Daunorubicin + cytarabine with gemtuzumab ozogamicin

Daunorubicin + cytarabine + gemtuzumab ozogamicin is a combination of medicines used to treat some people with acute myeloid leukaemia (AML).

Summary

- Daunorubicin + cytarabine + gemtuzumab ozogamicin is a combination of three different cancer medicines. They are used to treat some people with acute myeloid leukaemia (AML).
- You have the medicines through a drip into a vein.
- You have treatment in 28-day cycles, with treatment on some days and no treatment on others.
- You have regular blood tests to check how well the treatment is working and how your body is coping with it.
- You may get some side effects while you are having your treatment. Some people have very few side effects, whereas other people experience more serious side effects.
- Some side effects can be serious if not treated promptly. Contact your haematology team straight away if:
    - You are feeling sick or being sick, have tummy pain or diarrhoea
    - You have weight loss
    - You have muscle weakness
    - You have a high temperature (38°C or higher) or any other signs of infection
    - You are feeling confused, slurring your words, not making sense
    - You have blue, grey, pale or blotchy skin, lips or tongue (this may look different on black or brown skin)
    - You have a rash that doesn't fade when you roll a glass over it
    - You are having difficulty breathing, shortness of breath or breathing very fast
    - You have dark coloured pee and light-coloured poo

- You have yellowing of your skin or the whites of your eyes (this may look different on black or brown skin)
- You have fatigue

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About daunorubicin + cytarabine + gemtuzumab ozogamicin

This is a combination of daunorubicin + cytarabine + gemtuzumab ozogamicin. Your doctor might recommend it for you if:

- You have been newly diagnosed with AML **AND**
- Your leukaemia cells make a protein called CD33 **AND**
- You are able to have high intensity treatment

Daunorubicin

Daunorubicin is a chemotherapy medicine. It blocks an enzyme that cells need to divide and grow. Blocking this enzyme can help stop cancer cells from growing and dividing.

Daunorubicin does not have a brand name.

Cytarabine

Cytarabine is a chemotherapy medicine. It stops your cancer cells from making and repairing DNA. This can stop cancer cells from growing and dividing.

Cytarabine does not have a brand name. You might hear some people call it Ara-C.

Gemtuzumab ozogamicin

Gemtuzumab ozogamicin is an antibody treatment joined to a chemotherapy drug. The antibody part sticks to a protein called CD33 on the surface of cancer cells. The chemotherapy part then kills the cells.

The brand name for gemtuzumab ozogamicin is Mylotarg.

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Before having this treatment

Before you start treatment, your haematology team will carry out:

- Blood tests to measure your blood counts
- Blood tests to check your liver and kidney function
- Bone marrow tests
- A heart tracing (ECG) and heart scan (echocardiogram) to check how well your heart is working

Things to tell your haematology team

Before starting treatment, you should tell your doctor if you:

- Have any allergies, or have ever had an allergic reaction
- Have ever had any problems with your liver or kidneys
- Are or think you may be pregnant
- Have had chemotherapy or radiotherapy
- Have ever had gout
- Are due to have any vaccines
- Are taking any other medicines or herbal supplements

> **Daunorubicin + cytarabine + gemtuzumab ozogamicin may affect your fertility. If you may want to have children in the future, tell your medical team. They can give you advice on sperm or egg storage before starting treatment.**

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Having your treatment

Treatment for AML can be divided into three stages:

- Induction (to get AML under control)
- Consolidation (to keep AML under control)
- Maintenance (to reduce the risk of AML coming back)

Daunorubicin + cytarabine + gemtuzumab ozogamicin is an option during the induction and consolidation stages.

It is an intensive treatment. You usually stay in hospital while you have treatment and until your blood counts recover.

You have the medicines through a drip into a vein.

You have treatment in 28-day cycles, with treatment on some days and no treatment on others. You will usually need to stay in hospital for the days you have treatment.

The number of doses you have and when you have them depends on your stage of treatment.

Your doctor or nurse will let you know how often you need to have treatment. They will also tell you how you will have treatment, and how long it will take.

First induction treatment

Here we give an example of a common induction cycle. This can vary between hospitals. You may only have two doses of gemtuzumab ozogamicin:

- Day 1: daunorubicin + cytarabine + gemtuzumab ozogamicin
- Day 2: daunorubicin + cytarabine
- Day 3: daunorubicin + cytarabine
- Day 4: daunorubicin + cytarabine + gemtuzumab ozogamicin
- Day 5: cytarabine
- Day 6: cytarabine
- Day 7: cytarabine + gemtuzumab ozogamicin
- Day 8 to 28: no treatment

Second induction treatment

Depending on how you respond to your first cycle, you might need a second induction cycle.

