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# Gemtuzumab Ozogamicin (GO) for Acute Myeloid Leukaemia (AML)

**A Guide for  
Patients**

# Introduction

**GO (Mylotarg, Pfizer/Wyeth-Ayerst Laboratories) is a drug specifically developed for the treatment of acute myeloid leukaemia. It combines a man-made antibody to leukaemia cells and a chemotherapy drug which kills living cells.**

This booklet was compiled by Saloua Najjam and peer reviewed by one of our medical professionals who is specialised in leukaemia therapy, Dr Steve Knapper, University of Wales, Cardiff. This booklet has then been updated by our Patient Information Writer, Isabelle Leach. We are also grateful to leukaemia patients Julie Quigley and Amanda Menage for their valuable contributions.

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

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# 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 8:30am – 5:00pm Monday - Friday and 7:00pm – 10:00pm on Thursdays and Fridays. If you need someone to talk to, call **08088 010 444**.

Alternatively, you can send a message via WhatsApp on **07500068065** on weekdays 9:00am – 5:00pm.

### Nurse service

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

### 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.leukaemicare.org.uk/support-and-information/help-and-resources/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.leukaemicare.org.uk/support-and-information/support-for-you/find-a-support-group/**

### 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 **support@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**.

### 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 magazine includes inspirational patient and carer stories as well as informative articles by medical professionals: **www.leukaemiacare.org.uk/communication-preferences/**

# What is gemtuzumab ozogamicin?

**Gemtuzumab ozogamicin (GO) is a combination of an antibody and a cytotoxic drug that has shown efficacy in the treatment of patients with acute myeloid leukaemia (AML).**

GO combines gemtuzumab and ozogamicin:

- **Gemtuzumab** – A man-made antibody against CD33 proteins found on the surface of acute myeloid leukaemia cells.
- **Ozogamicin** – A cytotoxic antitumour antibiotic drug (also called calicheamicin).

CD33 proteins on the surface of leukaemia cells are known to be present in 80% of patients with AML. Cytotoxic drugs kill cells by preventing them growing and increasing in number.

# Who receives gemtuzumab ozogamicin?

GO is indicated in combination with daunorubicin and cytarabine for the treatment of patients aged 15 years or older with previously untreated, de novo, CD33-positive AML, excluding acute promyelocytic leukaemia. Its use is restricted to those patients who have favourable or intermediate risk cytogenetics, where cytogenetic analysis has failed, or where the result of the cytogenetic analysis is not yet available but treatment needs to be commenced urgently on clinical grounds.

In patients with AML, the CD33 protein antibody gemtuzumab seeks out the leukaemia cells and binds to them. The cytotoxic drug, which is attached to gemtuzumab, starts damaging the DNA of the leukaemia cells and killing them.

Patients with de novo AML have no clinical history of prior myelodysplastic syndrome, myeloproliferative disorder, or exposure to agents/drugs thought to be related to the development of leukaemia.

The combination of GO with daunorubicin and cytarabine is also recommended by NICE for untreated de novo CD33-positive AML on the following conditions:

- The chromosome analysis of a patient shows their AML has either favourable or standard/intermediate-risk changes. Use of GO is also permitted if the results of the chromosome analysis are not yet available, or in cases where the test fails to yield an interpretable result.
- Pfizer/Wyeth-Ayerst Laboratories provides GO in accordance with the simple discount patient access scheme agreed with NICE.

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](http://www.leukaemiacare.org.uk)

# How is gemtuzumab ozogamicin administered?

GO is supplied as a vial of concentrated powder that requires making up with water to achieve the correct dose as prescribed by your consultant. It is then diluted in a sodium chloride solution ready for intravenous administration.

Methods of administration are as follows:

- For a small dose of GO (less than 3.9mg), the solution is administered by a syringe into a vein.
- For a large dose of GO (greater than 3.9mg), the solution must be filtered and infused intravenously over two hours.
- One hour before your infusion with GO, you will be given paracetamol, an antihistamine and a steroid to help reduce the likelihood of infusion reactions, which generally manifest themselves as fever and chills.

