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).

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MYLOTARG SmPC

Pfizer

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Acknowledgements and abbreviations

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ADC	Antibody–drug conjugate
AE	Adverse event
ALP	Alkaline phosphatase
ALT	Alanine transaminase
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
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

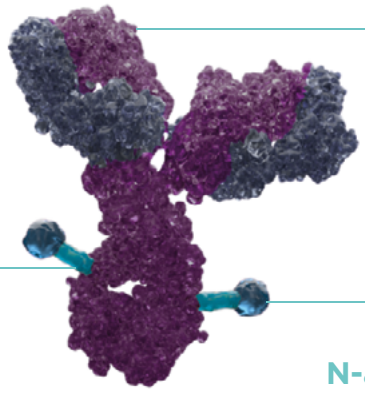
Introduction

MYLOTARG is an ADC that combines the specificity of an anti-CD33 monoclonal antibody with the anti-tumour activity of calicheamicin.[1,2]

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[3]
CD33 is a specific biomarker of myeloid precursor cells[4,5] and is expressed in up to 90% of AML cases[4]

Selectively stable linker[3]

Cytotoxic drug payload: N-acetyl gamma calicheamicin[3]

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

Indication for MYLOTARG

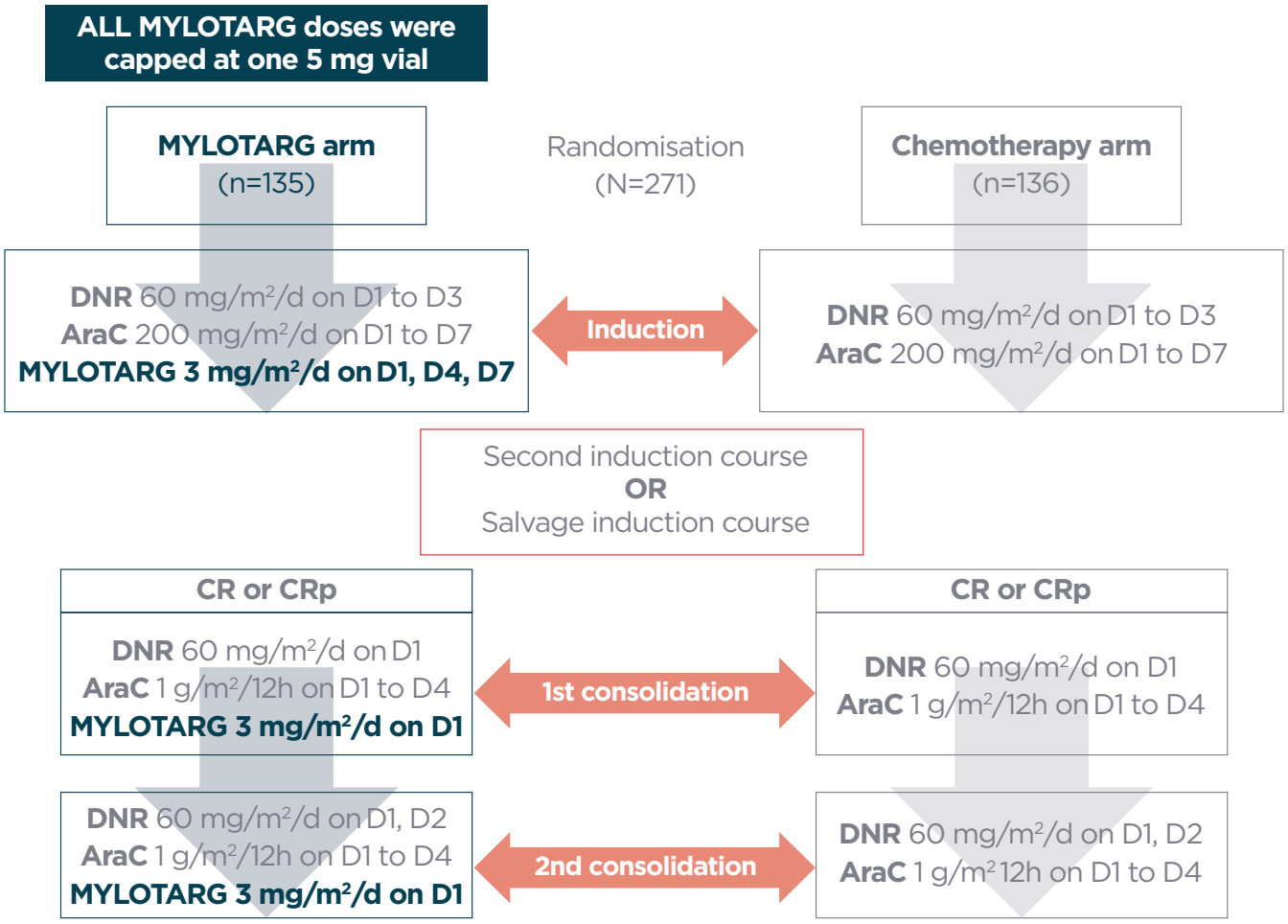
MYLOTARG is indicated for combination therapy with DNR and AraC for the treatment of patients age 15 years and above with previously untreated, *de novo* CD33-positive AML, except APL.[2]

