MYLOTARG™
(gemtuzumab ozogamicin) INJECTION FOR IV INFUSION

Therapy Management

A guide to treatment with MYLOTARG

▼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

INDICATION

MYLOTARG is indicated for combination therapy with daunorubicin (DNR) and cytarabine (AraC) 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).

Click here for **MYLOTARG SmPC**

Before prescribing Mylotarg, please refer to the full Summary of Product Characteristics (SmPC). Please refer to your local authorities concerning reimbursement status. Medicinal products subject to medical prescription. For healthcare professionals only.
https://www.ema.europa.eu/en/documents/product-information/mylotarg-epar-product-information_en.pdf
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Pfizer

June 2022. PP-MYL-GLB-0080

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Acknowledgements and abbreviations

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ADC	Antibody–drug conjugate
AE	Adverse event
ALP	Alkaline phosphatase
ALT	Alanine aminotransferase
AML	Acute myeloid leukaemia
ANC	Absolute neutrophil count
APL	Acute promyelocytic leukaemia
AraC	Cytarabine
AST	Aspartate aminotransferase
BMA	Bone marrow aspirate
CI	Confidence interval
CR	Complete remission
CRp	Complete remission with incomplete platelet recovery
DNR	Daunorubicin
ECOG	Eastern Cooperative Oncology Group
EFS	Event-free survival
ELN	European LeukemiaNet
HR	Hazard ratio
HSCT	Haematopoietic stem cell transplantation
IV	Intravenous
mITT	Modified intention-to-treat
NCCN	National Comprehensive Cancer Network
NCI CTCAE	National Cancer Institute Common Terminology Criteria for Adverse Events
NE	Not estimable
ORR	Overall response rate
OS	Overall survival
RFS	Relapse-free survival
TLS	Tumour lysis syndrome
ULN	Upper limit of normal
VOD	Veno-occlusive disease
VOD/SOS	Veno-occlusive disease/ sinusoidal obstruction syndrome
WBC	White blood cell

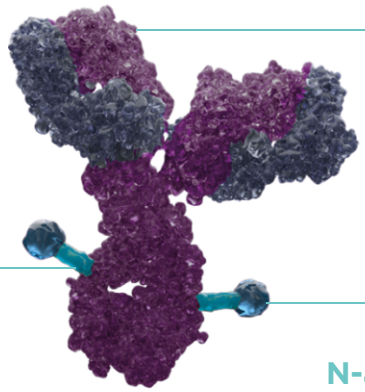
Introduction

MYLOTARG is an ADC that combines the specificity of an anti-CD33 monoclonal antibody with the anti-tumour activity of cytotoxic agent N-acetyl gamma calicheamicin.[1]

Objectives of this guide

- Describe MYLOTARG and how it works
- Provide an overview of the efficacy and safety profile for MYLOTARG
- Explain the dosing and route of administration for MYLOTARG
- Provide guidance on the effective management of AEs associated with MYLOTARG

MYLOTARG antibody–drug conjugate



Delivery vehicle: anti-CD33 antibody[2]
CD33 is a specific biomarker of myeloid precursor cells[3,4] and is expressed in up to 90% of AML cases[3]

Selectively stable linker[2]

Cytotoxic drug payload: N-acetyl gamma calicheamicin[2]