No other drugs should be administered at the same time as GO administration.

The schedule for GO when

administered with daunorubicin and cytarabine is as follows:

## Induction treatment

Induction is the first treatment after diagnosis and is intended to kill the majority of the leukaemia cells and achieve remission.

- GO is infused over two hours on day one, and up to two further doses may be given during cycle one.
- Daunorubicin is infused over 30 minutes on days one to three.
- Cytarabine is given twice daily for ten days.

## Consolidation treatment

Consolidation is the treatment following remission and is intended to kill any cancer cells that may be left in the body.

For patients experiencing a complete remission after induction treatment, up to two consolidation courses are permitted as follows:

- GO is infused over two hours on

day one.

- Daunorubicin is infused for one hour on days one, three and five.
- Cytarabine is given for eight days.

When GO is administered on the same days as daunorubicin and cytarabine, administration of GO should be separate.

# What are the side effects of gemtuzumab ozogamicin?

Everyone will experience different side effects with GO. It is important to report side effects to your doctor or nurse so that they can be managed and treated.

When GO is administered as combination therapy, the most common side effects are haemorrhages and infection.

Uncommon side effects (occurring in less than 3% of patients) which are important to be aware of and require monitoring because they may be life-threatening are as follows:

## Veno-occlusive disease (VOD)

VOD is a condition where the small veins in the liver become obstructed resulting in the decrease of the blood flow in the liver. If severe, this can lead to liver damage.

Symptoms of VOD include:

- Weight gain due to fluid retention
- Enlarged liver
- Raised levels of bilirubin in the blood

VOD may be linked to high-dose chemotherapy and is slightly more common when GO is given in combination with other chemotherapy such as daunorubicin and cytarabine. Rates of VOD in trials of GO were greater when GO was used in higher (or multiple) doses.

VOD has also been linked to chemotherapy given after or before an allogeneic stem cell transplant; however, no definitive relationship has been found between VOD and the timing of a stem cell transplant. In addition, VOD has been reported with several chemotherapy drugs and high dose radiation, where no stem cell transplants were involved.

In patients with abnormal liver tests, frequent monitoring of any symptoms of VOD and the results of liver function tests (including elevations of the liver enzymes alanine transferase, aspartate transaminase, bilirubin, and alkaline phosphatase), should be performed before and after each dose of GO.

In patients who experience VOD,

GO should be stopped and their symptoms treated according to standard medical practice. Sometimes defibrotide may be used to treat VOD.

## Tumour Lysis Syndrome

Tumour lysis syndrome is a serious side effect that occurs with most of the highly effective anticancer drugs. The rapid destruction of large numbers of white blood cells in the case of AML can increase the blood uric acid levels which may cause damage to the kidneys, heart or liver, seizures, and death due to multi-organ failure.

It is important to tell your doctor immediately if you experience dizziness, decreased urination, confusion, vomiting, nausea, swelling, or shortness of breath which may be the initial symptoms of tumour lysis syndrome.

The risk of tumour lysis syndrome is greater in patients with high white blood cell counts, and those with poor renal function. In patients with AML and very high levels

of white blood cells, reducing the number of white blood cells with hydroxycarbamide or leukapheresis to reduce the count of white blood cells to below 30000/mm<sup>3</sup> of blood before administering GO is important to help avoid tumour lysis syndrome.

Appropriate measures to help prevent the development of tumour lysis-related hyperuricaemia include hydration and administration of antihyperuricemics such as allopurinol or rasburicase.

# What happens if gemtuzumab ozogamicin doesn't work?

If the combination of GO, daunorubicin or cytarabine has not worked for you, there are other drug regimens which may be effective.

Nevertheless, your medical team will be best placed to advise you on alternative treatments based on their opinion as to why the combination regimen (GO with daunorubicin and cytarabine) was not effective.

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

# Glossary

## Acute Myeloid Leukaemia (AML)

A rapid and aggressive cancer of the myeloid cells in the bone marrow.

## Acute Promyelocytic Leukaemia (APL)

A rare sub-type of AML in which there is an increased production in bone marrow of immature, abnormal white blood cells called promyelocytes.

