

---

# Liposomal daunorubicin- cytarabine for Acute Myeloid Leukaemia (AML)

**A Guide for  
Patients**

**Leukaemia Care**  
YOUR Blood Cancer Charity

# Introduction

**Daunorubicin and cytarabine are two chemotherapy drugs that have been used as a first treatment for acute myeloid leukaemia (AML) for a long time. Liposomal daunorubicin-cytarabine is a new ‘drug delivery system’ which combines daunorubicin and cytarabine within a tiny fat droplet called a liposome.**

For more information, talk to your haematologist, clinical nurse specialist or hospital pharmacist.

This booklet was put together by our Patient Information Writer, Isabelle Leach. It was then peer reviewed by Dr Steve Knapper. We are also grateful to Dave Wilson and Katherine Murray for their contributions as patient reviewers.

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

# In this booklet

Introduction	2
In this booklet	3
About Leukaemia Care	4
What is liposomal daunorubicin-cytarabine?	6
How is liposomal daunorubicin-cytarabine given?	8
What are the side effects of liposomal daunorubicin-cytarabine?	9
What happens if liposomal daunorubicin-cytarabine doesn't work for me?	12
Glossary	13
Useful contacts and further support	19

# 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 - 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@leukaemicare.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.

## Webinars

Our webinars provide an opportunity to ask questions and listen to patient speakers and medical professionals who can provide valuable information and support. For information on

upcoming webinars, go to **www.leukaemicare.org.uk/support-and-information/support-for-you/onlinewebinars/**

## Website

You can access up-to-date information on our website, **www.leukaemicare.org.uk**.

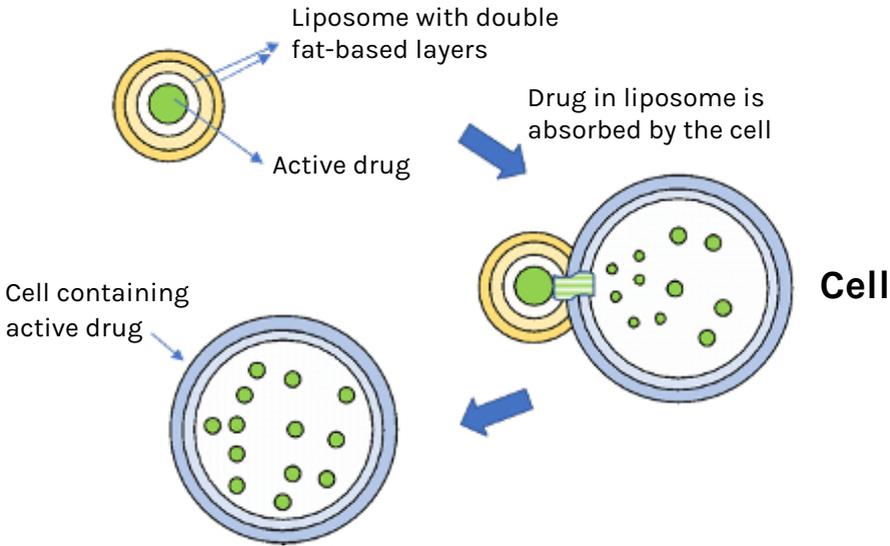
## Campaigning and Advocacy

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@leukaemicare.org.uk**

## Patient magazine

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

# What is liposomal daunorubicin-cytarabine?



**Figure 1: Liposome drug delivery mechanism**

Daunorubicin and cytarabine are two chemotherapy drugs that have been used as a first treatment for AML for a long time. In the past, a patient would receive cytarabine for seven days and daunorubicin (or a similar drug) for three days. This was known as the 7+3 regimen of chemotherapy.

Now, liposomal daunorubicin-cytarabine

is a new 'drug delivery system' which combines daunorubicin and cytarabine within a tiny fat droplet called a liposome. A liposome is a small capsule made of two layers of fat cells, which gives a structure very similar to a cell membrane (Figure 1). The liposome holds the doses of drugs within it and delivers them to the body as a whole. Liposomes have become a popular way for patients to

be given drugs.