AML, acute myeloid leukaemia; CD33, cluster of differentiation-33

Indication for MYLOTARG

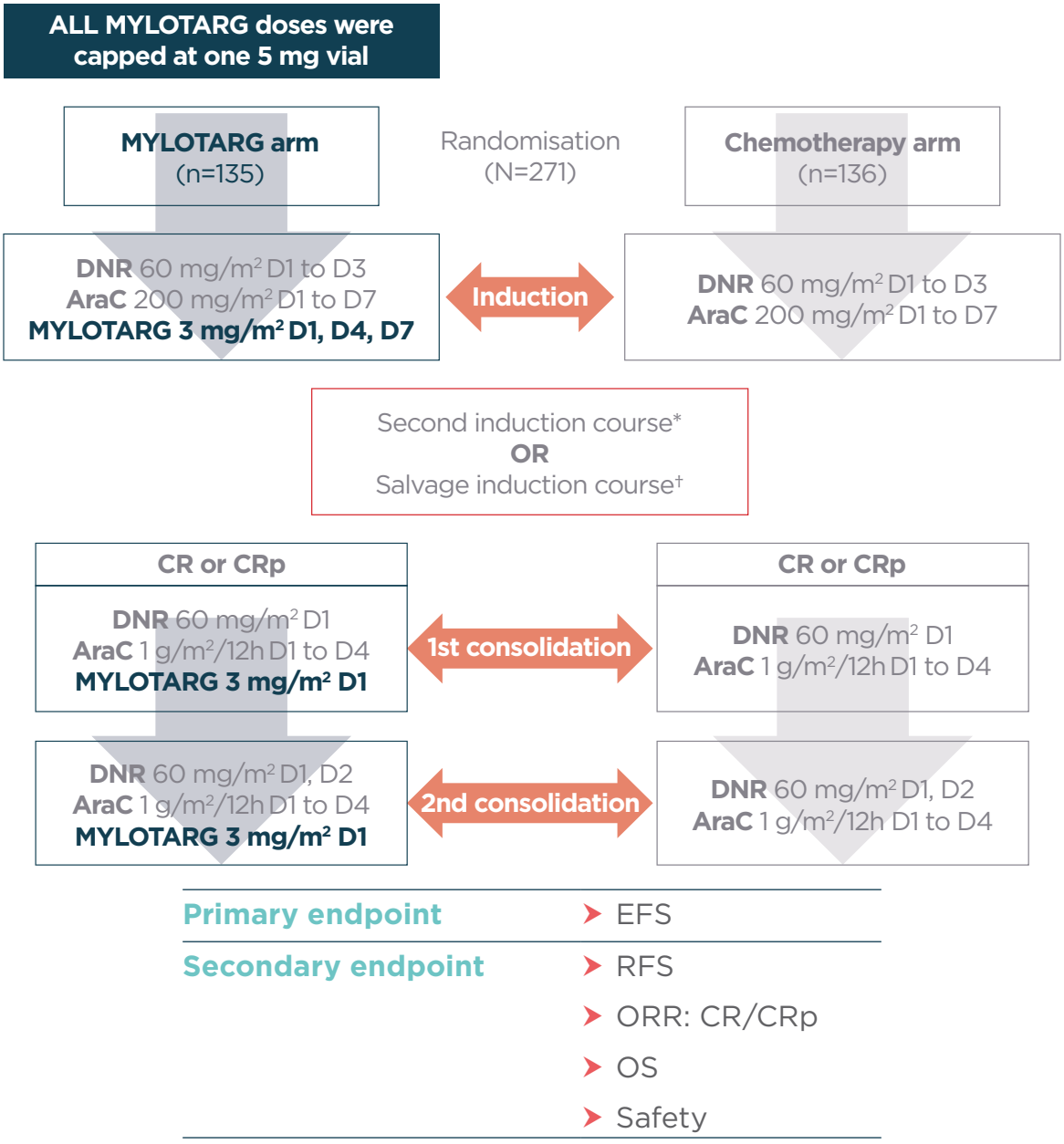
MYLOTARG is indicated for combination therapy with DNR and AraC for the treatment of patients age 15 years and above with previously untreated, *de novo* CD33-positive AML, except APL.[1]

1. Pfizer. MYLOTARG summary of product characteristics. 2022
2. Ricart AD. *Clin Cancer Res* 2011;17:6417–6427
3. Ehninger A *et al. Blood Cancer J* 2014;4:e218
4. Garnache-Ottou F *et al. Blood* 2005;105:1256–1264

ALFA-0701 study

Study design

ALFA-0701 was a Phase III study that evaluated the efficacy and safety of fractionated dosing of MYLOTARG plus chemotherapy versus chemotherapy alone in previously untreated, *de novo* AML.[1]



Primary endpoint	➤ EFS
Secondary endpoint	➤ RFS
	➤ ORR: CR/CRp
	➤ OS
	➤ Safety

*A second course of induction therapy with DNR + AraC but without MYLOTARG, regardless of the randomisation arm, was allowed. In the second induction cycle, DNR + AraC should be administered at the following recommended dosing: DNR 35 mg/m²/day on Days 1 and 2, and AraC 1 g/m²/every 12 hours, on Day 1 to Day 3; †Patients in either arm who did not receive the second course of induction therapy and did not achieve a CR after induction could receive a salvage course comprised of idarubicin, AraC and granulocyte colony-stimulating factor

AraC, cytarabine; CR, complete remission; CRp, complete remission with incomplete platelet recovery; DNR, daunorubicin; EFS, event-free survival; ORR, overall response rate; OS, overall survival; RFS, relapse-free survival

1. Pfizer. MYLOTARG summary of product characteristics. 2021

Key patient characteristics

Characteristics of the patients in the mITT population were balanced between treatment arms, with the exception of sex.[1]

	MYLOTARG arm (n=135)	Chemotherapy arm (n=136)
Male, %	54.8	44.1
Median age (range), years	62 (50–70)	
ECOG performance status 0–1, %	87.8	
CD33 expression <30%, %	13.7	
Favourable/intermediate cytogenetics by NCCN, %	59.0	
Favourable/intermediate cytogenetics by ELN 2010, %	65.3	

ECOG, Eastern Cooperative Oncology Group; ELN, European LeukemiaNet; NCCN, National Comprehensive Cancer Network

