

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)**NEOSPECT****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 NeoSpect?

NeoSpect is a kit for preparing a radiolabelled medicine. NeoSpect includes a white powder for solution for injection, which contains the active substance depreotide.

What is NeoSpect used for?

NeoSpect is not used on its own, but it must be radiolabelled before use. Radiolabelling is a technique where a substance is tagged (labelled) with a radioactive compound. NeoSpect is radiolabelled by mixing it with a solution of radioactive technetium (^{99m}Tc).

The radiolabelled medicine is for diagnostic use. NeoSpect is used in patients who have a single pulmonary nodule (a small, round lesion in the lungs) detected by a chest X-ray or computerised tomography (CT) scan to see if the nodule is malignant (cancerous).

The medicine can only be obtained with a prescription.

How is NeoSpect used?

NeoSpect is only handled and given by specialised personnel who have experience in the safe handling of radioactive material. Once made up into a radiolabelled solution, NeoSpect is given by intravenous injection (into a vein), and a scan is taken two to four hours after the injection. It should not usually be used on more than one occasion in any one patient.

How does NeoSpect work?

The active substance in NeoSpect, depreotide, is a somatostatin analogue. This means that it acts like somatostatin, and binds to the same receptors as somatostatin in the body. These receptors are found in large numbers on some malignant tumours such as lung tumours. When NeoSpect is radiolabelled, the radioactive element technetium-99m (^{99m}Tc) is attached to depreotide. As depreotide binds to the receptors, it carries the radioactivity with it, and this can be detected using special imaging equipment, such as scintigraphy or single photon emission computed tomography (SPECT). If the solitary pulmonary nodule is labelled with NeoSpect, it is likely to be malignant. If it is not, then it is likely to be benign (non-malignant).

How has NeoSpect been studied?

NeoSpect has been studied in two main trials involving 258 patients with suspected lung cancer. The patients underwent a chest X-ray or a CT scan as well as a SPECT scan using radiolabelled NeoSpect. The outcome of the NeoSpect scan was compared to the actual diagnosis, based on the histology of the

nodule (when the tissue of the nodule is analysed under the microscope after it has been removed in an operation). The main measure of effectiveness was the accuracy of diagnosing a malignant tumour (positive) or a benign tumour (negative).

What benefit has NeoSpect shown during the studies?

The result of the NeoSpect scan was in agreement with the result obtained by histology in between 80 and 90% of the cases. Adding a NeoSpect scan to a CT scan increased the specificity of the scan, making it easier for the doctor to identify a nodule as malignant.

What is the risk associated with NeoSpect?

Side effects with NeoSpect are uncommon, but the most common (seen in between 1 and 10 patients in 1000) are headache, nausea (feeling sick), vomiting, diarrhoea, abdominal (tummy) pain, dizziness, flushing and fatigue (tiredness).

NeoSpect should not be used in people who may be hypersensitive (allergic) to depreotide, sodium pertechnetate or any of the other ingredients. NeoSpect should not be used in women who are pregnant or breast-feeding.

Why has NeoSpect been approved?

The Committee for Medicinal products for Human Use (CHMP) decided that NeoSpect's benefits are greater than its risks for the scintigraphic imaging of suspected malignant lung tumours in the lung after initial detection, in combination with CT scan or chest X-ray, in patients with solitary pulmonary nodules. The Committee recommended that NeoSpect be given marketing authorisation.

Other information about NeoSpect:

The European Commission granted a marketing authorisation valid throughout the European Union for NeoSpect on 29 November 2000. The marketing authorisation was renewed on 29 November 2005. The marketing authorisation holder is CIS bio international.

The full EPAR for NeoSpect is available [here](#).

This summary was last updated in 09-2007.