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Isentress *(raltegravir)*

An overview of Isentress and why it is authorised in the EU

What is Isentress and what is it used for?

Isentress is an HIV medicine that is used in combination with other HIV medicines to treat patients who are infected with human immunodeficiency virus (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).

Isentress contains the active substance raltegravir.

How is Isentress used?

Isentress can only be obtained with a prescription and treatment should be started by a doctor who has experience in the management of HIV infection.

The medicine is available as tablets to be swallowed (400 and 600 mg), chewable tablets (25 and 100 mg) and sachets containing granules for an oral suspension (each sachet containing 100 mg). The granules are to make a mixture for babies and children to drink, the chewable tablets are for bigger children, and the 400- and 600-mg tablets are for different dose regimens in older children and adults, as recommended by the doctor. Equivalent doses of these different forms do not all produce the same levels of raltegravir in the body, so they must not be used interchangeably.

For more information about using Isentress see the package leaflet or contact your doctor or pharmacist.

How does Isentress work?

The active substance in Isentress, raltegravir, is an integrase inhibitor. It blocks an enzyme called integrase, which is involved in a step in the reproduction of HIV. When the enzyme is blocked, the virus cannot reproduce normally, slowing down the spread of infection. Isentress, taken in combination with other HIV medicines, reduces the amount of HIV in the blood and keeps it at a low level. Isentress does not cure HIV infection or AIDS, but it may hold off the damage to the immune system and the development of infections and diseases associated with AIDS.

What benefits of Isentress have been shown in studies?

Isentress has been studied in six main studies.

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- Two studies involved a total of 699 'treatment-experienced' patients who were already receiving treatment for HIV infection that was not working. The studies compared Isentress with placebo (a dummy treatment), which were added to 'optimised background therapy' (a combination of other HIV medicines chosen for each patient as it had the best chances of reducing the levels of HIV in the blood). The main measure of effectiveness was the reduction in the levels of HIV in the blood (viral load) after 16 weeks; 77% of the patients who took Isentress had viral loads below 400 copies/ml after 16 weeks, compared with 42% of those who took placebo. The response was sustained for at least 48 weeks;
- A third study involved 566 patients who had not taken HIV treatment before and compared Isentress with efavirenz (another HIV medicine). All of the patients also took tenofovir and emtricitabine (other HIV medicines). The main measure of effectiveness was the number of patients who had 'undetectable' viral loads (below 50 copies per millilitre of blood) after 48 weeks. Isentress was as effective as efavirenz. After 48 weeks, 86% of the patients taking Isentress had viral loads below 50 copies/ml (241 out of 281), compared with 82% of those taking efavirenz (230 out of 282);
- A fourth study in 802 patients who had not taken HIV treatment before showed that giving Isentress as a single dose of 1,200 mg once daily was as effective as giving 400 mg twice daily. Patients also received the medicine Truvada (emtricitabine with tenofovir disoproxil). After 48 weeks, 89% (472 of 531) of those on the once daily dose and 88% (235 of 266) of those taking Isentress twice daily had viral loads less than 40 copies/ml;
- Isentress has also been studied in a fifth study involving 126 HIV-1 infected children between 2 and 18 years whose existing treatment for HIV infection was not working. The study showed that Isentress, given as tablets to be swallowed or chewable tablets, was safe in children and levels of the medicine obtained in the blood in children were similar to those obtained in adults. Therefore, the effectiveness observed in adults is also expected in children.
- A sixth study included 26 children aged 4 weeks to 2 years who were given Isentress oral granules made into a suspension. This study looked at viral loads after 24 and 48 weeks. Isentress treatment led to a reduction in viral load and after 48 weeks 53% of the children had viral loads below 50 copies/ml.
- Additional supportive studies established doses that provide similar effective levels of Isentress in newborn infants as in young children.

What are the risks associated with Isentress?

The most common side effects with Isentress (seen in between 1 and 10 patients in 100) are headache, abdominal pain (stomach ache) and nausea (feeling sick). Side effects in children were comparable to those in adults. The most common serious side effects are immune reconstitution syndrome (symptoms of infection caused by a recovering immune system) and rash. There have also been uncommon reports of rhabdomyolysis (breakdown of muscle fibres). For the full list of side effects and restrictions with Isentress, see the package leaflet.

Why is Isentress authorised in the EU?

Isentress has been shown to be effective in helping control HIV when used with other HIV medicines. The European Medicines Agency therefore decided that Isentress's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Isentress?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Isentress have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Isentress are continuously monitored. Side effects reported with Isentress are carefully evaluated and any necessary action taken to protect patients.

Other information about Isentress:

Isentress received a conditional marketing authorisation valid throughout the European Union for Isentress on 20 December 2007. This was switched to a full marketing authorisation on 14 July 2009.

Further information on Isentress can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.

This overview was last updated in 03-2018.