1. Lambert J *et al. Haematologica* 2019;104:113–119
2. Pfizer. MYLOTARG summary of product characteristics. 2020
3. Ricart AD. *Clin Cancer* 2011;17:6417–6427
4. Ehninger A *et al. Blood Cancer J* 2014;4:e218
5. Garnache-Ottou F *et al. Blood* 2005;105:1256–1264

ALFA-0701 study

Study design[1]

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.



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

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. Lambert J *et al. Haematologica* 2019;104:113–119

Key patient characteristics[1]

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

	MYLOTARG arm (n=135)	Chemotherapy arm (n=136)
Age, y		
Median (range)	62 (50–70)	61 (50–70)
Male sex, n (%)	74 (54.8)	60 (44.1)
ECOG performance status, n (%)		
0–1	121 (89.6)	117 (86.0)
≥2	14 (10.4)	18 (13.2)
CD33 expression (positivity)		
N	100	94
<30%, n (%)	17 (12.6)	20 (14.7)
≥30%, n (%)	83 (61.5)	74 (54.4)
<70%, n (%)	37 (27.4)	31 (22.8)
≥70%, n (%)	63 (46.7)	63 (46.3)
Cytogenetics, n (%)*		
Favourable	3 (2.2)	6 (4.4)
Intermediate	91 (67.4)	89 (65.4)
Unfavourable	27 (20.0)	30 (22.1)

*As classified by Centre Hospitalier de Versailles
ECOG, Eastern Cooperative Oncology Group

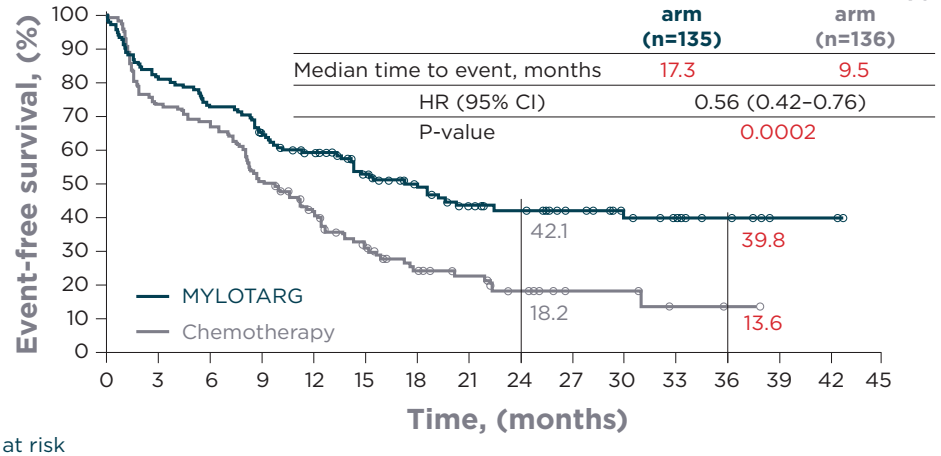
1. Lambert J *et al. Haematologica* 2019;104:113–119

Clinical outcomes of MYLOTARG

Event-free survival rate*

EFS was significantly longer when MYLOTARG was added to standard chemotherapy (median EFS was 17.3 months vs 9.5 months [HR 0.56; P=0.0002]).[1]

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



	MYLOTARG arm (n=135)	Chemotherapy arm (n=136)
Median time to event, months	17.3	9.5
HR (95% CI)	0.56 (0.42–0.76)	
P-value	0.0002	

