



EUROPEAN MEDICINES AGENCY
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EPAR summary for the public

Celsentri

maraviroc

This is a summary of the European public assessment report (EPAR) for Celsentri. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Celsentri.

For practical information about using Celsentri, patients should read the package leaflet or contact their doctor or pharmacist.

What is Celsentri and what is it used for?

Celsentri is an HIV medicine used to treat patients from 2 years of age and weighing at least 10 kg who are infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).

Celsentri is used in combination with other HIV medicines, and only in patients who have been treated for HIV infection before and only when the HIV-1 they are infected with is 'CCR5-tropic', which is determined by a blood test. This means that the virus, when infecting a cell, attaches to a specific protein called CCR5 on the surface of the cell.

Celsentri contains the active substance maraviroc.

How is Celsentri used?

Celsentri can only be obtained with a prescription and treatment should be started by a doctor who has experience in the management of HIV infection. Before treatment, the doctor must check that the patient's blood only shows infection with CCR5-tropic virus.

Celsentri is available as tablets (25, 75, 150 and 300 mg) and as a liquid (20 mg/ml) to be taken by mouth. In adults, the recommended dose is 150, 300 or 600 mg twice a day, depending on the other medicines that the patient is taking. In children, the dose is based on body weight. Patients who have reduced kidney function may need to take Celsentri less frequently.



For further information, see the package leaflet.

How does Celsentri work?

The active substance in Celsentri, maraviroc, is a 'CCR5 antagonist'. It blocks the CCR5 protein on the surface of the cells in the body that HIV infects. CCR5-tropic HIV uses this protein to enter the cells. By attaching itself to the protein, Celsentri prevents the virus from entering the cells. As HIV can only reproduce itself within cells, Celsentri, taken in combination with other HIV medicines, reduces the level of CCR5-tropic HIV, and keeps it at a low level. Celsentri cannot work against viruses that attach to another protein called CXCR4, or when it can attach to both CCR5 and CXCR4.

Celsentri 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 Celsentri have been shown in studies?

Celsentri has been shown to be effective at reducing the levels of HIV in the blood in two main studies involving a total of 1,076 mostly adult patients with CCR5-tropic HIV infection. In the studies Celsentri was compared with placebo (a dummy treatment). The patients had previously taken other treatments for HIV for at least six months, but these had stopped working. All of the patients also took 'optimised background therapy' (a combination of other HIV medicines chosen for each patient to increase the chances of reducing the levels of HIV in the blood).

Looking at the results of the two studies taken together, the levels of HIV in the blood had fallen by an average of 99% after 24 weeks in the patients adding Celsentri to optimised background therapy, compared with 90% in those adding placebo. The proportion of patients who had undetectable levels of HIV in their blood after 24 weeks was about 45% with Celsentri compared to 23% with placebo. Similar results were also seen when looking at the patients who continued treatment with Celsentri 300 mg twice a day for 48 weeks.

Additional data indicate that Celsentri given at a suitable dose to children is handled by their body in the same way as in adults. Based on these data, effectiveness is expected to be similar in children and adults.

What are the risks associated with Celsentri?

The most common side effects with Celsentri (which may affect up to 1 in 10 people) are nausea (feeling sick), diarrhoea, fatigue (tiredness) and headache. For the full list of all side effects reported with Celsentri, see the package leaflet.

Celsentri tablets must not be used in patients who are hypersensitive (allergic) to peanut and soya. For the full list of restrictions, see the package leaflet.

Why is Celsentri approved?

Celsentri used in combination with other HIV medicines has been shown to be effective at reducing the levels of HIV in the blood in adults, and similar effects are expected in children. The safety profile of Celsentri is considered acceptable and no major concerns have been identified.

The Agency's Committee for Medicinal Products for Human Use (CHMP) therefore decided that Celsentri's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

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

Other information about Celsentri

The European Commission granted a marketing authorisation valid throughout the European Union for Celsentri on 18 September 2007.

The full EPAR for Celsentri can be found on the Agency's website ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports. For more information about treatment with Celsentri, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2017.