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February 2023

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

▼ **Mylotarg® (gemtuzumab ozogamicin) 5 mg powder for concentrate for solution for infusion (PLGB 00057/1591): interim supply from US**

Dear Healthcare Professional,

Summary:

To ensure continuity in supply, Pfizer has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply Mylotarg (gemtuzumab ozogamicin) from the United States (US) (batch number GG8621; batch size 50 vials), which is expected to be on the GB market from 16th February to 2nd March 2023.

Please note the following:

- The Patient Information Leaflet (PIL), label and carton of US Mylotarg will state 4.5 mg/ml per vial. However, the nature and the content of the vial is identical to GB's Mylotarg formulation (i.e. both contain 5 mg of gemtuzumab ozogamicin).
- This product is considered equivalent to the UK product licensed under PL 00057/1591.
- For information on indication, dosing, administration, reconstitution, etc please follow/abide by UK Summary of Product Characteristics (SPC) https://www.medicines.org.uk/emc/product/9151 and PIL.

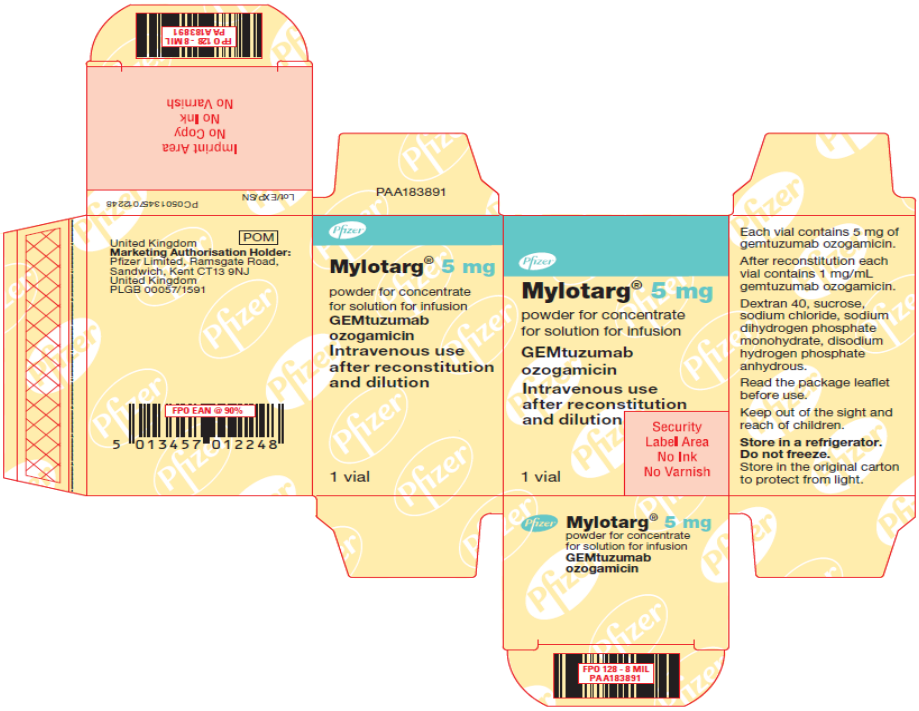
Mylotarg is indicated for combination therapy with daunorubicin and cytarabine for the treatment of patients age 15 years and above with previously untreated, *de novo* CD33-positive acute myeloid leukaemia (AML), except acute promyelocytic leukaemia (APL).

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to patients.

Product images are below:

US Mylotarg packaging

UK Mylotarg Packaging (for comparison)



Call for reporting

Healthcare professionals are asked to report suspected adverse reactions to the Yellow Card scheme. Report via the website https://yellowcard.mhra.gov.uk/, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Mylotarg (gemtuzumab ozogamicin) is subject to additional monitoring. When reporting an adverse event for Mylotarg, please remember to include product name and batch details in your report.

Company contact point
For any questions, please contact Pfizer Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS or Telephone: 01304 616 161 or https://www.pfizermedicalinformation.co.uk.

Yours faithfully

DocuSigned by:
Olivia Ashman February 2, 2023
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Dr Olivia Ashman
UK Oncology Medical Director
Pfizer UK