No. at risk

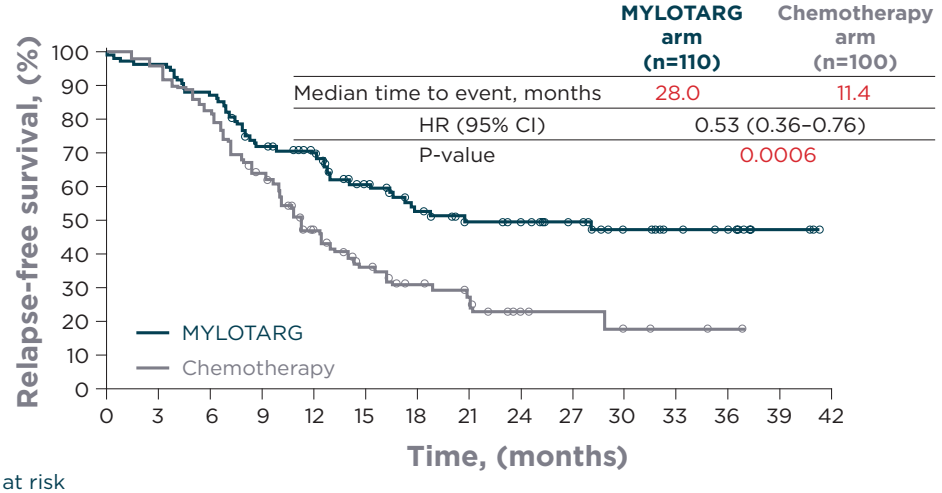
MYLOTARG	135	109	98	86	74	57	47	36	32	25	18	15	10	3	3	0
Chemotherapy	136	100	93	69	51	32	21	16	10	5	5	2	1	0		

*Defined as the time from randomisation to relapse, death from any cause, or failure to achieve CR or CRp[1]
CI, confidence interval; CR, complete remission; CRp, complete remission with incomplete platelet recovery; HR, hazard ratio

Relapse-free survival rate

RFS was significantly longer with MYLOTARG plus induction standard chemotherapy than with standard chemotherapy alone (median RFS was 28.0 months vs 11.4 months [HR 0.53; P=0.0006]).[1]

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



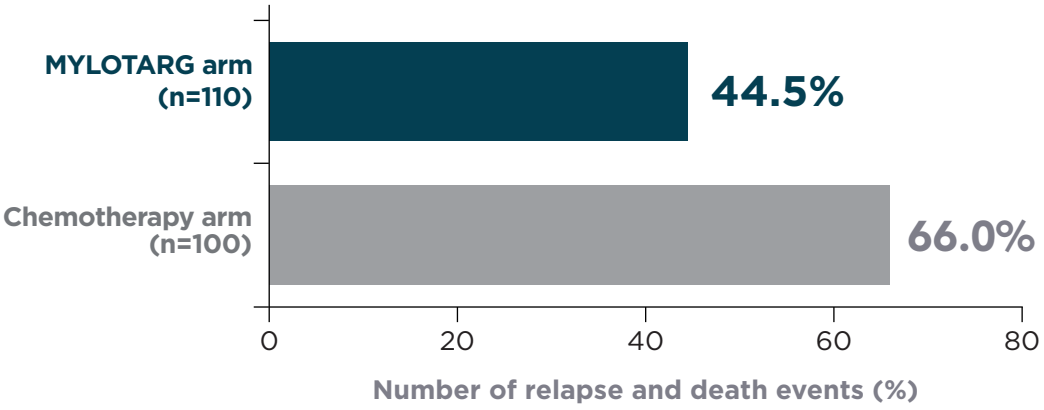
	MYLOTARG arm (n=110)	Chemotherapy arm (n=100)
Median time to event, months	28.0	11.4
HR (95% CI)	0.53 (0.36–0.76)	
P-value	0.0006	

No. at risk

MYLOTARG	110	108	97	77	67	50	40	32	29	23	16	11	8	3	0
Chemotherapy	100	96	83	62	38	25	18	13	6	5	3	2	1	0	

