▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may experience. You can report any side effects that you may get to the HPRA Pharmacovigilance, Website: www.hpra.ie. Any suspected adverse reactions may also be reported to Pfizer Medical Information on 1800 633 363.

A patient's guide to treatment with

MYLOTARG™

gemtuzumab ozogamicin SOLUTION FOR IV INFUSION

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, CD33 positive acute myeloid leukaemia (AML), except acute promyelocytic leukaemia (APL).[4,13]

MYLOTARG™ is a medicine used to treat a type of cancer called acute myeloid leukaemia (AML). It is used in combination with other medications, **and is only given to people who have not already tried other treatments.**[4]

Pfizer Oncology

PP-MYL-IRL-0102
Date of preparation October 2022

Table of contents

About this guide

This guide will:

- Explain what acute myeloid leukemia (AML) is and introduce the treatment options available to you
- Give you information about your treatment with MYLOTARG™ if you have AML and have not tried other treatments
- Help you manage any side effects that you may experience with MYLOTARG™
- Suggest places to go for more information and answer common questions about MYLOTARG™

Acknowledgements

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Zack Pemberton-Whiteley
Leukaemia Care: www.leukaemiacare.org.uk

Leukaemia Care
YOUR Blood Cancer Charity

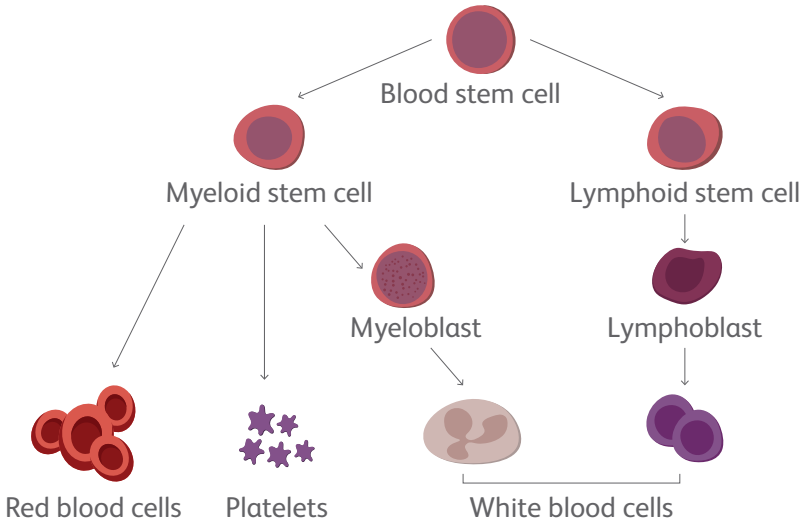
Anita Waldmann
LHRM.de: www.LHRM.de
[German language site]

LHRM

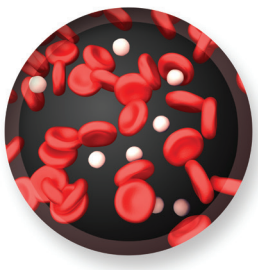
Introduction

What is AML?[1]

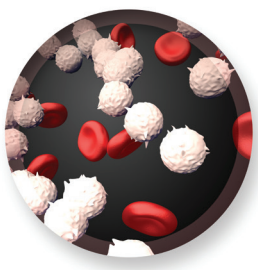
- In a healthy body, the bone marrow makes blood stem cells (immature cells) that become mature blood cells over time.
- A blood stem cell may become a myeloid stem cell or a lymphoid stem cell. A lymphoid stem cell becomes a white blood cell. A myeloid stem cell can become a red blood cell (carries oxygen around the body), a platelet (helps to form blood clots) or a white blood cell (fights infection or disease).



- In AML, the myeloid stem cells usually become a type of immature white blood cell called a myeloblast (or myeloid blast). The myeloblasts in AML are abnormal and do not develop into healthy white blood cells.
- It is also possible for too many stem cells to become abnormal red blood cells or platelets. These abnormal white blood cells, red blood cells or platelets are also called leukaemic cells or blasts. These cells build up in the bone marrow and blood, meaning that there is less room for healthy blood cells (see graphic below).



