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EPAR summary for the public

Scintimun

besilesomab

This is a summary of the European public assessment report (EPAR) for Scintimun. 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 Scintimun.

What is Scintimun?

Scintimun is a kit for the preparation of a radioactive solution for injection. It contains the active substance besilesomab.

What is Scintimun used for?

Scintimun is not used on its own, but must be radiolabelled before use. Radiolabelling is a technique where a substance is labelled with a radioactive compound. Scintimun is radiolabelled by mixing it with a solution of radioactive technetium (99mTc).

Scintimun is for diagnostic use only. It is used to locate areas of infection or inflammation in adults with suspected osteomyelitis (bone infection) in the limbs, in combination with other appropriate imaging methods.

Scintimun should not be used to diagnose diabetic foot infection (infection that occurs in the feet of patients with diabetes).

The medicine can only be obtained with a prescription.

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How is Scintimun used?

Scintimun should only be used in hospitals with a nuclear medicine department and should only be handled by authorised staff.

A radioactive Scintimun solution is made by mixing the powder and solvent provided in the kit and then radiolabelling it with technetium (99mTc). The solution is given to the patient as one injection into a vein. The amount of besilesomab injected varies between 0.25 to 1 mg, depending on how much radioactivity is required.

Three to six hours after the injection, the doctor takes a scan of the limbs to locate the areas in the bones affected by osteomyelitis.

How does Scintimun work?

The active substance in Scintimun, besilesomab, is a monoclonal antibody. A monoclonal antibody is an antibody (a type of protein) that has been designed to recognise and attach to a specific structure (called an antigen) that is found in the body. Besilesomab has been designed to attach to an antigen called NCA-95, which is found on the surface of granulocytes, a type of white blood cell involved in inflammation and fighting infection.

When Scintimun is radiolabelled, the radioactive compound technetium (99mTc) becomes attached to besilesomab. 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 in areas affected by osteomyelitis, where it can be detected by scans. The images will show where besilesomab has accumulated, which the doctor will use to locate the areas of infection or inflammation.

How has Scintimun been studied?

In one main study in 130 patients who had or were suspected to have osteomyelitis in their limbs, radiolabelled Scintimun was compared with a standard diagnostic technique using the patients' own white blood cells that were radiolabelled before being injected back into the patient. Patients limbs were then scanned and the images obtained using both techniques were compared. The main measure of effectiveness for Scintimun was based on how much the assessment of the images obtained with Scintimun agreed with that obtained with the radiolabelled white blood cells.

What benefit has Scintimun shown during the studies?

Scintimun produced comparable results to the radiolabelled white blood cells when used to diagnose and locate osteomyelitis in limbs. The agreement rate was 83%.

What is the risk associated with Scintimun?

The most common side effect with Scintimun (seen in more than 1 patient in 10) is the production of anti-mouse antibodies. For the full list of all side effects reported with Scintimun, see the package leaflet. Scintimun must not be used in people who are hypersensitive (allergic) to besilesomab, to other mouse antibodies or to any of the other ingredients. Scintimun must not be used in patients who have tested positive for human anti-mouse antibody (HAMA) and must not be used in pregnant women. As for all radioactive substances used in medicine, patients should be exposed to the lowest possible dose of Scintimun.

Why has Scintimun been approved?

The CHMP decided that Scintimun's benefits are greater than its risks. The Committee recommended that Scintimun be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Scintimun?

A risk management plan has been developed to ensure that Scintimun is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Scintimun, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition the company that makes Scintimun will make sure that all doctors who are expected to use it are provided with a letter explaining the risks associated with the medicine.

Other information about Scintimun

The European Commission granted a marketing authorisation valid throughout the European Union for Scintimun on 11 January 2010.

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

This summary was last updated in 07-2014.