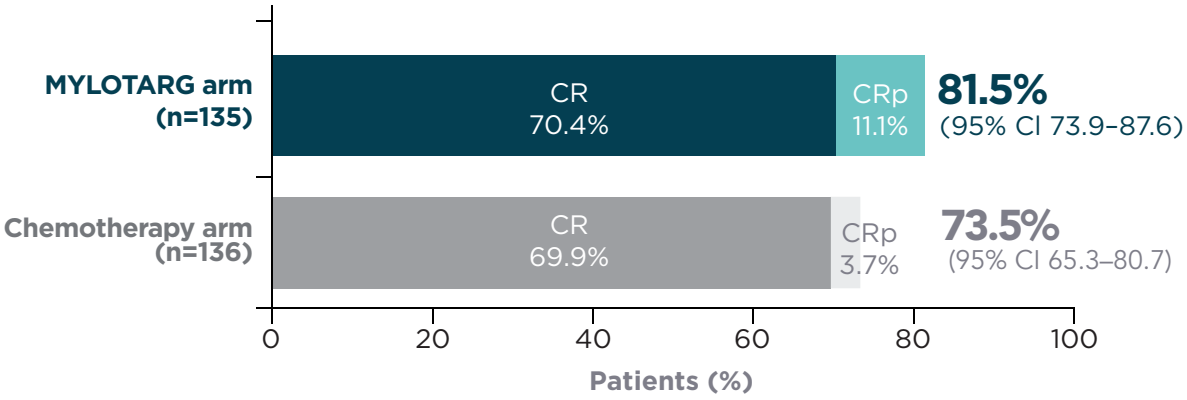
Figures adapted from Lambert J *et al. Haematologica* 2019;104:113–119
CI, confidence interval; HR, hazard ratio; RFS, relapse-free survival
1. Lambert J et al. *Haematologica* 2019;104:113–119

The addition of MYLOTARG to standard chemotherapy reduced the number of relapse and death events in responders by more than 20%.[2]



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=0.15).[1]



Risk difference: 7.95; (95% CI -3.79, 19.85); P=0.15[2]

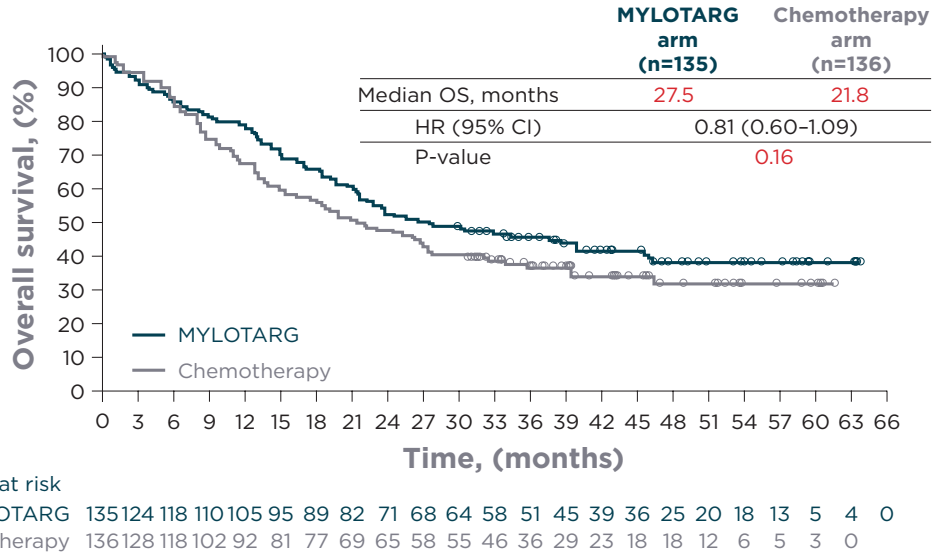
CI, confidence interval; CR, complete remission; CRp, complete remission with incomplete platelet recovery

1. Lambert J *et al. Haematologica* 2019;104:113–119
2. Pfizer. MYLOTARG summary of product characteristics. 2020

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 0.81; 95% CI 0.60–1.09; two-sided P=0.16]).[1,2]

- There was a 19% reduction in the risk of death with MYLOTARG plus induction standard chemotherapy versus standard chemotherapy alone[1,2]



CI, confidence interval; HR, hazard ratio; OS, overall survival
Figure adapted from Lambert J *et al. Haematologica* 2019;104:113–119

Safety of MYLOTARG

MYLOTARG added to standard chemotherapy offers an acceptable safety profile with an overall favourable benefit–risk.[1]

