
Mylotarg for Acute Myeloid Leukaemia (AML)

**A Guide for
Patients**

Leukaemia Care
YOUR Blood Cancer Charity

Introduction

Mylotarg (trade name for Gemtuzumab Ozogamicin) is an antibody drug that has mainly been used in clinical trials in combination with standard licensed chemotherapy, in the treatment of Acute Myeloid Leukaemia (AML).

Booklet compiled by one of our medical writers Saloua Najjam, PhD. and peer reviewed by one of our medical professionals who is specialised in leukaemia therapy, Dr Steven Knapper, University Hospital of Wales, Cardiff. We are also grateful to a leukaemia patient, Julie Quigley, for her valuable contribution.

If you would like any information on the sources used for this booklet, please email communications@leukaemicare.org.uk for a list of references.

In this booklet

Introduction	2
In this booklet	3
About Leukaemia Care	4
What is Mylotarg?	6
Who receives Mylotarg?	8
How is Mylotarg administered?	9
What are the side effects of Mylotarg?	10
What happens if Mylotarg doesn't work for me?	12
Glossary	14
Useful contacts and further support	15

About Leukaemia Care

Leukaemia Care is a national charity dedicated to ensuring that people affected by blood cancer have access to the right information, advice and support.

Our services

Helpline

Our helpline is available 9.00am - 10.00pm on weekdays and 9.00am - 12.30pm on Saturdays. If you need someone to talk to, call **08088 010 444**

Nurse service

We have two trained nurses on hand to answer your questions and offer advice and support, whether it be through emailing nurse@leukaemiacare.org.uk, over the phone on **08088 010 444** or via LiveChat.

Patient Information Booklets

We have a number of patient information booklets like this available to anyone who has been affected by a blood cancer. A full list of titles - both disease specific and general information titles - can be found on our

website at www.leukaemiacare.org.uk/resources/filter-by-resource-type/information-booklets

Support Groups

Our nationwide support groups are a chance to meet and talk to other people who are going through a similar experience. For more information about a support group local to your area, go to www.leukaemiacare.org.uk/our-support-groups

Buddy Support

We offer one-to-one phone support with volunteers who have had blood cancer themselves or been affected by it in some way. You can speak to someone who knows what you are going through. For more information on how to get a buddy call **08088 010 444** or email care@leukaemiacare.org.uk

Online Forum

Our online forum, www.healthunlocked.com/leukaemia-care, is a place for people to ask questions anonymously or to join in the discussion with other people in a similar situation.

Patient and carer conferences

Our nationwide conferences provide an opportunity to ask questions and listen to patient speakers and medical professionals who can provide valuable information and support.

Website

You can access up-to-date information on our website, www.leukaemiacare.org.uk, as well as speak to one of our care advisers on our online support service, LiveChat (9am-5pm weekdays).

Campaigning and Advocacy

Leukaemia Care is involved in campaigning for patient well-being, NHS funding and drug and treatment availability. If you would like an update on any of the work we are currently doing or want to know how to get involved, email advocacy@leukaemiacare.org.uk

Patient magazine

Our free quarterly magazine includes inspirational patient and carer stories as well as informative articles by medical professionals. To subscribe go to www.leukaemiacare.org.uk/resources/subscribe-to-journey-magazine

What is Mylotarg?

Mylotarg is the trade name for Gemtuzumab Ozogamicin that has been introduced as a treatment for Acute Myeloid Leukaemia (AML).

Mylotarg is used in combination with standard induction chemotherapy in the treatment of acute myeloid leukaemia. To date, it has mainly been used in the UK within national clinical trials (such as AML15, AML16, AML18 and AML19), but it has recently been approved for use outside clinical trials in the US and is currently going through regulatory approval processes in Europe (including UK).

Gemtuzumab Ozogamicin is an antibody-drug combination designed to target leukaemia cells.

Gemtuzumab, the monoclonal antibody is attached to the chemotherapy drug, Ozogamicin, to make this combination, also known as a conjugate. Once the drug is administered, the antibody part binds specifically to a protein, called the CD33 protein,

which is found on the surface of leukaemia cells. Compared to other cells, leukaemia cells express more CD33 proteins on their surface.

Then, Ozogamicin is introduced into the cancer cell where it starts its cytotoxic activity (damaging and killing cells).



Who receives Mylotarg?

Mylotarg has been used to treat patients who are newly-diagnosed with acute myeloid leukaemia. Most of the experience with Mylotarg comes from clinical trials that took place in the UK, France and the US.

Mylotarg is now available on the NHS for previously untreated CD33+ AML patients (except APL) with favourable, intermediate or unknown cytogenetics.

If you want to find out if this is a suitable treatment for your disease type, speak to your consultant and they will be able to provide you with more information.

If you wish to have further information on AML, please view our collection of patient information booklets that are available on our website at www.leukaemiacare.org.uk

How is Mylotarg administered?

The administration of Mylotarg is usually done in combination with standardised chemotherapy drugs and could be done in one of the following ways:

- Into a vein in your arm or hand.
- Into a vein that goes under the skin of your chest, known as the central line.
- Into a vein in your arm that goes up into a vein in your chest (PICC line).

It is mostly given as a single dose, usually on the first day of the first cycle of induction chemotherapy. Clinical trials are currently assessing whether adding a second dose (usually on day four of treatment) may further add to the clinical improvements seen with one dose. Previous studies in the UK and France have demonstrated that patients with 'good risk' and 'intermediate risk' AML gain benefit from Mylotarg through reduction of relapse risk

and improved overall survival.

