



EUROPEAN MEDICINES AGENCY  
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## **Mylotarg (*gemtuzumab ozogamicin*)**

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

### **What is Mylotarg and what is it used for?**

Mylotarg is a medicine used to treat a blood cancer called acute myeloid leukaemia (AML) in patients aged 15 years and above who are newly diagnosed and have not tried other treatments.

It is used in combination with daunorubicin and cytarabine (other cancer medicines).

Mylotarg is used in patients with a protein called CD33 on their cancer cells (which is the case in most patients with AML). It is not used for a type of AML called acute promyelocytic leukaemia (APL).

AML is rare, and Mylotarg was designated an 'orphan medicine' (a medicine used in rare diseases) on 18 October 2000. Further information on the orphan designation can be found here: [ema.europa.eu/Find\\_medicine/Human\\_medicines/Rare\\_disease\\_designation](http://ema.europa.eu/Find_medicine/Human_medicines/Rare_disease_designation).

Mylotarg contains the active substance gemtuzumab ozogamicin.

### **How is Mylotarg used?**

Mylotarg is given as an infusion into a vein lasting 2 hours. The patient usually receives 3 infusions within one week. The patient will also be given two other medicines: daunorubicin and cytarabine.

If the cancer responds to initial treatment, the patient may receive further 'consolidation' treatment to keep the cancer from coming back.

Mylotarg infusions must be given in a place (such as a hospital) where the patient can be resuscitated if there are severe reactions. The patient is also given medicines to help prevent reactions such as reddening of the skin, chills and fever.

For more information about using Mylotarg, see the package leaflet or contact your doctor or pharmacist. Mylotarg can only be obtained with a prescription.

### **How does Mylotarg work?**

The active substance in Mylotarg, gemtuzumab ozogamicin, consists of two parts: a cytotoxic (cell-killing) substance and a monoclonal antibody (a type of protein).



The monoclonal antibody part (gemtuzumab) has been designed to attach to CD33. When the antibody attaches to CD33 on leukaemia cells, the cells absorb the antibody, as well as the cytotoxic substance that it is attached to. Inside the cells, the cytotoxic substance, which is called calicheamicin, is released. The calicheamicin then breaks up the cells' DNA, eventually killing the cells.

### **What benefits of Mylotarg have been shown in studies?**

A main study in 271 patients with AML has shown that adding Mylotarg to daunorubicin and cytarabine can prolong the time patients live without their cancer coming back by around 8 months.

In patients receiving Mylotarg in combination with daunorubicin and cytarabine, it took an average of 17.3 months until the treatment failed, the cancer came back or the patient died, compared with 9.5 months in patients receiving a combination of only daunorubicin and cytarabine.

### **What are the risks associated with Mylotarg?**

The most common side effects with Mylotarg when given in combination with daunorubicin and cytarabine (which may affect more than 3 in 10 people) are bleeding and severe infections. These side effects can be serious in more than 1 in 10 people. Other serious side effects with the combination therapy are liver disease, including veno-occlusive disease (a liver injury), and tumour lysis syndrome (a complication due to the breakdown of cancer cells).

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

### **Why is Mylotarg authorised in the EU?**

Mylotarg, given in combination with daunorubicin and cytarabine, has been shown to prolong the time patients lived before the cancer came back by up to 8 months. Although some side effects with Mylotarg can be serious, they were considered acceptable in light of the severity of the patients' condition.

The European Medicines Agency decided that Mylotarg'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 Mylotarg?**

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

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

### **Other information about Mylotarg**

Mylotarg received a marketing authorisation valid throughout the EU on 19 April 2018.

Further information on Mylotarg can be found on the Agency's website: [ema.europa.eu/Find/medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find/medicine/Human_medicines/European_public_assessment_reports).

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