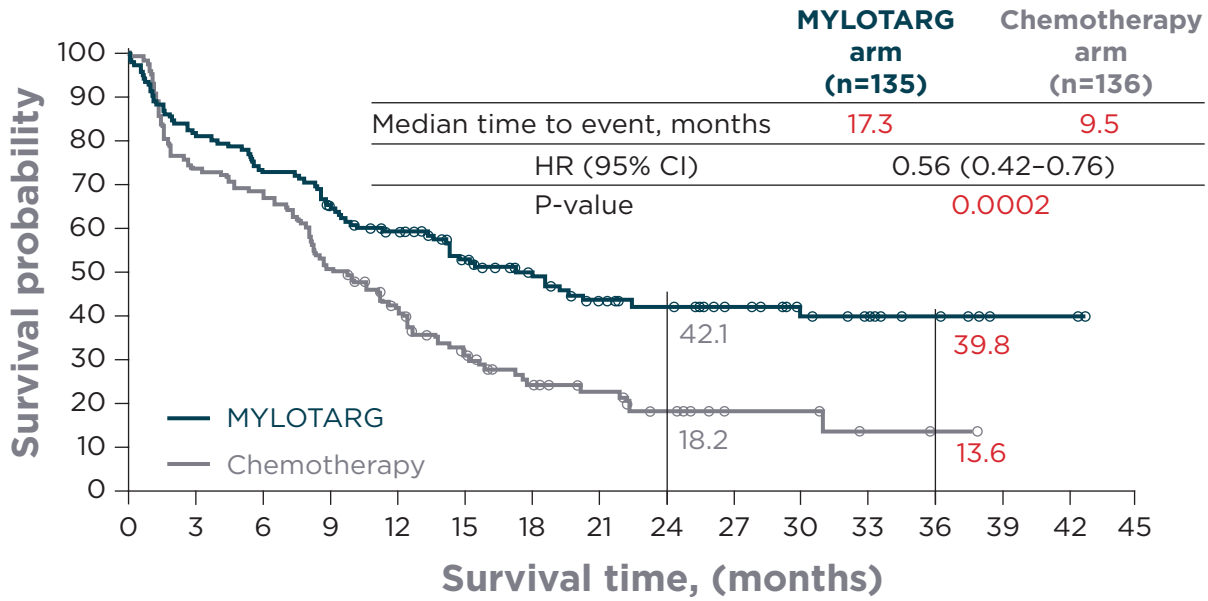
1. Pfizer. MYLOTARG summary of product characteristics. 2021

Clinical outcomes of MYLOTARG

Event-free survival rate

Median EFS was significantly longer when MYLOTARG was added to standard chemotherapy (17.3 months vs 9.5 months [HR 0.562; P=0.0002]).[1]

The significant reduction in risk of events was maintained, with 39.8% of patients in the MYLOTARG arm remaining alive at 3 years.[1]



No. at risk

MYLOTARG	135	109	98	86	74	57	47	36	32	25	18	15	10	3	3	0
Chemotherapy	136	100	93	69	51	32	21	16	10	5	5	2	1	0		

CI, confidence interval; HR, hazard ratio

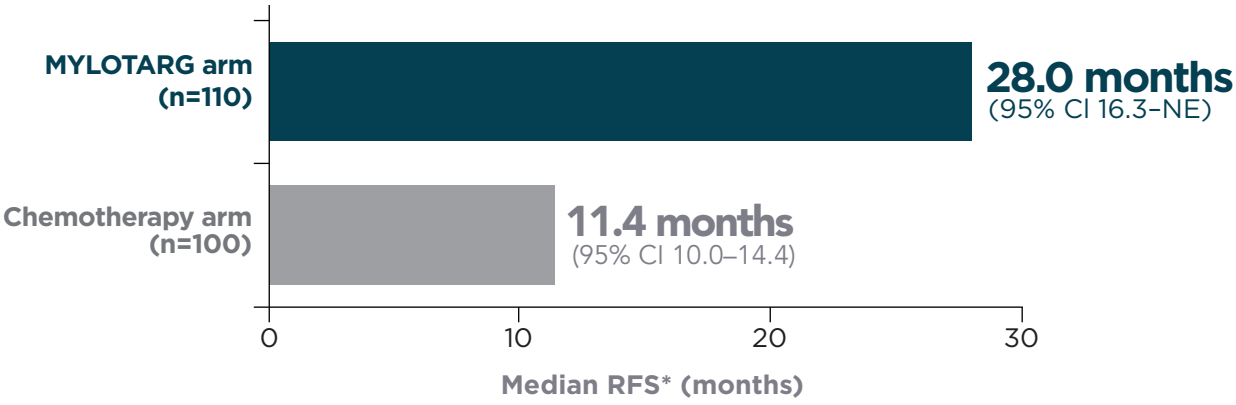
Figure adapted from Pfizer. MYLOTARG summary of product characteristics. 2021

