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Livtencity (maribavir)

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

What is Livtencity and what is it used for?

Livtencity is an antiviral medicine used to treat illness caused by cytomegalovirus (CMV) in adults who have had a haematopoietic stem cell transplant or an organ transplant. It is used in patients whose CMV illness has not responded to at least one other treatment, including ganciclovir, valganciclovir, cidofovir or foscarnet.

Haematopoietic stem cell transplantation involves using stem cells from a donor to replace the recipient's bone marrow cells. The donated stem cells will form new bone marrow that produces healthy blood cells.

CMV is a common virus that usually only causes mild infection in healthy people. After infection, the virus remains in the body in an inactive form and does not cause harm. However, CMV can become active and cause illness in patients whose immune system (the body's natural defences) is weakened, such as those who have had a stem cell or organ transplant.

CMV disease is rare, and Livtencity was designated an 'orphan medicine' (a medicine used in rare diseases) on 18 December 2007 and 7 June 2013. Further information on the orphan designations can be found here: ema.europa.eu/en/medicines/human/orphan-designations/eu307519 and ema.europa.eu/en/medicines/human/orphan-designations/eu-3-13-1133.

Livtencity contains the active substance maribavir.

How is Livtencity used?

Livtencity can only be obtained with a prescription and should be used according to official recommendations. Treatment should be started by a doctor experienced in managing patients who have had a haematopoietic stem cell or organ transplant.

Livtencity is available as tablets to be taken by mouth and the recommended dose is 400 mg twice a day for 8 weeks. Treatment duration may be adjusted depending on the patient's condition and response to treatment.

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



How does Livtencity work?

Maribavir, the active substance in Livtencity, blocks an enzyme (a type of protein) from CMV called UL97 protein kinase, which the virus needs to multiply. This stops the virus from multiplying and infecting other cells.

What benefits of Livtencity have been shown in studies?

Livtencity was found to be more effective than other available CMV treatment at clearing CMV infection in adults who had undergone a stem cell or organ transplant and whose CMV infection had not responded to prior treatment. In a main study involving 352 adults, 56% (131 out of 235) of patients treated with Livtencity had undetectable levels of CMV after 8 weeks compared with 24% (28 out of 117) of those who received another CMV treatment chosen by their doctor.

What are the risks associated with Livtencity?

The most common side effects with Livtencity (which may affect more than 1 in 10 people) are taste disturbance, nausea (feeling sick), diarrhoea, vomiting and tiredness.

Serious side effects (which may affect more than 1 in 100 people) include diarrhoea, nausea, vomiting, weight loss, tiredness, and increased blood levels of immunosuppressant medicine (a medicine used to reduce activity of the immune system).

For the full list of side effects of Livtencity, see the package leaflet.

Livtencity must not be used together with ganciclovir or valganciclovir (other antiviral medicines).

For the full list of restrictions of Livtencity, see the package leaflet.

Why is Livtencity authorised in the EU?

Livtencity was effective at clearing CMV from the blood, and its safety profile is acceptable and more favourable than available treatments. The European Medicines Agency therefore decided that Livtencity'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 Livtencity?

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

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

Other information about Livtencity

Livtencity received a marketing authorisation valid throughout the EU on 9 November 2022.

Further information on Livtencity can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/livtencity.

This overview was last updated in 11-2022.