In the case of liposomal daunorubicin-cytarabine, there are two advantages:

- The liposomal membrane protects daunorubicin and cytarabine from being broken down early, so they remain in the body longer.
- The liposomes are also thought to build up in the bone marrow to enhance the effect against the leukaemia cells.

Liposomal daunorubicin-cytarabine is approved by the European Medicines Agency (EMA) for the treatment of adults with newly diagnosed, therapy-related acute myeloid leukaemia (AML) or AML with myelodysplasia-related changes. Additionally, it is also recommended by the National Institute for Health and Care Excellence (NICE) for patients with untreated AML.

The approval was based on the findings from Study 301 which indicated significantly higher rates of complete remission and overall survival using liposomal daunorubicin-cytarabine in comparison to the standard 7+3 regimen of chemotherapy (cytarabine and daunorubicin).

### **Who receives liposomal daunorubicin-cytarabine?**

Liposomal daunorubicin-cytarabine is approved for adults with newly diagnosed AML, therapy-related AML or AML with myelodysplasia-related changes.

# How is liposomal daunorubicin-cytarabine given?

Liposomal daunorubicin-cytarabine is given by intravenous infusion (into the vein) for over 90 minutes. The dose is calculated using your height and weight. It is normally administered on days one, three and five of the first induction treatment course. If the results are satisfactory and the haematologist decides to continue with this treatment, liposomal daunorubicin-cytarabine is then administered on days one and three of each subsequent treatment cycle (second induction, if needed, and consolidation).

Patients may receive up to two cycles of induction and up to two cycles of consolidation. Each cycle takes around five to six weeks, meaning that having three cycles (a typical number of cycles to receive) will take about four months on average.

The first cycle of treatment will be given

as an inpatient but, if appropriate, you may be able to receive subsequent cycles of treatment on an outpatient basis in a haematology day unit, but this is dependent on certain factors including the existence of comorbidities and whether or not the hospital is able to provide suitable care for you as an outpatient.

You will be required to read and sign a consent form confirming that you have received verbal and written information about your AML, treatment and potential side effects.

Blood tests will be carried out before each cycle of treatment to monitor blood cell counts and liver and kidney function. If blood counts become too low or the kidney tests are not satisfactory, the next treatment cycle may be delayed or the dose of liposomal daunorubicin-cytarabine may be adjusted.

# What are the side effects of liposomal daunorubicin-cytarabine?

As with most anti-cancer drugs, liposomal daunorubicin-cytarabine may cause some side effects. The most common side effects are below.

## Common side effects

- Hypersensitivity reactions: symptoms of hypersensitivity include rash, itching, flushing, breathlessness or chest discomfort
- Increased infection risk due to a low level of white blood cells
- Fever
- Oedema (a build-up of fluid in the body's tissue, often causing swelling)
- Decreased appetite, nausea, vomiting, abdominal pain, diarrhoea
- Mucositis (soreness and inflammation in your mouth or gut)

- Fatigue
- Muscle and bone pain
- Headache
- Heart problems: abnormal heart rhythms, low blood pressure and heart failure. Cardiotoxicity is a known risk of the anthracycline daunorubicin. Tell your doctor or nurse straight away if you experience chest pains, breathlessness or dizziness
- Insomnia
- Change in colour of urine, sweat or tears due to the strong purple colour of the treatment

It is important to report side effects to your doctor or nurse so that they can be managed and treated effectively.

# What are the side effects of liposomal daunorubicin-cytarabine? (cont.)

## Fertility, pregnancy and breastfeeding

### Fertility

There is no evidence of the effect of liposomal daunorubicin-cytarabine on fertility specifically. However, as with most forms of chemotherapy, it is possible that fertility may be compromised by treatment with liposomal daunorubicin-cytarabine.

Women of childbearing potential are advised to avoid becoming pregnant by using effective contraception if they or their male partner undergo treatment. Men are advised to use effective contraception while receiving treatment and for six months following the last dose.

After you have completed your course of chemotherapy, you can be referred for fertility testing

to see if your treatment has affected your ability to have children.

### Pregnancy

No studies of the use of liposomal daunorubicin-cytarabine in pregnant women are available. Given evidence from studies in animals and the way liposomal daunorubicin-cytarabine works, it is recommended not to be used during pregnancy, unless the clinical condition of the woman requires treatment and justifies the potential risk to the foetus.