1. Pfizer. MYLOTARG summary of product characteristics. 2021

Relapse-free survival rate*

Median RFS was significantly longer with MYLOTARG plus induction standard chemotherapy than with standard chemotherapy alone (28.0 months vs 11.4 months [HR 0.526; P=0.0006]).[1]

The addition of MYLOTARG to standard chemotherapy resulted in a 47% reduction in the risk of an event.[1]



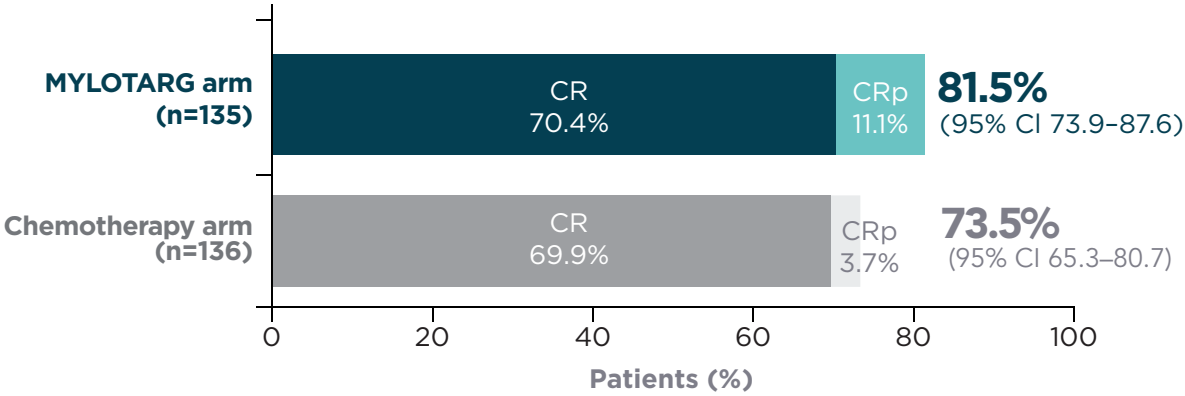
Between group difference:
16.6 months; HR 0.526 (95% CI 0.362–0.764); P=0.0006

Median estimated by Kaplan-Meier method

CI, confidence interval; HR, hazard ratio; NE, not estimable; RFS, relapse-free survival

Overall response rate

CR/CRp was achieved in 81.5% of patients with MYLOTARG plus induction standard chemotherapy; however, no significant difference in ORR between the two arms was noted (P=0.1457).[1]



Risk difference: 7.95; (95% CI -3.79, 19.85); P=0.1457

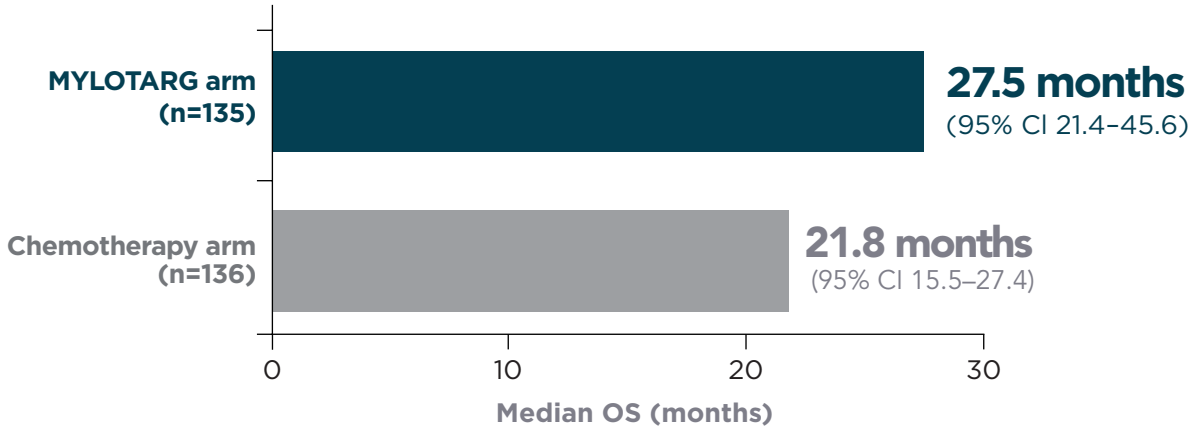
CI, confidence interval; CR, complete remission; CRp, complete remission with incomplete platelet recovery

1. Pfizer. MYLOTARG summary of product characteristics. 2021

Median overall survival

Median OS was higher with MYLOTARG plus induction standard chemotherapy than with standard chemotherapy alone; however, this difference did not reach statistical significance (27.5 months vs 21.8 months [HR 0.807; 95% CI 0.596–1.093; two-sided P=0.1646]).[1]

- There was a 19% reduction in the risk of death with MYLOTARG plus induction standard chemotherapy versus standard chemotherapy alone[1]



