European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

TESLASCAN

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 TESLASCAN?
TESLASCAN is a solution for infusion (drip into a vein) containing the active substance mangafodipir trisodium.

What is TESLASCAN used for?
TESLASCAN is for diagnostic use. TESLASCAN is used in patients who are undergoing magnetic resonance imaging (MRI) to detect lesions (damaged tissue) in the liver that might be caused by liver cancer or cancer that has spread to the liver from other parts of the body. TESLASCAN is a 'contrast medium' that is used to obtain a clearer scan. TESLASCAN can also be used with MRI to investigate lesions of the pancreas.
The medicine can only be obtained with a prescription.

How is TESLASCAN used?
TESLASCAN is used as a single intravenous infusion at a dose of 0.5 ml per kilogram body weight. The rate of infusion is 2 to 3 ml/min for liver imaging and 4 to 6 ml/min for imaging the pancreas. The enhancement of imaging starts 15 to 20 minutes after the start of the infusion, and lasts for about 4 hours. For more information, see the Package Leaflet.

How does TESLASCAN work?
The active substance in TESLASCAN, mangafodipir, contains manganese, a metal element. Manganese is used as a contrast medium to help obtain better pictures with MRI scanners. MRI is an imaging method that uses magnetic fields and radio waves. Water molecules in the body are affected by the magnetic fields, and produce a signal when the radio waves are applied. Manganese interacts with the water molecules. As a result of this interaction, the water molecules give a stronger signal, and this helps to obtain a brighter picture.
In TESLASCAN, the manganese is bound to another chemical in a 'chelate'. Once the medicine is injected, the manganese is released and taken up by normal liver and pancreatic tissues more effectively than by the cancer cells. This allows the difference between normal and abnormal tissue to be seen.

How has TESLASCAN been studied?
The studies of TESLASCAN in MRI for liver lesions involved 617 patients. The patients had between one and five liver lesions that had already been detected using MRI, ultrasound, or computerised

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tomography (CT). They underwent a TESLASCAN-enhanced MRI scan. The main measure of effectiveness was the difference in the number of liver lesions detected in the previous scan and when using TESLASCAN during MRI.
The studies of pancreatic disease involved 292 patients, and compared the effectiveness of TESLASCAN-enhanced MRI with that of 'spiral CT', another diagnostic method used to detect pancreatic lesions. The main measure of effectiveness was based on the agreement between the diagnosis made based on the scans, and the actual lesions as seen during surgery or biopsy.

What benefit has TESLASCAN shown during the studies?
In the detection of liver lesions, the use of TESLASCAN-enhanced MRI resulted in more lesions being detected. Overall, during the studies, 33% of patients had more lesions detected after TESLASCAN but 20% of patients had fewer lesions. In the detection of pancreatic lesions, TESLASCAN-enhanced MRI was as effective as spiral CT.

What is the risk associated with TESLASCAN?
The most common side effects with TESLASCAN (seen in between 1 and 10 patients in 100) are headache, nausea (feeling sick), flushing and feeling hot. For the full list of all side effects reported with TESLASCAN, see the Package Leaflet.
TESLASCAN should not be used in people who may be hypersensitive (allergic) to mangafodipir trisodium or any of the other ingredients. TESLASCAN should not be used in pregnant or breast-feeding women, patients with phaeochromocytoma (a tumour of the adrenal gland), or patients with severe problems with their liver or kidneys.

Why has TESLASCAN been approved?
The Committee for Medicinal products for Human Use (CHMP) decided that TESLASCAN's benefits are greater than its risks as a contrast medium for diagnostic MRI, for the detection of lesions of the liver suspected to be due to metastatic disease or hepatocellular carcinomas, and as an adjunct to MRI to aid in the investigation of focal pancreatic lesions. They recommended that TESLASCAN be given marketing authorisation.

Other information about TESLASCAN:
The European Commission granted a marketing authorisation valid throughout the European Union, for TESLASCAN to GE Healthcare AS on 22 May 1997. The marketing authorisation was renewed on 22 May 2002 and 22 May 2007.

The full EPAR for TESLASCAN is available here.

This summary was last updated in 04-2007.