Normal blood



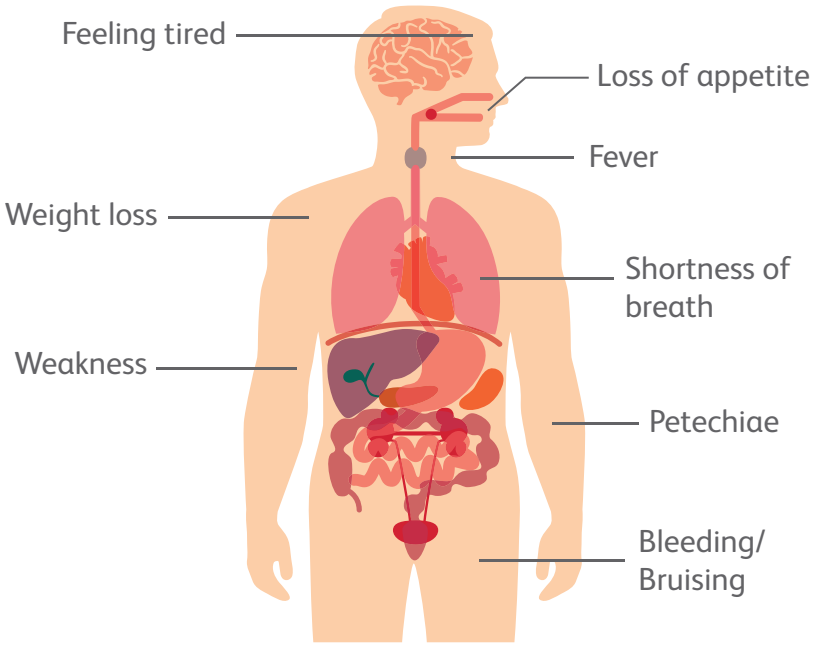
Leukaemia

Introduction

AML IS THE MOST COMMON TYPE OF ACUTE LEUKAEMIA IN ADULTS[1]

What are the signs and symptoms of AML?[1]

- A person with AML may experience fever or shortness of breath. They may bruise or bleed easily and have flat, pinpoint spots under the skin caused by bleeding (otherwise known as petechiae). They may also feel weak or tired, or experience weight loss or loss of appetite.



AML MUST BE TREATED QUICKLY[1]

What are the treatment options for AML?[1-3]

- AML is diagnosed by blood and bone marrow tests. After diagnosis, your medical team will talk to you about your treatment options. Please ask your medical team if you would like an explanation of any of these procedures.

- Treatment of AML in adults usually has two phases:[1]
  1. Remission induction therapy.[1]
     - The goal of remission induction therapy is to kill the leukaemia cells in the blood and bone marrow. This puts the leukaemia into remission (a decrease in, or disappearance of, signs and symptoms of leukaemia).
  2. Post-remission or remission continuation/consolidation therapy.[1]
     - This phase begins after remission is achieved. The goal of post-remission therapy is to kill any remaining leukaemia cells that may not be active but could regrow and cause AML to return (relapse).

- Treatment options for AML may include:
  1. Chemotherapy[1]
     - Uses drugs to stop the growth of cancer cells, either by killing the cells or stopping them from dividing.
  2. Radiation therapy[1]
     - Uses high energy X-rays or other types of radiation to kill cancer cells or stop them from growing.
  3. Stem cell transplant[1–3]
     - A procedure in which stem cells (cells that develop into new blood cells) are used to replace cells that have been destroyed by cancer treatment. A stem cell transplant may be autologous (using your own stem cells that were collected before cancer treatment and stored) or allogeneic (using stem cells donated by someone who is not your identical twin). The new blood cells are transplanted into your bloodstream through a catheter (a flexible tube) which is inserted directly into one of your veins.
  4. Targeted therapy[1]
     - A type of treatment that uses drugs or other substances to identify and attack specific cancer cells without harming normal cells.