HR 0.807 (95% CI 0.596–1.093); P=0.1646

CI, confidence interval; HR, hazard ratio; OS, overall survival

Safety of MYLOTARG

MYLOTARG added to standard chemotherapy offers an acceptable safety profile with an overall favourable benefit–risk.[5] **For information of management of specific AEs with MYLOTARG, please refer to page 13.**

1. Pfizer. MYLOTARG summary of product characteristics. 2021
5. Lambert J *et al*. *Haematologica* 2018;104:113-119

Dosing and administration

Reduce to <30,000/mm³

In patients with hyperleukocytic AML (leukocyte count ≥30,000/mm³), cytoreduction is recommended either with leukapheresis, oral hydroxyurea or AraC with or without hydroxyurea to reduce the peripheral WBC count 48 hours prior to administration of MYLOTARG.[1] **For information on management of hyperleukocytosis, please refer to page 18.**

Premedication is recommended

Before administering each dose of MYLOTARG, premedication with a corticosteroid, antihistamine and acetaminophen (or paracetamol) is recommended 1 hour prior to dosing to help ameliorate infusion-related symptoms.[1] **For information on the management of infusion-related reactions, please refer to page 17.**

In addition, complete blood counts and ALT, AST, total bilirubin and ALP levels should be monitored.[1]

AML with adverse-risk cytogenetics

The efficacy of MYLOTARG has been shown in patients with AML who have favourable- and intermediate-risk cytogenetics, and there is uncertainty regarding the size of the effect in patients with adverse cytogenetics.[1] For patients being treated with MYLOTARG in combination with DNR and AraC for newly diagnosed, *de novo* AML, on availability of cytogenetics test results, consideration should be given to whether the potential benefit of continuing treatment with MYLOTARG outweighs the risks for the individual patient.[1]

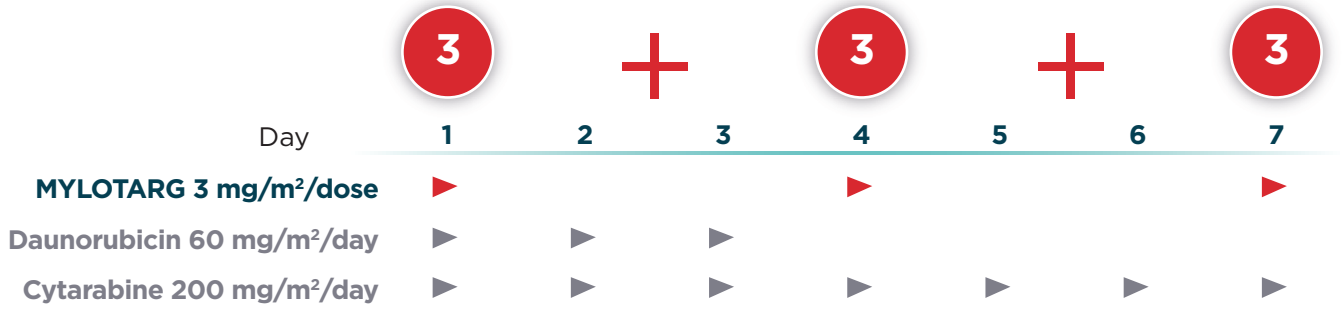
1. Pfizer. MYLOTARG summary of product characteristics. 2021

Treatment schedule[1]

Induction

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 on Days 1, 4 and 7, in combination with DNR 60 mg/m²/day infused over 30 minutes on Days 1–3, and AraC 200 mg/m²/day by continuous infusion on Days 1–7.

MYLOTARG fractionated dosing (3, 3, 3 schedule)



If a second induction course is required, MYLOTARG should not be administered during this second induction therapy. Only DNR and AraC should be administered during the second induction cycle, at the following recommended dosing: DNR 35 mg/m²/day on Days 1 and 2, and AraC 1 g/m² every 12 hours, on Day 1 to Day 3.

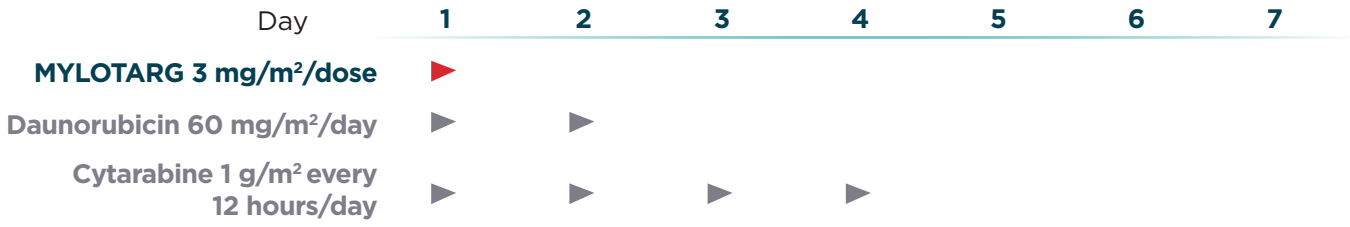
1. Pfizer. MYLOTARG summary of product characteristics. 2021

Consolidation

All patients experiencing[1] a CR after induction* can receive up to two consolidation courses with the recommended dose of IV MYLOTARG of 3 mg/m^2/dose (**up to a maximum dose of one 5 mg vial**) infused over a 2-hour period on Day 1 in combination with IV DNR (60 mg/m^2 for 1 day [first course] or 2 days [second course]) and IV AraC (1 g/m^2 every 12 hours, infused over 2 hours on Days 1–4).

