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Empliciti (*elotuzumab*)

An overview of Empliciti and why it is authorised in the EU

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 received at least one previous cancer treatment.

Empliciti is also used together with the medicines pomalidomide and dexamethasone to treat multiple myeloma that was previously treated with at least two other treatments but the cancer had come back. Patients' previous treatment should have included the multiple myeloma medicines lenalidomide and a class of medicines called proteasome inhibitors (e.g. bortezomib, carfilzomib and ixazomib).

Empliciti contains the active substance elotuzumab.

How is Empliciti used?

Empliciti is given as an infusion (drip) into a vein. Treatment is given in 28-day cycles. The dose of Empliciti depends on the patient's weight. It is given once a week for the first 2 cycles and less frequently in subsequent cycles. The patient is also given other cancer medicines (dexamethasone with either lenalidomide or pomalidomide) during each cycle.

To prevent infusion reactions, the patient is given an anti-inflammatory medicine, an antihistamine and paracetamol before every infusion.

Treatment must be started and supervised by a doctor experienced in treating multiple myeloma, and the medicine can only be obtained with a prescription.

For more information about using Empliciti, see the package leaflet or contact your doctor or pharmacist.

How does Empliciti work?

The active substance in Empliciti, elotuzumab, is a monoclonal antibody that attaches to SLAMF7, a protein on immune cells, causing the cells to attack the multiple myeloma cancer cells and thereby slow down the disease.

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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?

In a main study of 646 multiple myeloma patients a combination of Empliciti plus lenalidomide and dexamethasone was compared with only lenalidomide and dexamethasone. All patients had previously received other treatments but the treatments had not worked or the cancer had come back. The average time before the disease got worse was 18.5 months in patients treated with the Empliciti combination compared with 14.3 months in those treated with just lenalidomide and dexamethasone. In addition, the cancer cleared partially or completely in 79% of patients treated with the Empliciti combination compared with 66% of patients treated with the other two medicines.

A second main study involved 117 multiple myeloma patients who had received at least two other treatments previously, including a proteasome inhibitor and lenalidomide. Patients treated with a combination of Empliciti plus pomalidomide and dexamethasone lived on average for over 5.5 months longer without their disease getting worse compared with patients treated with pomalidomide and dexamethasone.

What are the risks associated with Empliciti?

The most common side effects with Empliciti (which may affect more than 1 in 10 people) are headache, tiredness, fever, diarrhoea, sore throat, nose and throat infections, cough, pneumonia (lung infection), low levels of white blood cells and weight loss.

For the full list of side effects and restrictions of Empliciti, see the package leaflet.

Why is Empliciti authorised in the EU?

Adding Empliciti to lenalidomide and dexamethasone can delay the worsening of multiple myeloma and improve clearance of the cancer in patients whose disease did not improve with previous treatment or whose disease came back. In patients who had already been treated with at least two treatments including a proteasome inhibitor and lenalidomide (and the treatment had not worked or the disease had come back), Empliciti plus pomalidomide and dexamethasone delayed worsening of the disease, compared with just pomalidomide and dexamethasone. Although side effects, particularly infections, were more common with Empliciti, the risks on the whole appear manageable.

The European Medicines Agency therefore decided that Empliciti's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Empliciti?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Empliciti have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Empliciti are continuously monitored. Side effects reported with Empliciti are carefully evaluated and any necessary action taken to protect patients.

Other information about Empliciti

Empliciti received a marketing authorisation valid throughout the EU on 11 May 2016.

Further information on Empliciti can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/empliciti.

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