without first talking with your child's doctor. It is very important that your child takes all their anti-HIV medicines as prescribed and at the correct times of day.

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

Children and Adolescents

- If your child is taking ISENTRESS CHEWABLE, your child's healthcare provider will decide the right dose based on your child's age and weight.
- Your child's healthcare provider will tell you how many tablets your child should take.
- The 100 mg chewable tablet is scored and can be split into equal halves.

Your child should not take more than 300 mg of the chewable tablet twice a day.

If you take more ISENTRESS than you should

If you take more than the prescribed dosage of ISENTRESS, contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ISENTRESS

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 a missed individual dose.

4. Possible side effects

ISENTRESS can cause side effects.

The most common side effects are inflammation of the nasal passages and throat, upper respiratory tract infection, cough, fever, bronchitis, nausea, headache, diarrhoea, tiredness, trouble sleeping, back pain and depression.

In some patients with advanced HIV infection (AIDS), signs and symptoms of inflammation from infections due to a weakening immune system may occur when combination antiretroviral treatment is started. Tell your doctor immediately if you notice any symptoms of infection.

The following have also been reported: suicidal thoughts and suicide, depression, low blood platelet count, clumsiness and lack of coordination, rash with or without increase in some white blood cells, severe skin reactions and liver failure.

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.

Not all side effects reported for ISENTRESS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ISENTRESS please consult your doctor, pharmacist or healthcare professional for advice.

How can I learn more about ISENTRESS and HIV?

You may obtain further information from your doctor or pharmacist who has more detailed information.

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ISENTRESS.

5. How to store ISENTRESS

How long should I keep my medicine?

Do not use this medicine after the month and year following EXP.: on the label of the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

How should I store ISENTRESS?

Store ISENTRESS at or below 30 °C. Keep container well closed. Do not remove the silica gel desiccant canister from the bottle.

Store ISENTRESS and all medicines out of reach of children.

6. Contents of the pack and other information

What ISENTRESS contains

ISENTRESS Tablets (400 mg): Each film-coated tablet contains raltegravir potassium equivalent to 400 mg raltegravir as the active ingredient.

The other ingredients are microcrystalline cellulose, lactose monohydrate, calcium phosphate dibasic anhydrous, hypromellose 2208, poloxamer 407 (contains 0,01 % butylated hydroxytoluene as antioxidant), sodium stearyl fumarate, magnesium stearate.

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

Contains sugar (lactose monohydrate).

ISENTRESS CHEWABLE 25 and 100 mg Tablets: Each chewable tablet contains raltegravir potassium equivalent to 25 mg or 100 mg of raltegravir as the active ingredient.

The other ingredients are hydroxypropyl cellulose, sucralose, saccharin sodium, sodium citrate dihydrate, mannitol, monoammonium 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/PEG 400. In addition, the 25 mg tablet contains yellow iron oxide and the 100 mg tablet contains yellow iron oxide and red iron oxide.

Contains aspartame.

Contains sugar (mannitol, sorbitol and fructose).

Contains sucralose, saccharin sodium.

What ISENTRESS looks like and contents of the pack

ISENTRESS Tablets (400 mg): Grey, oval, biconvex film-coated tablets debossed with 227 and Corporate logo on one side and plain on the other.

ISENTRESS CHEWABLE 25 mg Tablets: Pale yellow, round flat faced, bevelled edge tablets debossed with the Corporate logo on one side and 473 on the other.

ISENTRESS CHEWABLE 100 mg Tablets: Pale orange, oval shaped scored tablets, debossed with the Corporate logo on one side of the score and 477 on the other, and scored on the other side of the tablet.

ISENTRESS Tablets (400 mg): A round, white opaque, HDPE bottle with a white child-resistant closure containing 60 tablets as well as a 1 g silica gel desiccant canister. Each bottle is packed in a printed cardboard carton.

ISENTRESS CHEWABLE 25 mg Tablets: Round, white opaque, HDPE bottles with a white child-resistant polypropylene closure, with a foil induction seal containing 60 tablets as well as a 4 g silica gel desiccant. Each bottle is packed in a printed cardboard carton.
ISENTRESS CHEWABLE 100 mg Tablets: Round, white opaque, HDPE bottles with a white child-resistant polypropylene closure, with a foil induction seal containing 60 tablets as well as a 4 g silica gel desiccant. Each bottle is packed in a printed cardboard carton.

Holder of Certificate of Registration

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ISENTRESS Tablets (400 mg): 42/20.2.8/0687

ISENTRESS CHEWABLE 25 mg Tablets: 46/20.2.8/0863

ISENTRESS CHEWABLE 100 mg Tablets: 46/20.2.8/0864