Consolidation Course 1

Consolidation Course 2



Dose modification of MYLOTARG is recommended based on individual safety and tolerability. Management of some adverse reactions may require dose interruptions or permanent discontinuation of MYLOTARG.

*Defined as <5% blasts in a normocellular marrow and an ANC of >1.0 × 10^9 cells/l with a platelet count of ≥100 × 10^9/l in the peripheral blood in the absence of transfusion

1. Pfizer. MYLOTARG summary of product characteristics. 2021

MYLOTARG adverse event management

Hepatotoxicity including veno-occlusive disease

Hepatotoxicity, including life-threatening, and sometimes fatal, hepatic failure and VOD/SOS, has been reported in patients treated with MYLOTARG.

Incidence of abnormal liver function tests in patients receiving MYLOTARG (n=131)[1]

	All Grades, %	Grade 3/4, %
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

ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase

Incidence of VOD in patients receiving MYLOTARG[1]

	MYLOTARG arm (n=131)	Chemotherapy arm (n=137)
Total number of patients with VOD (all Grades), n (%)	6 (4.6)	2 (1.5)

VOD, veno-occlusive disease

In patients in the MYLOTARG arm

- Two VOD events were fatal
- Five VOD events occurred within 28 days of any dose of MYLOTARG
- One VOD event occurred >28 days after the final dose of MYLOTARG, with one of these events occurring a few days after having started an HSCT conditioning regimen
- The median time from the last MYLOTARG dose to onset of VOD was 9 days

In patients in the chemotherapy arm

- VOD was reported in two patients initially randomised into the chemotherapy arm who received MYLOTARG as a follow-up therapy after AML relapsed after study treatment
  - Both of these patients experienced VOD more than 28 days after the last dose of MYLOTARG
  - One of these patients experienced VOD 25 days after the subsequent HSCT

1. Pfizer. MYLOTARG summary of product characteristics. 2021

Monitoring and management[1]

- Due to the risk of VOD/SOS, signs and symptoms of VOD/SOS should be closely monitored, including hepatomegaly (which may be painful), rapid weight gain and ascites, as well as elevations in ALT, AST, total bilirubin and ALP
- Monitoring only total bilirubin may not identify all patients at risk of VOD/SOS
- In all patients, liver tests, including ALT, AST, total bilirubin and ALP, should be monitored prior to each dose of MYLOTARG
- For patients who develop abnormal liver tests, more frequent monitoring of liver tests and clinical signs and symptoms of hepatotoxicity is recommended
- For patients who proceed to HSCT, close monitoring of liver tests is recommended during the post-HSCT period, as appropriate
- No definitive relationship was found between VOD and time of HSCT relative to higher MYLOTARG monotherapy doses; however, the ALFA-0701 study recommended an interval of 2 months between the last dose of MYLOTARG and HSCT

Dose modifications[1]

No adjustment of the starting dose is required in patients with hepatic impairment, defined by total bilirubin ≤2 × ULN and AST/ALT ≤2.5 × ULN.

Toxicity	Dose modifications
VOD/SOS	➤ Discontinue MYLOTARG and treat patient according to standard medical practice
Total bilirubin >2 × ULN and AST and/or ALT >2.5 × ULN	➤ Postpone MYLOTARG until recovery of total bilirubin to ≤2 × ULN and AST and ALT to ≤2.5 × ULN prior to each dose ➤ Consider omitting scheduled dose if delayed more than 2 days between sequential infusions

ALT, alanine aminotransferase; AST, aspartate aminotransferase; ULN, upper limit of normal; VOD/SOS, veno-occlusive disease/sinusoidal obstruction syndrome

1. Pfizer. MYLOTARG summary of product characteristics. 2021

Myelosuppression and related complications

In clinical studies, neutropenia, thrombocytopenia, anaemia, leukopenia, febrile neutropenia, lymphopenia and pancytopenia, some of which were life-threatening or fatal, were reported.