Treatment with MYLOTARG™

What is MYLOTARG™? [4,14]

- MYLOTARG™ contains the active substance gemtuzumab ozogamicin, an anticancer medicine, which is made up of a monoclonal antibody linked to a substance intended to kill cancer cells. The antibody part recognises a specific protein called CD33 that is found on the surface of both leukaemia cells and healthy cells. MYLOTARG™ attaches to the CD33 protein. It is thought to work in AML by delivering the anticancer drug into leukaemia cells causing damage that contributes to their death.
- The aim of treatment with MYLOTARG™ is to enable you to reach complete remission, meaning that there is no sign of the cancer on tests or scans.

Why is MYLOTARG™ used to treat previously untreated AML and when is it given? [4,13]

- MYLOTARG™ has been tested in patients with **previously untreated AML**, in combination with other chemotherapy medicines.
- Your doctor may ask you to try MYLOTARG™ **if you have not tried other treatments.**[4]
- Your doctor has recommended MYLOTARG™ because they think it is the most appropriate treatment for you.[4]

Important information before you are given MYLOTARG™[4,14]

- You should not use MYLOTARG™ if you are allergic to gemtuzumab ozogamicin or any of its other ingredients (dextran 40, sucrose, sodium chloride, sodium dihydrogen phosphate monohydrate, disodium hydrogen phosphate anhydrous). Please ask your medical team if you are unsure about this.
- When you first receive MYLOTARG™ and during the course of treatment, tell your doctor or nurse if you:

1. Have or have ever had **liver problems.** During or after treatment, MYLOTARG™ may cause a potentially life-threatening condition called hepatic veno-occlusive disease (VOD), where blood vessels in the liver become damaged and blocked by blood clots. This can cause fluid retention, rapid weight gain, increased liver size (which may be painful) and ascites (build-up of fluid in the abdomen).

Liver problems can cause fluid retention, rapid weight gain, increased liver size (which may be painful) and ascites (build-up of fluid in the abdomen).[4]

2. Have an **allergic reaction.** Signs or symptoms may include a high-pitched whistling sound during breathing (wheezing), difficulty breathing, shortness of breath, a cough with or without mucous, hives, itching, swelling or fever and chills (signs of an infusion-related reaction). These can occur during or shortly after the MYLOTARG™ infusion.
3. Have or think you have an **infection**. Signs or symptoms may include chills or shivering, feeling warm or having a fever. Some infections may be serious and could be life threatening.
4. Have unusual **bleeding**, bleeding from your gums, are bruising easily or getting nosebleeds on a regular basis.
5. Have **anaemia**. Signs or symptoms may include headaches, feeling tired, dizziness or looking pale.
6. Have an **infusion reaction**. Signs or symptoms during or shortly after MYLOTARG™ infusion may include dizziness, decreased urination, feeling confused, vomiting,

nausea, swelling, shortness of breath or heart rhythm disturbances (this may be a potentially life-threatening complication known as tumour lysis syndrome).

- If you are pregnant (or think you could be pregnant), breastfeeding or planning to have a baby, you should ask your doctor or pharmacist for advice before you are given MYLOTARG™. You should also seek advice regarding fertility preservation before treatment.

  1. You must avoid becoming pregnant or fathering a child

  – Women must use two methods of effective contraception during treatment and for at least 7 months after the last dose of treatment.

  – Men must use two methods of effective contraception during treatment and for at least 4 months after the last dose of treatment.

  – Please speak to your medical team for advice about contraception.

  – Contact your doctor immediately if you or your partner becomes pregnant while taking MYLOTARG™.

  2. If you need treatment with MYLOTARG™, you must stop breast feeding during treatment and for at least 1 month after your treatment ends. Please talk to your doctor for further advice regarding this.