All-causality AEs of special interest in the as-treated population[1]

	MYLOTARG arm (n=131), n (%)	Chemotherapy arm (n=137), n (%)
Infections: Severe (Grade ≥3)	102 (77.9)	106 (77.4)
Haemorrhage: All Grade (Grade ≥1)	118 (90.1)	107 (78.1)
Grade 3	23 (17.6)	12 (8.8)
Grade 4	4 (3.1)	0
Grade 5	3 (2.3)	1 (0.7)
VOD: All Grade (Grade ≥1)	6 (4.6)	2 (1.5)
Grade 3	2 (1.5)	1 (0.7)
Grade 4	1 (0.8)	1 (0.7)
Grade 5	2 (1.5)	0

1. Lambert J *et al. Haematologica* 2019;104:113–119
2. Pfizer. MYLOTARG summary of product characteristics. 2020

All-causality treatment-emergent SAEs occurring in ≥2% of patients in the as-treated population[1]

Preferred terms (≤2%)	MYLOTARG arm (n=131), n (%)	Chemotherapy arm (n=137), n (%)
Any SAE	88 (67.2)	76 (55.5)
Thrombocytopenia	34 (26.0)	6 (4.4)
Bronchopulmonary aspergillosis	14 (10.7)	10 (7.3)
Septic shock	12 (9.2)	9 (6.6)
Febrile bone marrow aplasia	12 (9.2)	8 (5.8)
Bacterial sepsis	7 (5.3)	0
Acute kidney injury	6 (4.6)	4 (2.9)
Pneumonia	5 (3.8)	6 (4.4)
Sepsis	5 (3.8)	4 (2.9)
Acute respiratory distress syndrome	5 (3.8)	3 (2.2)
Escherichia sepsis	5 (3.8)	1 (0.7)
Veno-occlusive liver disease	5 (3.8)	0
AML	5 (3.8)	0
Hepatocellular injury	4 (3.1)	2 (1.5)
Cholestatic liver injury	3 (2.3)	2 (1.5)
Febrile neutropenia	3 (2.3)	1 (0.7)
Mucosal inflammation	3 (2.3)	1 (0.7)
Disease progression	3 (2.3)	0
Enterococcal sepsis	3 (2.3)	0
Staphylococcal sepsis	2 (1.5)	5 (3.6)
Toxic skin eruption	1 (0.8)	3 (2.2)

For information on management of specific AEs with MYLOTARG, please refer to page 12.

1. Lambert J *et al. Haematologica* 2019;104:113–119

Dosing and administration

Reduce to <30,000/mm³

In patients with high WBC 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.[2] **For information on management of hyperleukocytosis, please refer to page 17.**

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.[2] **For information on the management of infusion-related reactions, please refer to page 16.**

In addition, complete blood counts and ALT, AST, total bilirubin and ALP levels should be monitored.[2]

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.[1,2] 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.[2]

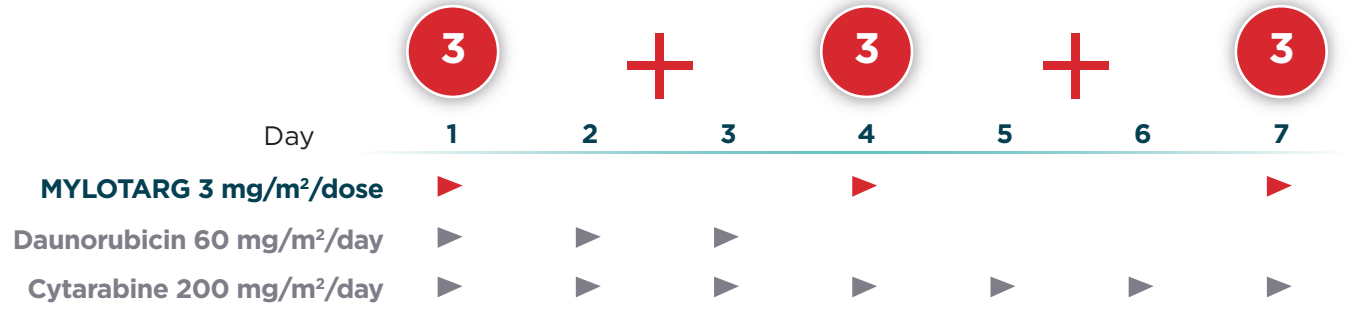
Treatment schedule[2]

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.