Complications associated with neutropenia and thrombocytopenia, including infections and bleeding/haemorrhagic events, were reported in some patients:

- The most frequent Grade 3 bleeding/haemorrhagic events were haematemesis (3.1%), haemoptysis (3.1%) and haematuria (2.3%)
- Treatment-related death due to septic shock was reported in one (0.8%) patient
- Fatal severe infection was reported in two (1.5%) patients

Incidence of myelosuppression in patients receiving MYLOTARG (n=131)[1,*]

	All Grades, %	Grade 3/4, %
Thrombocytopenia	100	100
Leukopenia	100	100
Anaemia	100	86.2
Lymphopenia	98.5	90.7
Neutropenia	97.7	96.1

*Frequency is based on laboratory values (Grade per NCI CTCAE v4.03)

Incidence of persistent thrombocytopenia in patients receiving MYLOTARG[1]

Thrombocytopenia with platelet counts <50,000/mm^3 persisting 45 days after the start of therapy for responding patients (CR and CRp).

	MYLOTARG arm
With persistent thrombocytopenia, n (%)*	22 (20.4)

*The number of patients with persistent thrombocytopenia after any phase

1. Pfizer. MYLOTARG summary of product characteristics. 2021

Incidence of myelosuppression-related complications in patients receiving MYLOTARG (n=131)[1]

	MYLOTARG arm	
	All Grades*, %	**Grade 3/4, %**
Severe infection†	77.9	76.3
Haemorrhage*	90.1	20.6

*Including fatal outcome; †Grade ≥3

Monitoring and management[1]

- Complete blood counts should be monitored prior to each dose of MYLOTARG, and signs and symptoms of infection or bleeding/haemorrhage or other effects of myelosuppression should be monitored during treatment
- Routine clinical and laboratory surveillance testing during and after treatment is indicated

Dose modifications[1]

Management of myelosuppression may require a dose delay or permanent discontinuation of MYLOTARG.

Toxicity	Dose modification
Persistent thrombocytopenia (defined as platelets <100,000/mm^3 at the **planned start date of the consolidation course**)	➤ Postpone start of consolidation course
	➤ If platelet count recovers to ≥100,000/mm^3 within 14 days following the planned start date of the consolidation course: initiate consolidation therapy
	➤ If platelet count recovers to <100,000/mm^3 and ≥50,000/mm^3 within 14 days following the planned start date of the consolidation course: MYLOTARG should not be reintroduced and consolidation therapy should consist of DNR and AraC only
	➤ If platelet count recovery remains <50,000/mm^3 for greater than 14 days, takes longer than 14 days or if platelet count does not recover to ≥50,000/mm^3, consolidation therapy should be re-evaluated and a BMA should be performed to re-assess patients' status
Persistent neutropenia	➤ If neutrophil count does not recover to greater than 500/mm^3 within 14 days following the planned start date of the consolidation cycle (14 days after haematologic recovery following previous cycle), discontinue MYLOTARG (do not administer MYLOTARG in the consolidation cycles)

AraC, cytarabine; BMA, bone marrow aspirate; DNR, daunorubicin

1. Pfizer. MYLOTARG summary of product characteristics. 2021

Infusion-related reactions

Infusion-related reactions, including anaphylaxis, were reported in clinical studies of MYLOTARG. Fatal infusion-related reactions have been reported in the post-marketing setting with MYLOTARG.

Incidence of infusion-related reactions in patients receiving MYLOTARG[1]

	All Grades, %	Grade 3/4, %
Infusion-related reactions*,†	7.6	3.6

*Reported during MYLOTARG monotherapy and post-marketing ; †Infusion-related reaction includes the following reported preferred terms: infusion-related reaction, urticaria, hypersensitivity, bronchospasm, drug hypersensitivity, and injection site urticaria (singular cases)

Monitoring and management[1]

- Infusion of MYLOTARG should be performed under close clinical monitoring, including pulse, blood pressure and temperature
- MYLOTARG is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients (dextran 40, sucrose, sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate)
- Premedication with a corticosteroid, antihistamine and acetaminophen (or paracetamol) is recommended 1 hour prior to MYLOTARG dosing
- Patients should be monitored closely for signs and symptoms of infusion-related reactions, e.g. fever and chills, and (less frequently) hypotension, tachycardia and respiratory symptoms, that may occur during the first 24 hours after administration
- Patients should be monitored until signs and symptoms completely resolve

Dose modifications[1]

Toxicity	Dose modifications
Infusion-related reactions	Interrupt the infusion and institute appropriate medical management based on the severity of symptoms. Patients should be monitored until signs and symptoms completely resolve and infusion may resume Consider permanent discontinuation of treatment for severe or life-threatening infusion reactions

1. Pfizer. MYLOTARG summary of product characteristics. 2021

Tumour lysis syndrome

TLS, which may be life-threatening or fatal, was reported with MYLOTARG. Fatal reports of TLS complicated by acute renal failure have been reported in the post-marketing setting.