If liposomal daunorubicin-cytarabine is taken during pregnancy, or if a woman becomes pregnant while receiving it, they should be informed about the potential risks to their baby. Blood counts and cardiovascular examination - which involves looking at how

your heart and blood vessels are doing - are recommended for foetuses and new-borns.

### Breastfeeding

It is not known if liposomal daunorubicin-cytarabine comes out in human milk. Because of the potential harm to breastfeeding children, mothers are advised not to breastfeed while taking liposomal daunorubicin-cytarabine. Alternatives to breastfeeding include formula, or using donated breastmilk.

If you have any questions about using donated breastmilk, go to UKAMB's website at: <http://www.ukamb.org>

If you need any NHS advice about breastfeeding generally, you can message the Start4Life Breastfeeding Friend chatbot at: <https://m.me/Start4LifeBreastFeedingFriend>

# What happens if liposomal daunorubicin-cytarabine doesn't work for me?

If your AML has not gone into remission following your treatment with liposomal daunorubicin-cytarabine, or you have relapsed after achieving remission, your consultant is the best person to discuss what other treatments would be suitable for you, and help you decide the next course of action. Knowledge of your type of AML, your physical condition and any new treatments which may help you will guide your consultant's next treatment option.

Other options that could be available to you are:

- For those who are relatively healthy and can withstand the high dose chemotherapy required to prepare the bone marrow, a bone marrow stem cell transplant may be a good and even curative treatment for AML.
- For those patients who are elderly or unsuitable for chemotherapy, hypomethylating agents such as azacitidine are effective in patients with refractory or relapsed AML to increase overall survival with an acceptable quality of life.
- Subcutaneous low-dose cytarabine 20mg twice daily for 10 days per 28-day cycle is also effective for some patients with AML.
- Recently approved new drugs for the treatment of AML could be potentially helpful depending on your circumstance. You can find further details of these drugs on our website at [www.leukaemicare.org.uk](http://www.leukaemicare.org.uk).
- Finally, the best palliative/supportive care which includes blood product transfusions and antibiotics will be received in any event, including having no further treatment.

# Glossary

## Acute Leukaemia

Leukaemia which progresses rapidly and is generally aggressive. There are two main types: acute lymphoblastic leukaemia and acute myeloid leukaemia.

## Acute lymphoblastic leukaemia (ALL)

A leukaemia in which lymphocytes start multiplying uncontrollably in the bone marrow, resulting in high numbers of abnormal, immature lymphocytes.

## Acute myeloid leukaemia (AML)

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

## Amino Acids

Organic molecules which are the building blocks for making proteins.

## Anaemia

A condition where the number of red blood cells are reduced. Red blood cells contain haemoglobin and transport oxygen to body cells. This may be due to a lack of iron,

leukaemia, or sickle cell disease.

## Anthracycline

An antibiotic derived from the bacteria *Streptomyces peucetius* which was found to be an effective anticancer drug.

## Antibiotic

A drug used to treat or prevent bacterial infections.

## Antimetabolite

A drug that interferes with DNA synthesis, therefore preventing growth or reproduction of cells.

## Blood Cancer

Cancer of blood cells from the bone marrow or lymphatic system. There are three main types of blood cancer:

- Leukaemia begins in the bone marrow and is classified according to the type of blood cell it affects (either myeloid or lymphoid) and whether it grows quickly (acute) or slowly (chronic).
- Lymphoma starts in the lymphocyte white

# Glossary (cont.)

blood cells within the lymphatic system.

- Myeloma is a cancer of the plasma cells and starts in the bone marrow. Plasma cells are a type of white blood cell that makes antibodies.

## Blood Cells

Cells present in the blood and bone marrow which include red blood cells, white blood cells and platelets. These three types of blood cell make up 45% of the blood volume, with the remaining 55% being plasma, the liquid component of blood.

## 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.

## Cardiotoxicity

Damage to heart tissues.

## 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.

## Clinical Trials

Trials designed and planned to determine a specific answer or aim; for example, whether treatment A is better than treatment B. The study will be conducted in patients who meet particular inclusion criteria, and the results are collected and analysed to provide an answer.