1. Lambert J *et al. Haematologica* 2019;104:113–119
2. Pfizer. MYLOTARG summary of product characteristics. 2020

MYLOTARG fractionated dosing (3, 3, 3 schedule)[2]



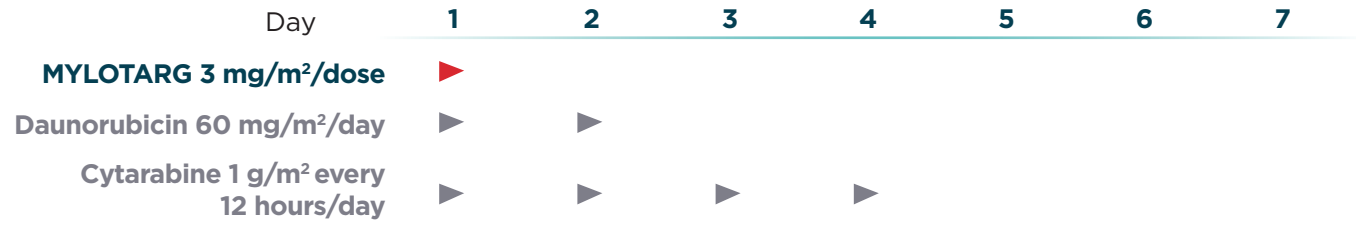
If a second induction course is required, MYLOTARG should not be administered during this second induction therapy.

Consolidation

All patients experiencing a CR after induction* can receive up to two consolidation courses with the recommended dose of MYLOTARG of 3 mg/m²/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/m² for 1 day [first course] or 2 days [second course]) and IV AraC (1 g/m² 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

2. Pfizer. MYLOTARG summary of product characteristics. 2020

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[1]

	N	All Grades, %	Grade 3/4, %
AST increased	129	89.2	14.0
ALP increased	128	79.7	13.3
ALT increased	129	78.3	10.9
Blood bilirubin increased	126	51.6	7.1

ALP, alkaline phosphatase; ALT, alanine transaminase; 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)
Grade 3, n (%)	2 (1.5)	1 (0.7)
Grade 4, n (%)	1 (0.8)	1 (0.7)
Grade 5, n (%)	2 (1.5)	0

VOD, veno-occlusive disease

In patients in the MYLOTARG arm[2]

- 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
- The median time from the last MYLOTARG dose to onset of VOD was 9 days

1. Lambert J *et al. Haematologica* 2019;104:113–119
2. Pfizer. MYLOTARG summary of product characteristics. 2020

In patients in the chemotherapy arm[2]

- 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

Monitoring and management[2]

- 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[2]

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

2. Pfizer. MYLOTARG summary of product characteristics. 2020

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.[2]

Complications associated with neutropenia and thrombocytopenia, including infections and bleeding/haemorrhagic events, were reported in some patients:[2]

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

Incidence of myelosuppression in patients receiving MYLOTARG[1]

	N	All Grades, %	Grade 3/4, %
Thrombocytopenia	131	100	100
Leukopenia	131	100	100
Anaemia	130	100	86.2
Lymphopenia	129	98.5	90.7
Neutropenia	129	97.7	96.1

Incidence of severe persistent thrombocytopenia in patients receiving MYLOTARG[1,2]

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. Lambert J *et al. Haematologica* 2019;104:113–119
2. Pfizer. MYLOTARG summary of product characteristics. 2020

Incidence of myelosuppression-related complications in patients receiving MYLOTARG (n=131)[1,2]

	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[2]

- 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[2]

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, 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. Lambert J *et al. Haematologica* 2019;104:113–119
2. Pfizer. MYLOTARG summary of product characteristics. 2020

Infusion-related reactions[2]

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

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

*Reported during MYLOTARG monotherapy and post-marketing

Monitoring and management

- 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

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

2. Pfizer. MYLOTARG summary of product characteristics. 2020

Tumour lysis syndrome[2]

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

	MYLOTARG arm All Grades, %
TLS	1.5

TLS, tumour lysis syndrome

Monitoring and management

- 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

2. Pfizer. MYLOTARG summary of product characteristics. 2020

Other severe or life-threatening non-haematological toxicities[2]

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

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

2. Pfizer. MYLOTARG summary of product characteristics. 2020

References

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