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EPAR summary for the public

Lymphoseek

tilmanocept

This is a summary of the European public assessment report (EPAR) for Lymphoseek. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Lymphoseek.

For practical information about using Lymphoseek, patients should read the package leaflet or contact their doctor or pharmacist.

What is Lymphoseek and what is it used for?

Lymphoseek is a diagnostic medicine used in patients with cancer to identify sentinel lymph nodes. The sentinel lymph nodes are the regional lymph nodes where the cancer is likely to spread to first. When sentinel lymph nodes are found they are removed surgically and checked for cancer cells. This helps to decide if further surgery to remove more lymph nodes is needed. If the sentinel nodes are found to have no cancer then more extensive lymph nodal surgery can be avoided.

Lymphoseek is used in patients with breast cancer, melanoma (a skin cancer) and a type of cancer of the mouth known as squamous cell carcinoma. It contains the active substance tilmanocept.

How is Lymphoseek used?

Lymphoseek is a solution that is injected either around or inside the cancerous tissue and and is expected to attach to and build up in the nearby lymph nodes. Before being injected into the patient, Lymphoseek is 'radiolabelled', which means that it is tagged with a small amount of radiation. A special camera that detects radiation is then used to see where the lymph nodes are and therefore where the cancer is likely to spread.

Lymphoseek should only be used by healthcare professionals with expertise in mapping lymph nodes. The medicine can only be obtained with a prescription.

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How does Lymphoseek work?

The active substance in Lymphoseek, tilmanocept, attaches to proteins called mannose binding proteins which are found in high amounts in certain immune cells in the lymph nodes. Because it attaches to these proteins, the radiolabelled medicine builds up in the lymph nodes surrounding the cancer, making them visible with the special camera. The lymph nodes can then be checked for cancer cells.

What benefits of Lymphoseek have been shown in studies?

The benefits of Lymphoseek were shown in two main studies in which 311 patients with breast or skin cancer had their lymph nodes first mapped with Lymphoseek and then with another method involving the use of a dye known as 'vital blue dye'. The blue dye is used during surgery to stain the lymph nodes so they can be seen and then checked for cancerous tissue. .

In these two studies, doctors were able to detect a higher number of sentinel lymph nodes with Lymphoseek than with the blue dye: almost all of the lymph nodes identified using the blue dye (98% in one study and 100% in the other) were identified using Lymphoseek, while only around 70% and 60%, respectively, of the lymph nodes detected using Lymphoseek were detected with the blue dye.

In a third study in patients with cancer of the head and neck including mouth cancer, Lymphoseek was used to detect sentinel lymph nodes before patients had their lymph nodes removed surgically. Almost all the patients (38 out of 39) with cancerous lymph nodes were identified by Lymphoseek.

What are the risks associated with Lymphoseek?

The most common side effects with Lymphoseek seen in clinical studies are pain and irritation at the injection site (seen in less than 1 patient in 100). Other side effects seen were uncommon, mild and short-lived. For the full list of all side effects and restrictions with Lymphoseek, see the package leaflet.

Why is Lymphoseek approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) noted that studies showed that the use of Lymphoseek led to a higher detection rate for sentinel lymph nodes than the use of vital blue dye. Given the importance of locating lymph nodes in the treatment of cancers and the manageable side effects seen with Lymphoseek, the Committee concluded that its benefits are greater than its risks and recommended that it be approved for use in the EU.

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

A risk management plan has been developed to ensure that Lymphoseek 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 Lymphoseek, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Lymphoseek

The European Commission granted a marketing authorisation valid throughout the European Union for Lymphoseek on 19 November 2014.

The full EPAR and risk management plan summary for Lymphoseek 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 Lymphoseek, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2014.