- If you feel unusually tired, dizzy or have a headache (these are very common side effects of MYLOTARG™), you should not drive or use machines.

How will I be given MYLOTARG™? [4,13,14]

Your doctor has prescribed MYLOTARG™ in addition to chemotherapy.

- You will receive chemotherapy (2 different drugs; daunorubicin (which will be given over a 30-minute infusion for the first 3 days) and cytarabine[13] (which will be given for 7 days by continuous infusion). This is called induction therapy.[4]
- During the same week, you will also receive MYLOTARG™ on Day 1, Day 4, and Day 7. A doctor or nurse will give you MYLOTARG™ gradually over a 2-hour period through an intravenous infusion in one of your veins.[4]
- You may need a second round of induction chemotherapy, but MYLOTARG™ will not be added to the second round.[4,13]
- If you respond to induction, you may receive chemotherapy with MYLOTARG™ for up to 2 more times. This is known as consolidation therapy.[4]
- During your consolidation treatment, MYLOTARG™ will still be given in combination with daunorubicin and cytarabine. MYLOTARG™ is only given on Day 1 of each consolidation course over a 2-hour period. Daunorubicin will be given over a 30-minute period (for the first day of your first course and the first 2 days of your second course), and cytarabine will be given over a 2-hour period every 12 hours (for the first 4 days of your first and second courses).[4,13]
- Your doctor will decide the number of treatments that is right for you. [14]
- Your doctor or nurse will decide on the correct MYLOTARG™ dose for you and your doctor may lower your dose based on how your cancer responds to treatment.[4,14]
- Your doctor may change your dose or interrupt or completely stop treatment with MYLOTARG™ if you have certain side effects.[4,14]
- Your doctor will carry out blood tests during treatment to check for side effects and for response to treatment.[4,14]
- Before you receive MYLOTARG™, you will be given medication to help reduce symptoms such as fever and chills (also known as infusion reactions), which can occur during or shortly after the MYLOTARG™ infusion.[4,14]
- Please talk to your doctor or nurse if you have any further questions on the use of MYLOTARG™ [4,14].

Side Effects of MYLOTARG™

Like all medicines, MYLOTARG™ can cause side effects, although not everyone will experience them. Some side effects can be serious and may occur during or after treatment with MYLOTARG™. Contact your doctor immediately if you experience any of the side effects mentioned in this section of the booklet.[4,14]

Please read the important information in the **Package leaflet: Information for the user** that came with your medicine. If you do not have this leaflet, please ask your medical team for a copy.

If you experience any side effects, talk to your medical team. This includes any possible side effects not listed in this leaflet.

Serious side effects[4,14]

MYLOTARG™ may cause serious side effects that can be severe, life-threatening, or even lead to death. These may include:

Liver problems, including a condition called hepatic veno-occlusive disease (VOD)

Bleeding

Infusion reactions (a type of allergic reaction)

Infections

Complication known as tumour lysis syndrome

Common side effects[4,14]

The most common side effects experienced with MYLOTARG™ were

- Bleeding
- Infection
- Fever
- Nausea
- Vomiting
- Constipation
- Rash
- Headache
- Mouth sores
- Increases in lab tests measuring liver function

Managing the side effects of MYLOTARG™

Changes in your liver function[4,14]

- More than 1 in 10 people receiving MYLOTARG™ may develop raised liver enzymes during treatment. This could be a sign of liver damage.
- Your medical team may monitor your liver function with blood tests before each dose of MYLOTARG™. Abnormalities in liver blood tests could be a sign of a potentially life-threatening condition called hepatic VOD.

