European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

LEUKOSCAN

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 LeukoScan?

LeukoScan is a vial containing a powder to be made into a solution for injection. The powder contains the active substance sulesomab.

What is LeukoScan used for?

LeukoScan is not used on its own, but must be radiolabelled before use. Radiolabelling is a technique where a substance is tagged (labelled) with a radioactive compound. LeukoScan is radiolabelled by mixing it with a solution of radioactive technetium (^{99m}Tc).
This radiolabelled medicine is for diagnostic use. LeukoScan is used to find the site and extent of infection or inflammation in patients with suspected osteomyelitis (bone infection), including patients with diabetic foot ulcers.
The medicine can only be obtained with a prescription.

How is LeukoScan used?

Radiolabelled LeukoScan treatment should only be handled and given by someone who is authorised to use radioactive medicines. The radiolabelled solution is given as an intravenous injection, and a scintigraphy is carried out 1 to 8 hours later. Scintigraphy is a scanning method that uses a special camera (gamma camera) that can detect radioactivity. Because LeukoScan has not been studied in patients aged 17 years or younger, doctors should carefully weigh the benefits and the risks of its use before administering it to a patient in this age group.

How does LeukoScan work?

The active substance in LeukoScan, sulesomab, is a monoclonal antibody. A monoclonal antibody is an antibody (a type of protein) that has been designed to recognise and bind to a specific structure (called an antigen) that is found in certain cells in the body. Sulesomab has been designed to target an antigen called NCA90, which is present on the surface of granulocytes (a type of white blood cell). When LeukoScan is radiolabelled, the radioactive compound technetium-99 (^{99m}Tc) becomes attached to sulesomab. When the radiolabelled medicine is injected into the patient, the monoclonal antibody carries the radioactivity to the target antigen on the granulocytes. As large numbers of granulocytes gather at the site of an infection, the radioactivity will accumulate where there is an infection, and it can be detected using special scanning techniques, such as scintigraphy or SPECT (single photon emission computed tomography).

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How has LeukoScan been studied?
LeukoScan has been studied in two main studies. The first investigated LeukoScan in the detection of osteomyelitis in 102 patients with diabetic foot ulcers. The second study investigated LeukoScan in 130 patients with suspected long bone osteomyelitis. Among these 232 patients, 158 had also undergone a scan using a standard scintigraphy technique (when the patient receives a specially prepared injection of their own white blood cells radiolabelled with a suitable radioactive marker). The main measure of effectiveness was the comparison of the diagnosis made using LeukoScan imaging with the diagnosis from bone biopsy histopathology and microbial culture (when a bone sample is taken and grown in a laboratory to see if it is carrying an infection).

What benefit has LeukoScan shown during the studies?
When the results of both studies were looked at together, LeukoScan was shown to be as effective in diagnosing bone infections as the biopsy and culture technique. LeukoScan was more effective than the standard technique of radiolabelled white blood cells, with a higher sensitivity (detection of 88% of the infections with LeukoScan, compared to 73% with the radiolabelled white blood cells).

What is the risk associated with LeukoScan?
Rare side effects are eosinophilia (increase in eosinophils, a type of white blood cells) and facial rash. For the full list of all side effects reported with LeukoScan, see the Package Leaflet.
LeukoScan should not be used in people who may be hypersensitive (allergic) to sulesomab, mouse proteins, or any of the other ingredients. It should not be used in pregnant women.

Why has LeukoScan been approved?
The Committee for Medicinal products for Human Use (CHMP) decided that LeukoScan's benefits are greater than its risks for determining the location and extent of infection/inflammation in bone in patients with suspected osteomyelitis, including patients with diabetic foot ulcers. They recommended that LeukoScan be given marketing authorisation.

Other information about LeukoScan:
The European Commission granted a marketing authorisation valid throughout the European Union, for LeukoScan to Immunomedics GmbH on 14 February 1997. The marketing authorisation was renewed on 14 February 2002 and 14 February 2007.

The full EPAR for LeukoScan is available here.

This summary was last updated in 02-2007.