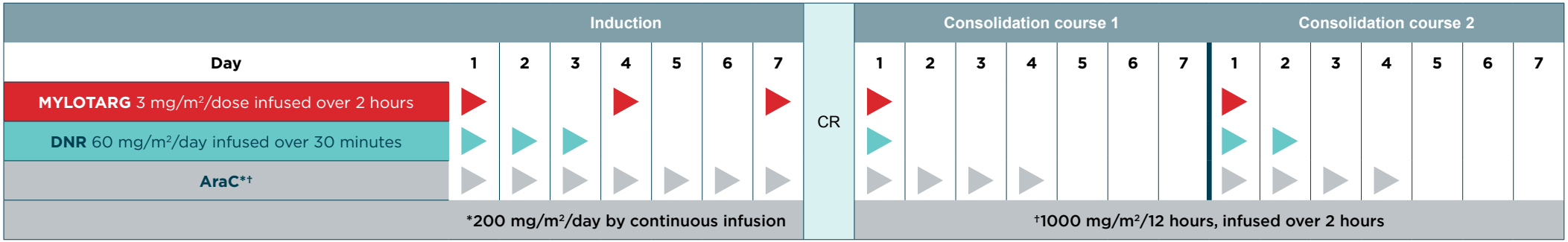
MYLOTARG™ (gemtuzumab ozogamicin) INJECTION FOR IV INFUSION

MYLOTARG is indicated for combination therapy with DNR and AraC for the treatment of patients age 15 years and above with previously untreated, de novo CD33-positive AML, except APL[1]

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions

Click here for **MYLOTARG SmPC**

The recommended dose of MYLOTARG is 3 mg/m²/dose (up to a maximum dose of one 5 mg vial) infused over a 2-hour period in combination with DNR and AraC[1]



Toxicity management

Incidence[1,2]

AEs of special interest, (%)	All Grades	Grade 3/4
Haemorrhage	90.1	20.6
Infection	77.9	76.3
VOD	4.6	2.3
Haematological toxicities, (%)		
Leukopenia	100	100
Thrombocytopenia	100	100
Anaemia	100	86.2
Lymphopenia	98.5	90.7
Neutropenia	97.7	96.1
Persistent thrombocytopenia*		20.4
Non-haematological toxicities, (%)		
AST increased	89.2	14.0
ALP increased	79.7	13.3
ALT increased	78.3	10.9
Blood bilirubin increased	51.6	7.1

* Thrombocytopenia with platelet counts <50,000/mm³ persisting 45 days after the start of therapy for responding patients

Before- and on-treatment monitoring[1]

Pre-medications (1 hour prior to dosing): Corticosteroid, antihistamine and acetaminophen (or paracetamol)

Measures to help prevent the development of tumour lysis-related hyperuricaemia: Hydration and administration of anti-hyperuricemic or other agents for treatment of hyperuricaemia

Prior to each MYLOTARG dose, monitor: Complete blood counts and liver tests, including ALT, AST, total bilirubin and ALP levels

Recommended dose modifications[1]

Hepatotoxicity including VOD	• For patients with VOD/SOS, discontinue MYLOTARG • No adjustment of the starting dose is required for total bilirubin ≤2× ULN and AST/ALT ≤2.5× ULN • For patients with total bilirubin >2× ULN and AST and/or ALT >2.5× ULN, it is recommended to postpone MYLOTARG until recovery of total bilirubin to ≤2× ULN and AST/ALT to ≤2.5× ULN, prior to each dose. Consider omitting scheduled dose if delayed >2 days between sequential infusions
Persistent thrombocytopenia (Platelets < 100,000/mm³ at the planned start date of the consolidation course)	• Postpone start of consolidation course • If platelet count ≥100,000/mm³ within 14 days, initiate consolidation therapy • If platelet count ≥50,000/mm³ and <100,000/mm³ within 14 days, MYLOTARG should not be re-introduced; consolidation therapy should consist of DNR and AraC only • If platelet count <50,000/mm³ for >14 days, consolidation therapy should be re-evaluated and BMA should be performed to assess patient status
Persistent neutropenia	• If neutrophil count does not recover to >500/mm³ within 14 days after the planned start date of the consolidation cycle (14 days after haematological recovery following previous cycle), discontinue MYLOTARG (do not administer MYLOTARG in the consolidation cycles)

1. Pfizer. MYLOTARG Summary of Product Characteristics. December 2020;
2. Lambert J *et al. Haematologica* 2019;104:113–119

Date of preparation: May 2021. PP-MYL-GLB-0066

MYLOTARG added to standard chemotherapy offers a manageable safety profile, with an overall favourable benefit/risk. For further information about MYLOTARG, please refer to the SmPC and the therapy management guide.

AE=adverse event; ALP=alkaline phosphatase; ALT=alanine aminotransferase; AML=acute myeloid leukemia; APL=acute promyelocytic leukemia; AraC=cytarabine; AST=aspartate aminotransferase; BMA=bone marrow aspirate; DNR=daunorubicin; SOS=sinusoidal obstruction syndrome; ULN=upper limit of normal; VOD=veno-occlusive disease

Before prescribing Mylotarg, please refer to the full Summary of Product Characteristics (SmPC).
Please refer to your local authorities concerning reimbursement status. Medicinal product subject to medical prescription.

Pfizer