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EPAR summary for the public

Empliciti

elotuzumab

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

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

What is Empliciti and what is it used for?

Empliciti is a medicine for treating multiple myeloma (a cancer of the bone marrow). It is used together with two other medicines (lenalidomide and dexamethasone) and is given to adults who have tried at least one previous cancer treatment.

Empliciti contains the active substance elotuzumab.

How is Empliciti used?

Empliciti is given as an infusion (drip) into a vein. Treatment takes place in 28-day cycles, with Empliciti given once a week in the first 2 cycles (on days 1, 8, 15 and 22) and once every 2 weeks in subsequent cycles (days 1 and 15). The dose is 10 mg per kilogram body weight.

Because of the risk of infusion reactions, the patient is to be given preventive treatment consisting of an anti-inflammatory medicine, an antihistamine and paracetamol before every infusion. In addition, during each 28-day cycle, the patient also receives cancer treatment with lenalidomide and dexamethasone.

Empliciti is available as a powder to be made up into a solution. Treatment must be started and supervised by a doctor experienced in treating multiple myeloma, and the medicine can only be obtained with a prescription.

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How does Empliciti work?

The active substance in Empliciti, elotuzumab, is a monoclonal antibody that activates the body's immune cells to attack the multiple myeloma cancer cells. It does this by attaching to a protein on the surface of the immune cells called SLAMF7, causing them to act against the cancer cells and thereby slow down the disease.

Elotuzumab also attaches to SLAMF7 on the cancer cells, making them more vulnerable to attack by the immune cells.

What benefits of Empliciti have been shown in studies?

A main study of 646 multiple myeloma patients compared the effects of taking Empliciti plus lenalidomide and dexamethasone with the effects of taking only lenalidomide and dexamethasone. In this study, adding Empliciti to the two other medicines extended the average time before the disease got worse from 14.3 months to 18.5 months. In addition, more patients had a partial or complete clearing of their cancer with the Empliciti combination (79% of patients) than with only the other two medicines (66% of patients).

All patients in the study had previously tried other treatments but their disease had either not responded or had come back.

What are the risks associated with Empliciti?

The most common side effects with Empliciti (which may affect more than 1 in 10 people) are infusion reactions (with symptoms such as fever and chills), diarrhoea, shingles (painful, blistering rash), sore throat, cough, pneumonia (lung infection), colds, low levels of white blood cells and weight loss. The majority of side effects are mild or moderate in severity, and the most serious is pneumonia. For the full list of all side effects, see the package leaflet.

Why is Empliciti approved?

The main study showed that adding Empliciti to lenalidomide and dexamethasone can delay the worsening of multiple myeloma and improve response rates in patients whose disease had come back or did not respond to previous treatment. Although side effects, particularly infections, were more common with Empliciti, the risks on the whole appear manageable.

The Agency's Committee for Medicinal Products for Human Use (CHMP) therefore concluded that Empliciti's 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 Empliciti?

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

Other information about Empliciti

The European Commission granted a marketing authorisation valid throughout the European Union for Empliciti on 11 May 2016.

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

This summary was last updated in 05-2016.