## Alanine Aminotransferase (ALT)

ALT is an enzyme primarily found in the liver and is a reliable and sensitive marker of liver disease. It is often measured together with other enzymes found in the liver as part of the liver function tests to detect liver damage.

## Alkaline Phosphatase

An enzyme found in various tissues throughout the body, with the highest concentrations being found in liver or bone. Raised levels of alkaline phosphatase in the blood are most commonly caused by liver disease.

## Allogeneic Stem Cell Transplant

The transplant of stem cells from a matching donor.

## Antibody

A large Y-shaped protein produced by B-cell lymphocytes in response to a specific antigen, such as

bacteria, virus, or a foreign substance in the blood. The antibodies neutralise the bacteria and viruses.

## Bone Marrow

The soft blood-forming tissue that fills the cavities of bones and contains fat, immature and mature blood cells, including white blood cells, red blood cells and platelets.

## Bilirubin

Bilirubin is an orange-yellow substance made during the normal breakdown of red blood cells. Bilirubin passes through the liver and is eventually excreted out of the body. Elevated levels of bilirubin may indicate liver damage or disease.

## Chemotherapy

Drugs that work in different ways to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing.

## Chromosomes

Thread-like structures which carry the genes, and are located in the nuclei of every cell in the body. There are 46 chromosomes (23 pairs) in humans.

# Glossary (cont.)

## Complete Remission

Complete remission has occurred when:

- Blood cells have returned to normal
- Less than 5% of blasts (abnormal, immature leukaemia cells) are still present in the bone marrow

## Fatigue

Tiredness and weakness rendering the patient unable to work or perform usual activities.

## Genes

Genes are made up of DNA which stores the genetic information required to make human proteins.

## Hyperuricaemia

High levels of uric acid in the blood.

## Leukapheresis

A process that involves collecting blood from a vein in one arm, passing it through a machine to remove the excess of white blood cells, and then re-inserting the blood back through a vein in the other arm.

## Red Blood Cells

Small blood cells that contain haemoglobin and carry oxygen to all tissues of the body.

## Relapse

Relapse occurs when a patient initially responds to treatment, but after six months or more, the response stops. This is also sometimes called a recurrence.

## Steroids (also called corticosteroids)

Man-made versions of the hormones normally produced by the adrenal glands; two small glands found above the kidneys. Steroids reduce inflammation (redness and swelling) and the activity of the immune system.

## White Blood Cells

White blood cells are one of the types of cells found in the blood and bone marrow, along with red blood cells and platelets. White blood cells create an immune response against both infectious disease and foreign invaders. Granulocyte white blood cells, include the neutrophils (protect against bacterial infections and inflammation), eosinophils (protect against parasites and allergens) and basophils (create the inflammatory reactions during an immune response). Other white blood cells include the lymphocytes (recognise bacteria, viruses and toxins, to which they produce antibodies) and monocytes (clear infection products from the body).

# 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.leukaemicare.org.uk](http://www.leukaemicare.org.uk)**  
**[support@leukaemicare.org.uk](mailto:support@leukaemicare.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](http://www.bloodwise.org.uk)**

## Cancer Research UK

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

**0808 800 4040**  
**[www.cancerresearchuk.org](http://www.cancerresearchuk.org)**

## Macmillan

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

**0808 808 0000**  
**[www.macmillan.org.uk](http://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](http://www.maggiescentres.org)**

## Citizens Advice Bureau (CAB)

Offers advice on benefits and financial assistance.

**08444 111 444**  
**[www.adviceguide.org.uk](http://www.adviceguide.org.uk)**

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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](http://www.leukaemicare.org.uk)**

**[support@leukaemicare.org.uk](mailto:support@leukaemicare.org.uk)**

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Leukaemia Care is registered as a charity in England and Wales (no.1183890) and Scotland (no. SC049802).  
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Registered office address: One Birch Court, Blackpole East, Worcester, WR3 8SG

**Leukaemia Care**  
YOUR Blood Cancer Charity