Veno-occlusive disease (VOD)[4,14]

- MYLOTARG™ may cause a potentially life-threatening condition called hepatic VOD, which can occur during or after treatment.
- Up to 1 in 10 people receiving MYLOTARG™ may develop VOD during or after treatment with MYLOTARG™.
- Your medical team will monitor you closely for signs and symptoms of VOD.
- **Please tell your medical team immediately if you notice any of the following, which could be signs or symptoms of VOD:** abnormalities in liver blood tests, rapid weight gain, pain in the upper right side of your abdomen or build-up of fluid causing abdominal swelling.[4]

Managing the side effects of MYLOTARG™

Low numbers of blood cells[4,14]

- More than 1 in 10 people receiving MYLOTARG™ may have decreased numbers of platelets (cells that help blood to clot), white blood cells (cells that fight infection) and red blood cells (cells that transport oxygen around your body). This is associated with complications such as bleeding, infections, fatigue and shortness of breath. Please tell your doctor immediately if you notice any of these symptoms.
- Before your treatment with MYLOTARG™, your medical team will monitor your blood counts.

Bleeding[4,14]

- More than 1 in 10 people receiving MYLOTARG™ may experience bleeding events.[4] Common bleeding events associated with MYLOTARG™ include nosebleeds or bruising easily.
- During and after your treatment, your medical team will monitor you for signs and symptoms of bleeding.

- **Please tell your medical team immediately if you experience any of the following, which could be signs or symptoms of bleeding complications:** bruising easily, having regular nosebleeds, black tarry stools, coughing up blood, bloody sputum or change in mental status.

- **TOP TIPS if bleeding occurs[5]**

1. Apply direct pressure to the bleeding site (if it is an open area of bleeding skin).
2. If you have a nosebleed, apply ice and pressure over the bridge of your nose.
3. After applying pressure, contact your medical team.
4. If you are unable to control the bleeding, go to a local emergency (A&E) department.

Infection [4-8,14]

- More than 1 in 10 people receiving MYLOTARG™ may develop an infection because of a low number of white blood cells.[4,14] Infections associated with MYLOTARG™ include:

  1. Infections of the blood (symptoms may include a fever or low body temperature, chills and shivering, a fast heartbeat or fast breathing)[4,6,14]
  2. Upper and lower respiratory tract infections (symptoms may include a cough, a tight feeling in your chest or breathlessness)[4,7]
  3. Fungal, viral or bacterial infections[4]
  4. Gastrointestinal or skin infections[4]

- Tell your medical team immediately if you develop an infection during treatment with MYLOTARG™ [8]

• TOP TIPS to help lower your risk of infection[9–10]

1. Wash your hands regularly.[10]
2. Avoid contact with unwell individuals.[10]
3. Check your temperature and contact your medical team if you have a fever (rectal or ear temperature of 38˚C or higher, oral temperature of 37.8˚C or higher, or armpit temperature of 37.2˚C or higher).[9]
4. Take extra care with your hygiene:[10]
   - If you have a catheter (e.g. an IV catheter), keep the area around it clean and dry
   - Brush your teeth thoroughly and perform daily checks for mouth sores or other signs of infection
   - If you get a scrape or cut, clean it well
   - Let your doctor or nurse know if your bottom is sore or bleeds, because this could increase your risk of infection

Tumour lysis syndrome[4,11,14]

- Up to 1 in 10 people receiving MYLOTARG™[4] may develop tumour lysis syndrome, which may cause damage to organs, including the kidneys, heart and liver.[4,11,14] This happens when cancer cells break down and release their contents into the bloodstream, either spontaneously or because of the effect of MYLOTARG™. [11]
- If you have a high number of leukaemia cells in your blood (otherwise known as hyperleukocytic AML), you may be given medication or IV fluid before your treatment with MYLOTARG™ to reduce the number of white blood cells in order to prevent tumour lysis syndrome. [4]
- **Please tell your medical team immediately if you experience any of the following, which could be signs or symptoms of tumour lysis syndrome:** dizziness, decreased urination, feeling confused, vomiting, nausea, swelling, shortness of breath or heart rhythm disturbances.

