European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

OPTISON

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is OPTISON?

OPTISON is a suspension for injection. It contains microspheres (tiny bubbles) of heat-treated human albumin containing perflutren gas as the active substance.

What is OPTISON used for?

OPTISON is for diagnostic use only. It is a 'contrast agent', which helps make internal body structures easier to see during imaging tests. OPTISON is used to obtain a clearer scan 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). OPTISON is used in patients with suspected or known cardiovascular disease, when scans without a contrast agent have not been conclusive.
The medicine can only be obtained with a prescription.

How is OPTISON used?

OPTISON should only be used by doctors who have experience in diagnostic ultrasound imaging. The ultrasound scan must be carried out during the injection of OPTISON, as the best effect is within the first 2.5 to 4.5 minutes after dosing. OPTISON is slowly injected into a vein, usually in the right arm. The recommended dose is 0.5 to 3.0 ml per patient. The total dose should not exceed 8.7 ml per patient. The patient's heart should be monitored with an electrocardiogram (ECG) during an ultrasound scan with OPTISON. For more information, see the Package Leaflet.

How does OPTISON work?

OPTISON is an ultrasound contrast medium. Ultrasound uses high-frequency sound waves to create images of certain areas inside the body. The sound waves produced by the ultrasound equipment can be reflected by different parts of the body, such as the heart. OPTISON contains gas-filled albumin microspheres (tiny bubbles) that generate echoes very differently from the surrounding tissues when used during an ultrasound scan. When OPTISON is injected, it travels in the veins to the heart. This helps to obtain better contrast between the area where the gas bubbles are (such as the chambers of the heart) and the surrounding tissue during the echocardiography. The gas is then cleared through the lungs.

How has OPTISON been studied?

The effects of OPTISON were first tested in experimental models before being studied in humans. There were two main studies of the effectiveness of OPTISON, involving a total of 203 patients. Each patient received OPTISON, and air-filled albumin microspheres injected into a vein as a reference

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medicine. The injections were on different days, with a delay of between 2 and 10 days between the two medicines. The main measures of effectiveness were the length of the endocardium (inner surface) of the left ventricle of the heart that could be seen before and after injection of OPTISON and the reference medicine, and the observer's assessment of the change in the ability to see the endocardium of the left ventricle before and after each injection.

What benefit has OPTISON shown during the studies?
OPTISON was more effective than the reference medicine at increasing the ability to see the endocardium of the left ventricle. In the first study, the length of endocardium that could be seen increased by 7.8 cm with OPTISON, compared with 3.7 cm with the reference medicine. In the other study, the increases were 7.1 cm for OPTISON and 3.1 cm for the reference medicine. In both studies, the observer reported that the ability to see the endocardium improved for more patients after injection of OPTISON than after injection of the reference medicine.

What is the risk associated with OPTISON?
The most common side effects with OPTISON (seen in between 1 and 10 patients in 100) are dysgeusia (altered taste), headache, flushing, and a warm sensation. For the full list of all side effects reported with OPTISON, see the Package Leaflet.
OPTISON should not be used in patients who may be hypersensitive (allergic) to any of the ingredients, particularly human albumin, or in patients with pulmonary hypertension (high blood pressure in the pulmonary artery, the blood vessel that leads from the heart to the lungs).

Why has OPTISON been approved?
The Committee for Medicinal products for Human Use (CHMP) decided that OPTISON's benefits are greater than its risks to help diagnose patients with suspected or established cardiovascular disease. The committe recommended that OPTISON be given marketing authorisation.

Other information about OPTISON:
The European Commission granted a marketing authorisation valid throughout the European Union, for OPTISON on 18 May 1998. The marketing authorisation was renewed 15 May 2003. The marketing authorisation holder is GE Healthcare AS.

The full EPAR for OPTISON is available here.

This summary was last updated in 01-2007.