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EPAR summary for the public

MabCampath

alemtuzumab

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

What is MabCampath?

MabCampath is a concentrate that is made up into a solution for infusion (drip into a vein). It contains the active substance alemtuzumab (10 mg/ml or 30 mg/ml).

What is MabCampath used for?

MabCampath is used to treat patients with B-cell chronic lymphocytic leukaemia (B-CLL), a cancer of a type of white blood cell called B lymphocytes. MabCampath is used in patients for whom treatment combinations including fludarabine (another medicine used in leukaemia) are not appropriate.

The medicine can only be obtained with a prescription.

How is MabCampath used?

MabCampath treatment should be supervised by a doctor experienced in the use of cancer treatments. Patients should be given steroids, an antihistamine and a painkiller before the first dose and before any increase in dose. They should also receive antibiotics and antiviral medicines during and after treatment.

MabCampath is given as an infusion lasting about two hours. During the first week of treatment, MabCampath should be given in increasing doses: 3 mg on day 1, 10 mg on day 2 and 30 mg on day 3, as long as each dose is well tolerated. This is called 'dose escalation'. After this, the recommended dose is 30 mg three times a week (every other day) for a maximum of 12 weeks.

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Patients should be monitored during treatment to see how they respond, but also to check their blood levels of platelets (components that help the blood to clot) and neutrophils (a type of white blood cell that fights infection): if these are too low the treatment should be interrupted or stopped. See the summary of product characteristics (also part of the EPAR) for full details.

How does MabCampath work?

The active substance in MabCampath, alemtuzumab, 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 (called an antigen) that is found in certain cells in the body. In CLL, too many lymphocytes are produced. Alemtuzumab has been designed to attach to a glycoprotein (a protein that is coated with sugar molecules) called CD52 that is found on the surface of lymphocytes. As a result, the lymphocytes die, and this helps to control the CLL.

How has MabCampath been studied?

MabCampath has been looked at in four main studies involving a total of 446 patients with CLL. One study included 297 patients who had not received treatment before. It compared a 12-week course of MabCampath with a year-long course of chlorambucil (another anticancer medicine). The main measure of effectiveness was how long it took until the disease got worse or the patient died.

The other three studies looked at a total of 149 patients who had already received other treatments. In these studies, MabCampath was not compared with any other treatment. One of these studies included 93 patients in whom previous treatment with fludarabine had stopped working. The main measure of effectiveness was the overall response to treatment.

What benefit has MabCampath shown during the studies?

In patients who had not received treatment before, MabCampath was more effective than chlorambucil. In the patients receiving MabCampath, it took an average of 14.6 months for the disease to get worse or for the patient to die, compared with 11.7 months in those taking chlorambucil.

In the study of patients who had been treated with fludarabine before, 33% responded partially or completely to treatment with MabCampath. Similar results were seen in the other two studies of previously treated patients.

What is the risk associated with MabCampath?

The most frequent side effects with MabCampath are: infusion reactions (fever, chills, low blood pressure, itching, feeling sick, hives, increased heart rate, breathlessness), low counts of blood cells (white blood cells, platelets and red blood cells), infections (signs of cytomegalovirus in the blood, cytomegalovirus infection or other infections), gastrointestinal symptoms (feeling sick, vomiting, abdominal pain) and neurological symptoms (insomnia, anxiety). The most frequent serious adverse reactions are low counts of blood cells, infusion reactions, and infections or immunosuppression (reduced activity of the immune system). For the full list of all side effects reported with MabCampath, see the package leaflet.

MabCampath should not be used in people who may be hypersensitive (allergic) to alemtuzumab, mouse proteins, or any of the other ingredients. MabCampath must not be used in patients:

- who have an active infection that has spread throughout the body;
- with HIV infection;

- who have an active, second cancer;
- who are pregnant.

Why has MabCampath been approved?

The CHMP noted that the effectiveness of MabCampath had been demonstrated, but that there is no information from studies directly comparing MabCampath with treatment combinations including fludarabine, which are widely used to treat patients with CLL. Therefore, the Committee concluded that MabCampath's benefits are greater than its risks for the treatment of patients with B-CLL for whom fludarabine combination chemotherapy is not appropriate. The Committee recommended that MabCampath be given marketing authorisation.

MabCampath was originally authorised under 'exceptional circumstances', because, for scientific reasons, it had not been possible to obtain complete information on the medicine. As the company had supplied the additional information requested, the 'exceptional circumstances' ended on 04 July 2008.

What measures are being taken to ensure the safe use of MabCampath?

The company that makes MabCampath will provide a brochure containing information on the medicine's safety to all doctors in all Member States who prescribe the medicine.

Other information about MabCampath

The European Commission granted a marketing authorisation valid throughout the European Union for MabCampath on 6 July 2001. The marketing authorisation is valid for an unlimited period. The marketing authorisation holder is Genzyme Europa BV.

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

This summary was last updated in 04-2011.