Infusion-related reactions[4,14]

- Up to 1 in 10 people receiving MYLOTARG™ may develop an infusion-related reaction.[4,14]
- **Please tell your medical team immediately if you experience any of the following, which could be signs or symptoms of an infusion-related reaction:** rash, shortness of breath, difficulty breathing, a tight chest, chills, fever or back pain.[4]
- Before receiving MYLOTARG™, you will be given medication to reduce infusion-related reactions, such as:[4,14]
  1. Corticosteroid (to reduce inflammatory reactions)
  2. Antihistamine (to reduce allergic reactions)
  3. Paracetamol
- Your medical team will monitor you while you receive MYLOTARG™ until your signs and symptoms completely resolve.[4]

The complete list of known side effects can be found in the **Package leaflet: Information for the user** that came with your medicine. If you experience any side effects, please talk to your medical team.

Getting the support you need

When to contact your medical team

- Not everyone will respond to MYLOTARG™ in the same way and some people will experience more side effects than others.
- It is important to be aware of the possible side effects of MYLOTARG™:
  1. Some side effects may only be mild and short-lived.
  2. Others may come and go.
  3. Some might be more serious and require medical attention.
- Please speak to your medical team if you experience any side effects with MYLOTARG™ treatment, including any that are not listed in this guide.[4]

General resources and information

For further information on AML, please visit https://www.cancer.ie/cancer-information-and-support/cancer-types/acute-myeloid-leukaemia-aml.

For confidential advice, support and information, you can speak to an Irish Cancer Society nurse by contacting their **Support Line** on Freephone 1800 200 700.

The Irish Cancer Society Daffodil Centres are located in thirteen hospitals nationwide. The centres are staffed by cancer nurses and trained volunteers who provide free, confidential advice, support and information to anyone affected by cancer.
To find your nearest Daffodil Centre, visit www.cancer.ie/support/daffodil-centres.

Frequently asked questions

Can I take MYLOTARG™ at home?

- **No**. MYLOTARG™ must be given under the supervision of a doctor experienced in cancer therapy and in a setting where full resuscitation facilities are immediately available.[4]

Is there anything I cannot eat, drink or take when being treated with MYLOTARG™?

- **No**, but please tell your medical team if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines.[4]

Will I experience side effects when I take MYLOTARG™?

- Like all medicines, MYLOTARG™ can cause side effects, although not everyone experiences them. Some of these side effects may be serious. If you experience any side effects, please talk to your medical team. This includes any possible side effects not listed in the Package Leaflet or the side effects section of this guide.[4]

What if my doctor says I need to change my dose?

- Your doctor may interrupt or completely stop treatment with MYLOTARG™ if you have certain side effects or based on how your cancer responds to treatment.[4]

How will I know if MYLOTARG™ is working?

- Your doctor will take blood or bone marrow samples for testing during your treatment to check if MYLOTARG™ is working and may lower your dose based on how your cancer responds to treatment.[4]

Frequently asked questions

What happens if my doctor says I need to stop taking MYLOTARG™?

- Not everyone will respond to MYLOTARG™ in the same way. If your cancer does not respond to MYLOTARG™, your treatment will be stopped. Your doctor may also completely stop treatment with MYLOTARG™ if you have certain side effects.[4,14] If this happens, your doctor will talk to you about other treatment options available to you.

Why does MYLOTARG™ sometimes not work?

- Not everyone will respond to treatment with MYLOTARG™ in the same way.[4] Your doctor will check for response to treatment and if you are able to tolerate it well.
- Your doctor may recommend stopping treatment if your cancer is not responding to MYLOTARG™.
- If MYLOTARG™ does not work for you, your doctor will talk to you about other available treatment options.

