EMA/718156/2011
EMEA/H/C/000596

EPAR summary for the public

Yttriga

yttrium (^{90}Y) chloride

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

What is Yttriga?

Yttriga is a radioactive liquid that contains the active substance yttrium (^{90}Y) chloride. ^{90}Y, or yttrium-90, is a radioactive form of the chemical element yttrium.

What is Yttriga used for?

Yttriga is not used on its own but is used for radiolabelling other medicines. Radiolabelling is a technique where a substance is labelled (tagged) with a radioactive compound. Once the substance is labelled with Yttriga, it then carries the radioactivity to where it is needed in the body, for example the site of a tumour.

Yttriga is used to label medicines that have been specially developed for use with yttrium (^{90}Y) chloride.

The medicine can only be obtained with a prescription.

How is Yttriga used?

Yttriga is only to be used by specialists who have experience in radiolabelling.

Yttriga is never given directly to a patient. Radiolabelling of a medicine takes place outside the body in a laboratory setting. The radiolabelled medicine is then given to the patient according to the instructions in that medicine's summary of product characteristics (SmPC).

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How does Yttriga work?

The active substance in Yttriga, yttrium (^{90}Y) chloride, is a radioactive compound that emits a type of radiation known as beta radiation. The effect of Yttriga depends on the nature of the medicine that is radiolabelled with it. An example of its use is the treatment of some type of tumours, where the radiolabelled medicine carries the radioactivity to the site of a tumour to destroy the tumour cells.

How has Yttriga been studied?

As Yttriga will only be used to prepare radiolabelled medicines, no studies of Yttriga have been done in humans. The company presented information from scientific articles already published on ^{90}Y. The company also presented published information on the effect of using ^{90}Y to radiolabel other medicines, including one study of non-Hodgkin's lymphoma (a cancer of the lymph tissue, part of the immune system).

What benefit has Yttriga shown during the studies?

The information supplied by the company shows the utility of Yttriga as a precursor to radiolabel medicines with ^{90}Y.

What is the risk associated with Yttriga?

Yttriga is a precursor and will not be given on its own. The side effects seen with treatment involving Yttriga will therefore depend largely on the medicine being labelled and will be described in that medicine's package leaflet. Yttriga itself is radioactive and so its use in radiolabelling may carry a risk of cancer and hereditary defects. The doctor will ensure that the risks linked to the radioactive exposure are lower than the risks from the disease itself.

Yttriga must not be given directly to any patient. Medicines radiolabelled with Yttriga should not be used in people who may be hypersensitive (allergic) to yttrium chloride or any of the other ingredients. A medicine labelled with Yttriga must not be used in women who are or may be pregnant. More information on the restrictions on the use of medicines radiolabelled with Yttriga will be found in their package leaflets.

Why has Yttriga been approved?

The CHMP decided that Yttriga's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Yttriga

The European Commission granted a marketing authorisation valid throughout the European Union for Yttriga on 19 January 2006.

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

This summary was last updated in 09-2011.