What are the side effects of Mylotarg?

Everyone will experience different side effects from induction chemotherapy. It is important to report them, so your nurse is able to monitor them and where possible, have them treated. This treatment can have serious or possibly life-threatening side effects; therefore, it is very important that you report side effects straight away.

The general side effects of induction chemotherapy (including Mylotarg) could be, but not limited to:

- **Tumour lysis syndrome** - characterised by metabolic abnormalities such as high level of uric acid in the blood (not eliminated in time by the kidney). This could happen during the initiation of therapy due to the cytotoxic effect of the drug. The risk of this is higher for patients with a high white cell count at diagnosis - in these cases it is usual to delay the Mylotarg until day 4-5 of treatment, by which time the white cell count has fallen to

safer levels.

- **Infection** - This is due to a low number of white blood cells. Symptoms include fever, shivering, discomfort when you pass urine, sweats, sore throat, diarrhoea, cough or breathlessness.
- **Tiredness or breathlessness** - Because of low number of red blood cells (anaemia).
- **Nausea or vomiting** - You may feel sick because of the cytotoxicity activity of the drug.
- **Digestive problems** - Such as being constipated or having diarrhoea.
- **Muscle and joint pain.**

Side effects more specific to Mylotarg:

- **Allergic reactions** - Mylotarg is an antibody-based treatment and can cause allergic reactions in a small proportion of patients. This will generally occur during the infusion itself. Prior to receiving a first dose of Mylotarg, pre-medications

(steroid and anti-histamine) to reduce the risk and severity of allergic reactions will be generally be given.

- **Liver poisoning** - Abnormal levels of liver function tests may be seen with toxicity of Mylotarg. There is also a low risk of a liver veno-occlusive disease (VOD). Liver function tests will be monitored closely during (and after) Mylotarg therapy and the introduction of other potentially liver-toxic treatment like anti-fungal medications will generally be delayed for a few days after receiving Mylotarg.

What happens if Mylotarg doesn't work for me?

At the moment, in the UK, your consultant will be the best person to give you advice. They will be able to discuss possible alternatives to consider if Mylotarg does not work in the clinical trial you decided to participate in.

Leukaemia Care offers nationwide support groups for people affected by a diagnosis of a blood or lymphatic cancer. Visit www.leukaemiacare.org.uk, or call **08088 010 444**, to find out more and to find a group near you.



Glossary

Chemotherapy

A type of cancer treatment that uses one or more drugs with powerful chemical to kill growing cancer cells.

Clinical trial

A highly regulated research study, which assigns patients and non-patients to participate in the study and to evaluate the efficacy of a drug or a combination of drugs.

Cytotoxic

Any chemical or molecule that has a toxic effect on cells.

Efficacy of a drug

The effectiveness or performance of the drug when tested in clinical trials.

Immune system

All that is involved (organs and processes) in protecting our body from infections and foreign invaders.

Leukaemia

A cancer of the blood with many different subtypes. Some forms are acute (develop quickly) and others are chronic (develop slowly). Leukaemia is an excess number of abnormal cells in the blood, usually white blood cells,

which stop the bone marrow working properly.

Monoclonal antibody

An antibody produced by a single clone of cells consisting of identical antibody molecules.

Tumour lysis syndrome

This is characterised by metabolic abnormalities such as high level of uric acid in the blood (not eliminated on time by kidney).

Useful contacts and further support

There are a number of helpful sources to support you during your diagnosis, treatment and beyond, including:

- Your haematologist and healthcare team
- Your family and friends
- Your psychologist (ask your haematologist or CNS for a referral)
- Reliable online sources, such as Leukaemia Care
- Charitable organisations

There are a number of organisations, including ourselves, who provide expert advice and information.

Leukaemia Care

We are a charity dedicated to supporting anyone affected by the diagnosis of any blood cancer. We provide emotional support through a range of support services including a helpline, patient and carer conferences, support group, informative website, one-to-one buddy service and high-quality patient information. We also have a nurse on our help line for any medical queries relating to your diagnosis.

Helpline: **08088 010 444**
www.leukaemiacare.org.uk
care@leukaemiacare.org.uk

Bloodwise

Bloodwise is the leading charity into the research of blood cancers. They offer support to patients, their family and friends through patient services.

020 7504 2200
www.bloodwise.org.uk

Cancer Research UK

Cancer Research UK is a leading charity dedicated to cancer research.

0808 800 4040
www.cancerresearchuk.org

Macmillan

Macmillan provides free practical, medical and financial support for people facing cancer.

0808 808 0000
www.macmillan.org.uk

Maggie's Centres

Maggie's offers free practical, emotional and social support to people with cancer and their families and friends.

0300 123 1801
www.maggiescentres.org

Citizens Advice Bureau (CAB)

Offers advice on benefits and financial assistance.

08444 111 444
www.adviceguide.org.uk

Leukaemia Care is a national charity dedicated to providing information, advice and support to anyone affected by a blood cancer.

Around 34,000 new cases of blood cancer are diagnosed in the UK each year. We are here to support you, whether you're a patient, carer or family member.

Want to talk?

Helpline: **08088 010 444**

(free from landlines and all major mobile networks)

Office Line: **01905 755977**

www.leukaemicare.org.uk

care@leukaemicare.org.uk

Leukaemia Care,
One Birch Court,
Blackpole East,
Worcester,
WR3 8SG

Registered charity
259483 and SC039207

Leukaemia Care
YOUR Blood Cancer Charity