Incidence of TLS in patients receiving MYLOTARG[1]

	MYLOTARG arm All Grades, %
TLS	1.5

TLS, tumour lysis syndrome

Monitoring and management[1]

- Patients should be monitored for signs and symptoms of TLS, and treated according to standard medical practice
- Appropriate measures to help prevent the development of tumour lysis-related hyperuricaemia, such as hydration and administration of antihyperuricaemics (e.g. allopurinol) or other agents for the treatment of hyperuricaemia (e.g. rasburicase) must be taken
- In patients with hyperleukocytic AML (leukocyte count ≥30,000/mm^3), cytoreduction is recommended either with leukapheresis, oral hydroxyurea or AraC with or without hydroxyurea to reduce the peripheral WBC count 48 hours prior to administration of MYLOTARG
- If AraC is used for leukoreduction with or without hydroxyurea, the induction dosing schedule should be modified as follows:

Schedule modification for the treatment of hyperleukocytosis with AraC

Treatment course	MYLOTARG	DNR	AraC	Hydroxyurea
Induction	3 mg/m^2/dose (up to a maximum of one 5 mg vial) on **Days 3, 6 and 9**	60 mg/m^2/day on Day 3 to Day 5	200 mg/m^2/day on Day 1 to Day 7	Day 1 (as per standard medical practice)

AraC, cytarabine; DNR, daunorubicin

1. Pfizer. MYLOTARG summary of product characteristics. 2021

Other severe or life-threatening non-haematological toxicities

For all the other severe or life threatening non-haematological toxicities not described previously, MYLOTARG should be modified as follows:[1]

Other severe or life-threatening non-haematological toxicities	➤ Delay treatment with MYLOTARG until recovery to a severity of no more than 'mild' ➤ Consider omitting scheduled dose if delayed more than 2 days between sequential infusions

References

1. Pfizer Limited. MYLOTARG summary of product characteristics. 2021
2. Ricart AD. Antibody-drug conjugates of calicheamicin derivative: Gemtuzumab ozogamicin and inotuzumab ozogamicin. *Clin Cancer Res* 2011;17:6417–6427
3. Ehninger A, Kramer M, Röllig C *et al.* Distribution and levels of cell surface expression of CD33 and CD123 in acute myeloid leukemia. *Blood Cancer J* 2014;4:e218
4. Garnache-Ottou F, Chaperot L, Biichle S *et al.* Expression of the myeloid-associated marker CD33 is not an exclusive factor for leukemic plasmacytoid dendritic cells. *Blood* 2005;105:1256–1264
5. Lambert J, Pautas C, Terré C *et al*. Gemtuzumab ozogamicin for de novo acute myeloid leukemia: final efficacy and safety updates from the open-label, phase 3 ALFA-0701 trial. *Haematologica* 2019;104:113-119

Fachkurzinformation

▼Dieses Arzneimittel unterliegt einer zusätzlichen Überwachung. Dies ermöglicht eine schnelle Identifizierung neuer Erkenntnisse über die Sicherheit. Angehörige von Gesundheitsberufen sind aufgefordert, jeden Verdachtsfall einer Nebenwirkung zu melden. Hinweise zur Meldung von Nebenwirkungen, siehe Abschnitt 4.8 der Fachinformation.

MYLOTARG 5 mg Pulver für ein Konzentrat zur Herstellung einer Infusionslösung

Qualitative und quantitative Zusammensetzung: Jede Durchstechflasche mit Pulver für ein Konzentrat zur Herstellung einer Infusionslösung enthält 5 mg Gemtuzumab Ozogamicin. Nach der Rekonstitution enthält die konzentrierte Lösung 1 mg/ml Gemtuzumab Ozogamicin. **Liste der sonstigen Bestandteile:** Dextran 40, Sucrose, Natriumchlorid, Natriumdihydrogenphosphat-Monohydrat, wasserfreies Dinatriumhydrogenphosphat. **Anwendungsgebiete:** MYLOTARG wird angewendet für die Kombinationstherapie mit Daunorubicin (DNR) und Cytarabin (AraC) zur Behandlung von Patienten ab 15 Jahren mit nicht vorbehandelter *de novo* CD33-positiver akuter myeloischer Leukämie (AML), ausgenommen akuter Promyelozytenleukämie (APL). **Gegenanzeigen:** Überempfindlichkeit gegen den Wirkstoff oder einen einen der in Abschnitt 6.1 der Fachinformation genannten sonstigen Bestandteile. **Pharmakotherapeutische Gruppe:** Antineoplastische Mittel, monoklonale Antikörper, ATC Code: L01XC05. **Inhaber der Zulassung:** Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Brüssel, Belgien. **Stand der Information:** März 2022. **Rezeptpflicht/Apothekenpflicht:** Rezept- und apothekenpflichtig, wiederholte Abgabe verboten. **Angaben zu besonderen Warnhinweisen und Vorsichtsmaßnahmen für die Anwendung, Wechselwirkungen mit anderen Arzneimitteln und sonstigen Wechselwirkungen, Fertilität, Schwangerschaft und Stillzeit und Nebenwirkungen entnehmen Sie bitte der veröffentlichten Fachinformation.**

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