Glossary[1–4,12]

Acute myeloid leukaemia (AML)	AML is a type of cancer in which the bone marrow makes abnormal myeloblasts (a type of white blood cell), red blood cells, or platelets
Acute promyelocytic leukaemia (APL)	An aggressive (fast growing) type of AML, in which there are too many immature blood-forming cells in the blood and bone marrow. MYLOTARG™ is not approved for the treatment of APL
Anaemia	A condition in which the number of red blood cells is below normal. Signs and symptoms include headaches, tiredness, dizziness or looking pale
Blood count (or complete blood count)	A measure of the number of red blood cells, white blood cells and platelets in the blood. It is used to help diagnose and monitor many conditions
Bone marrow	Soft, sponge-like tissue in the centre of most bones. It produces white blood cells, red blood cells and platelets
Catheter	A flexible tube used to deliver fluids into or withdraw fluids from the body
Consolidation therapy	Treatment that is given after cancer has disappeared following the initial therapy. Consolidation therapy is used to kill any cancer cells that may be left in the body
Cytarabine	A chemotherapy drug used in combination with other drugs to treat leukaemia. Cytarabine blocks cells from making DNA and may kill cancer cells
Daunorubicin	The active ingredient in a chemotherapy drug used to treat acute leukaemias and some other types of cancer

Glossary[1–4,12]

Gemtuzumab ozogamicin	MYLOTARG™ (gemtuzumab ozogamicin) is made up of a monoclonal antibody (a protein that recognises a specific type of cell), linked to an active substance intended to kill cancer cells
Induction therapy	The first treatment given for a disease
Infusion reaction	A reaction that occurs during or shortly after infusion of a medicine such as MYLOTARG™. Symptoms can include a rash, shortness of breath, difficulty breathing, a tight chest, chills, fever or back pain
Intravenous (IV) infusion	A method of putting fluids, including drugs, into the bloodstream
Liver enzymes	Proteins found in the liver that can be measured through blood testing and indicate liver function. Liver enzymes include alanine aminotransferase and aspartate aminotransferase. Elevated liver enzymes may indicate an inflamed or injured liver
Myeloblast	A type of immature white blood cell that forms in the bone marrow
Nausea	A feeling of sickness or discomfort in the stomach that may come with an urge to vomit
Platelet	A type of blood cell that helps to form blood clots which slow or stop bleeding and help wounds heal
Red blood cell	A type of blood cell that is made in the bone marrow and contains a protein called haemoglobin which carries oxygen from the lungs to all parts of the body

Glossary[1–4,12]

Relapse	The return of AML or signs and symptoms of AML after a period of improvement
Remission	A decrease in, or disappearance of, signs and symptoms of cancer. Remission can be partial or complete. Complete remission is the disappearance of all signs of cancer in response to treatment. In partial remission, some, but not all, signs and symptoms of cancer disappear
Stem cell transplant	A method of replacing immature blood-forming cells in the bone marrow that have been destroyed by drugs, radiation or disease. Stem cells are injected into the patient and make healthy blood cells
Tumour lysis syndrome	A condition that can occur after treatment of a fast-growing cancer, especially certain leukaemias (cancers of the blood). As cancer cells die, they break apart and release their contents into the blood. This causes a change in certain chemicals in the blood that may cause damage to organs including the kidneys, heart and liver
Veno-occlusive disease (VOD)	A condition in which the blood vessels in the liver become damaged and blocked by blood clots
Vomiting	The process of ejecting some or all of the contents of the stomach through the mouth
White blood cell	A type of blood cell that is made in the bone marrow and found in the blood and lymph tissue. White blood cells are part of the body's immune system and help to fight infection and disease

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12. Mayo Clinic. Elevated liver enzymes. Available at: http://www.mayoclinic.org/symptoms/elevated-liver-enzymes/basics/definition/sym-20050830 [accessed September 2022]

13. Pfizer Cytarabine Summary of Product Characteristics.

14. Pfizer MYLOTARG® Patient Information Leaflet.

Notes

You can use these pages to write down any details about AML, your treatment or any questions that you would like to ask your medical team

Notes

Pfizer Oncology

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