## Colitis

Inflammation of the lining of the colon.

## Complete Molecular Remission

Complete remission with no leukaemia cells anywhere in the body (i.e., no minimal residual disease).

## Complete Remission

Complete remission has occurred when:

- Blood cell counts have returned to normal
- Less than 5% of abnormal, leukaemia cells are still present in

the bone marrow

### Cytarabine

An antimetabolite drug which works by disrupting the DNA of cancer cells, thereby slowing or stopping their growth.

### DNA (Deoxyribonucleic Acid)

The thread-like chain of amino acids found in the nucleus of each cell in the body which carries genetic instructions used in the growth, development and functioning of the individual's cells.

### Fatigue

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

### First-line Treatment

First treatment given for a disease. It is generally the treatment accepted by the medical profession as the best initial treatment for a given type and stage of cancer.

### Granulocyte-macrophage Colony-stimulating Factor

The growth factor required to stimulate the growth of

living cells.

### Granulocytes

Group of white blood cells, which have granular bodies in their cytoplasm. They include the neutrophils, eosinophils and basophils white blood cells, all of which protect the body from bacteria, allergens and inflammation. For more information, see White blood cells in this glossary.

### Hypomethylating Agents

A drug that inhibits the DNA methyltransferase enzyme, which prevents DNA from producing the proteins required for the normal development of CMML cells.

### Induction (Phase)

The first treatment after diagnosis intended to kill the majority of the leukaemia cells and stimulate remission.

### Leukaemia

A group of cancers that usually begin in the bone marrow and result in high numbers of abnormal blood cells. These cells are

## Glossary (cont.)

not fully developed and are called blasts or leukaemia cells. Depending on the type of blood cell involved, there are different types of leukaemia with varying characteristics, such as being acute (develop quickly) or chronic (develop slowly).

### Mucous membranes

Mucous membranes protect the inside parts of your body that are exposed to air. Examples of mucous membranes include lips, mouth, nasal passages, and the middle ear. Mucous membranes are rich in mucous glands that secrete mucus to help keep membranes moist.

### Myelodysplastic Syndromes (MDS)

Also called myelodysplasia, myelodysplastic disorders occur when the bone marrow does not make enough normal blood cells. The blood cells made are not fully developed and not able to work normally. These blood cells include red blood cells which supply oxygen to the body's tissues, white blood

cells which fight infection and platelets which help blood clot.

### Neutrophils

White blood cells involved in fighting inflammation and infection specifically bacterial infections.

### Oedema

An excess build-up of fluid in an area of the body which usually causes swelling of the area.

### Paediatric Patients

Patients from birth up to the age of 18.

### Platelets

One of the types of blood cell which helps to stop bleeding.

### Red Blood Cells

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

### Refractory Condition

Condition for which treatment does not result in a remission. However, the condition may be stable.

## 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.

## Second-line Treatment

The treatment used other than the type used the first time (first-line treatment).

## Standard of Care Treatment

The treatment generally used by the medical establishment, and is understood to be the best treatment for a particular disease.

## Stem Cell

The most basic cell in the body that has the ability to develop into any of the body's specialised cell types, from muscle cells to brain cells. However, what makes these stem cells reproduce uncontrollably, as in cancer, is thought to be linked to chromosome abnormalities.

## 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).



**Leukaemia Care** is a national blood cancer charity supporting anybody affected by a blood cancer. This includes patients, family, friends and the healthcare professionals that support them.

To make a donation or become a regular giver, please visit [www.leukaemiacare.org.uk/donate](http://www.leukaemiacare.org.uk/donate)

**Thank you!**

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

## Blood Cancer UK

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

**0808 2080 888**  
**[www.bloodcancer.org.uk](http://www.bloodcancer.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)**

---

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)**

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

Leukaemia Care is registered as a charity in England and Wales (no.1183890) and Scotland (no. SC049802).  
Company number: 11911752 (England and Wales).  
Registered office address: One Birch Court, Blackpole East, Worcester, WR3 8SG

**Leukaemia Care**  
YOUR Blood Cancer Charity