European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

REMOVAB

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 Removab?
Removab is a concentrate that is made up into a solution for infusion (a drip). It contains the active substance catumaxomab.

What is Removab used for?
Removab is used to treat malignant ascites, fluid accumulation in the peritoneal cavity (abdominal space) that is caused by a cancer. It is used when standard treatment is not available or is no longer feasible.
Removab can only be used in patients with EpCAM-positive carcinomas. These are cancers where the tumour cells have large quantities of a molecule called EpCAM on their surface.
The medicine can only be obtained with a prescription.

How is Removab used?
Removab treatment should only be given under the supervision of a doctor who has experience in the use of anticancer medicines.
Removab must be given as an intraperitoneal (into the peritoneal cavity) infusion using a pump system. It is usually given as four infusions in increasing doses from 10 to 150 micrograms over 11 days. There must be an interval of at least two days between infusions, but the interval can be increased if the patient has side effects. The overall treatment period should not be longer than 20 days.
Patients should be monitored after each infusion. Removab must not be given all at once or by any other route. Before treatment, it is recommended that patients are given medicines to reduce pain, fever and inflammation. Patients who have severe problems with their liver, or moderate or severe kidney problems should only be given Removab treatment after careful consideration of the medicine's benefits and risks. Removab is not recommended for use in patients below the age of 18 years because of a lack of information on safety and effectiveness in this age group.

How does Removab work?
In patients with cancer, ascites forms because cancer cells develop on the peritoneum, the membrane around the peritoneal cavity, where they block the natural drainage of fluid from the abdomen.
The active substance in Removab, catumaxomab, 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

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(called an antigen) that is found on certain cells in the body. Catumaxomab has been designed to attach to two antigens: EpCAM, which is found in high levels on some types of cancer cells and CD3, which is found on T-cells. T-cells are part of the immune system (the body's natural defences), and are involved in coordinating the death of infected and abnormal cells. By attaching to these two antigens, catumaxomab forms a bridge between the cancer cells and the T-cells. This brings the cells close together so that the T-cells can kill the cancer cells. Catumaxomab also attaches to a third substance called the Fc-gamma receptor, which also helps the body's immune system to target the cancer cells.

How has Removab been studied?
The effects of Removab were first tested in experimental models before being studied in humans. Removab was studied in one main study involving 258 patients with malignant ascites caused by an EpCAM-positive cancer and for which standard therapy was not available or was no longer feasible. In this study, Removab used in combination with drainage of fluid from the abdomen was compared with drainage alone. The main measure of effectiveness was how long patients lived without the need for further drainage.

What benefit has Removab shown during the studies?
Removab with drainage was more effective at treating malignant acsites than drainage alone. On average, patients who received Removab lived for 46 days without the need for further drainage. This compared with 11 days for patients who were treated with drainage alone.

What is the risk associated with Removab?
Around 90% of patients treated with Removab have side effects. The most common side effects with Removab (seen in more than 1 patient in 10) are lymphopenia (low level of lymphocytes, a type of white blood cell), abdominal (tummy) pain, nausea (feeling sick), vomiting, diarrhoea, pyrexia (fever), fatigue (tiredness), chills and pain. For the full list of all side effects reported with Removab, see the Package Leaflet.
Removab should not be used in people who may be hypersensitive (allergic) to catumaxomab, to any of the other ingredients, or to murine (rat or mouse) proteins.

Why has Removab been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Removab's benefits are greater than its risks for the intraperitoneal treatment of malignant ascites in patients with EpCAM-positive carcinoma where standard therapy is not available or no longer feasible. The Committee recommended that Removab be given marketing authorisation.

Other information about Removab:
The European Commission granted a marketing authorisation valid throughout the European Union for Removab to Fresenius Biotech GmbH on 20 April 2009.

The full EPAR for Removab can be found here.

This summary was last updated in 03-2009.