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EPAR summary for the public

Luminity

perflutren-containing lipid microspheres

This is a summary of the European public assessment report (EPAR) for Luminity. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Luminity.

What is Luminity?

Luminity is a solution for injection or infusion (drip) into a vein that contains microspheres (tiny bubbles) of perflutren gas as the active substance.

What is Luminity used for?

Luminity is for diagnostic use only. It is a contrast agent (a medicine that helps obtain better images of organs and tissues during a scan).

Luminity is used in adults to obtain a clearer image of the chambers of the heart, especially of the left ventricle, during echocardiography (a diagnostic test where an image of the heart is obtained using ultrasound). Luminity is used in patients with suspected or confirmed coronary artery disease (obstruction of the blood vessels supplying the heart muscle), when the image obtained without a contrast agent is not good enough.

The medicine can only be obtained with a prescription.

How is Luminity used?

Luminity should only be given by doctors trained in performing and reading images obtained with contrast echocardiography, in hospitals or clinics where appropriate resuscitation equipment is available in case of heart or lung problems or allergic reactions.

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Before use, Luminity must be activated by shaking it using a mechanical device called Vialmix, which is supplied to doctors who need to prepare the medicine. This ensures that the medicine is shaken in the correct way and for long enough to make up a 'dispersion' of microspheres of perflutren gas of the right size to get a good quality image. This is then given into a vein either as a 'bolus' injection (given all at once) or as an infusion after being diluted. The way Luminity is given and the dose depend on the technique being used for the echocardiography.

For full details, see the summary of product characteristics (also part of the EPAR).

How does Luminity work?

When Luminity is injected, it travels in the veins to the heart. During echocardiography, the perflutren microspheres in Luminity reflect ultrasound waves differently from the surrounding tissues. This helps to obtain a better contrast between the area where the gas bubbles are (such as the heart chambers) and the surrounding tissue. The gas is then cleared through the lungs.

How has Luminity been studied?

There have been five main studies of Luminity, involving a total of 401 patients. Three studies looked at its ability to enhance the image of the left ventricle, comparing the echocardiography scan before and after administration of Luminity. In two of these studies, Luminity was compared with placebo (a dummy treatment). The last two studies were set up primarily to look at the ability of Luminity to improve the accuracy of the measurement of the ejection fraction (the percentage of the blood volume that is pumped out of the heart in one beat). These studies also looked at left ventricle image enhancement.

What benefit has Luminity shown during the studies?

Luminity was effective in enhancing the image of the left ventricle, and it was more effective than placebo in the studies where Luminity and placebo were compared. As all five original studies were carried out with a technique known as 'fundamental' ultrasound imaging, the company also presented the results of some studies to show that the results seen using fundamental imaging could also be obtained when using the imaging techniques known as 'harmonic' and 'non linear'.

What is the risk associated with Luminity?

The most common side effects with Luminity (seen in between 1 and 10 patients in 100) are headache and flushing (reddening of the skin). For the full list of all side effects and restrictions with Luminity, see the package leaflet.

Why has Luminity been approved?

The CHMP decided that Luminity'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 Luminity?

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

Other information about Luminity

The European Commission granted a marketing authorisation valid throughout the European Union for Luminity on 20 September 2006.

The full EPAR for Luminity 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 Luminity, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist

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