European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

YTRACIS

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 Ytracis?
Ytracis is a solution containing the active substance yttrium (^{90}Y) chloride. ^{90}Y, yttrium-90, is a radioactive form of the chemical element yttrium.

What is Ytracis used for?
Ytracis is used for radiolabelling. Radiolabelling is a technique where a substance is tagged (labelled) with a radioactive compound. In the case of Ytracis, the product is used to label medicines that have been specially developed for use with the active ingredient yttrium (^{90}Y) chloride. These medicines act as carrier to take the radioactivity to where it is needed. These may be substances such as antibodies that have been designed to recognise a particular type of cells in the body, including tumour cells.
The effects of the medicine that is radiolabelled with Ytracis will be fully explained in its Package Leaflet.
The medicine can only be obtained with a prescription.

How is Ytracis used?
Ytracis will only be handled and given by people who have experience in the safe handling of radioactive material.
Ytracis is never given on its own. It must be mixed outside the body, usually in a laboratory, with the medicine that needs radiolabelling. The ^{90}Y contained in Ytracis then attaches itself to the carrier medicine and the resulting mixture is given according to the instructions in the Package Leaflet of the carrier medicine. The quantity of Ytracis needed for radiolabelling and the quantity of the radiolabelled medicine that is given will depend on the medicine that is radiolabelled and the disease that is being treated.

How does Ytracis work?
The active substance in Ytracis, yttrium (^{90}Y) chloride, is a radioactive compound. It emits beta radiation. The effect of Ytracis depends on the nature of the carrier medicine that is radiolabelled with Ytracis. An example of its use is the treatment of some types of tumours, where the radiolabelled medicine carries the radioactivity to the site of a tumour. Once there, the radioactivity from Ytracis helps to destroy the tumour.

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How has Ytracis been studied?
As Ytracis is a 'precursor' and will not be given on its own, no studies have been done in humans. The company presented information from scientific articles already published on ^{90}Y. The company also presented published information supporting the use of ^{90}Y in radiolabelling other medicines.

What benefit has Ytracis shown during the studies?
The information supplied by the company supports the use of Ytracis as a precursor for radiolabelling medicines with ^{90}Y.

What is the risk associated with Ytracis?
As Ytracis is a precursor and will not be given on its own, it has no side effects. Patients may experience side effects following the injection of the medicine radiolabelled with Ytracis. These side effects will depend on the medicine being used, and they will be described in the Package Leaflet of the medicine labelled with Ytracis. Ytracis is radioactive and its use may carry a risk of cancer and hereditary defects. The doctor who prescribes Ytracis must ensure that the risks linked to the radioactive exposure are lower than the risks from the disease itself.
Ytracis must not be given directly to any patient. Medicines radiolabelled with Ytracis should not be used in people who may be hypersensitive (allergic) to yttrium chloride or any of the other ingredients. A medicine labelled with Ytracis should not be used in women who are or may be pregnant. More information on the restrictions for the medicines radiolabelled with Ytracis will be given in the Package Leaflet of the particular medicine that is radiolabelled with Ytracis.

Why has Ytracis been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Ytracis's benefits are greater than its risks for the radiolabelling of carrier molecules which have been specifically developed and authorised for radiolabelling with this radionuclide. The Committee recommended that Ytracis be given marketing authorisation.

Other information about Ytracis:
The European Commission granted a marketing authorisation valid throughout the European Union for Ytracis to CIS bio international on 24 March 2003. The marketing authorisation was renewed on 24 March 2008.

The full EPAR for Ytracis is available here.

This summary was last updated in 02-2008.