Here we give an example of a common second induction cycle. This can vary between hospitals. You may have different treatment on different days:

- Day 1: daunorubicin + cytarabine
- Day 2: daunorubicin + cytarabine
- Day 3: cytarabine
- Day 4 to 28: no treatment

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Consolidation treatment

You will have consolidation treatment if your AML enters complete remission after induction. Consolidation treatment involves more doses of daunorubicin, cytarabine and gemtuzumab ozogamicin. Your medical team will let you know what treatment you will have on what days.

After your first consolidation cycle, you will have a few weeks without treatment. This is to allow your blood counts to recover. If you respond well to your first consolidation treatment, you may have a second cycle.

Having treatment

Your doctor or nurse will give you treatment to prevent reactions to the medicines. You will have this around 1 hour before you have gemtuzumab ozogamicin. The treatment is usually a steroid, antihistamine, and fever-reducing and pain medicines.

- You have daunorubicin over about 30 minutes.
- For your first induction cycle you have cytarabine as a continuous drip over 7 days.
- For the rest of your treatment cycles, you have cytarabine over about 2 hours.
- You have gemtuzumab ozogamicin over about 2 hours.

Treatment with these medicines can increase your uric acid levels. This can cause gout. It is important to stay hydrated by drinking plenty of water to help prevent this. You might also have medicines to help reduce your risk of this.

Dose

Your medical team will work out the best dose of medicines for you. Your dose will be based on your height, weight and how well you respond to treatment. They will tell you what dose they recommend for you.

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Precautions

These medicines can cause side effects. This includes feeling confused or dizzy, headaches, fatigue and fits (seizures). Take care if you are driving or using tools or machinery.

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Pregnancy, breastfeeding and fertility

These medicines may harm unborn babies.

- If you could get pregnant, it is important to use two methods of contraception. You need to do this while you are having treatment and for 7 months after you stop.
- If you could make someone pregnant, it is important to use two methods of contraception. You need to do this while you are having treatment and for 6 months after you stop.
- If you think you think you might be pregnant, tell your haematology team as soon as possible. They may recommend stopping treatment for a while. They could also recommend switching to a different treatment.
- If you are planning to get pregnant, or make someone pregnant, tell your medical team. They can discuss your treatment options with you.

Breastfeeding

Scientists are not sure if these medicines pass into breast milk. If they do, it could be a risk for breastfed babies or children. You should not breastfeed when having treatment and for 1 month after you stop.

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Monitoring

During your treatment you will have blood tests:

- Before you start your treatment
- After each treatment course
- Regularly throughout your treatment

You may also have occasional bone marrow tests or other tests. Your haematology team will let you know what tests you need and how often.

Your haematology team will use the results of these tests to:

- Check how well your treatment is working for you

- Make sure your blood counts have not dropped too low
- Check how well your liver and kidneys are working

Tumour lysis syndrome

Chemotherapy kills cancer cells. When lots of cancer cells breakdown quickly they can release a large amount of chemicals. These chemicals then enter your bloodstream. This is known as tumour lysis syndrome. It can affect how well your kidneys work. It can also cause changes to your heartbeat and sometimes cause fits (seizures).

If you have a very high leukaemia cell count before treatment, you might have medicine to help prevent tumour lysis syndrome. Your medical team will also monitor you closely. If tumour lysis syndrome develops, they can treat it quickly.

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How long to have this treatment

The number of cycles you have depends on how you respond to treatment and how well your body is coping with it. You have a maximum of two induction and two consolidation cycles.

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Side effects

Like all medicines, daunorubicin + cytarabine + gemtuzumab ozogamicin can cause side effects. Some of these may be serious. Side effects are different for everyone, and we cannot predict what side effects you may or may not get.

Tell your medical team about any side effects you have. They may be able to suggest things you can do or give you medicines to help.

If you are getting side effects that are difficult to cope with, your medical team might suggest:

- Lowering your dose of treatment
- Changing how often you have treatment
- Stopping treatment

Gemtuzumab ozogamicin is a fairly new medicine. It is being monitored more closely than older medicines to help identify new safety information. If you get any side effects that you think are due to gemtuzumab ozogamicin, you can report them directly via the Yellow Card Scheme.

Serious side effects

Your medical team will closely monitor you for serious side effects so they can treat them promptly if they happen.

> **The following side effects may be serious and require urgent treatment. Contact your doctor or nurse straight away if you have any of these side effects.**

- Infections. Signs of infection include:
    - A high temperature (38°C or higher)
    - Sore throat, sneezing, blocked or runny nose or cough
    - Itchy nose, throat and eyes
    - Headache or pain around your eyes, nose and forehead
    - Shortness of breath
    - Burning or stinging when you pee, or peeing more often than usual
    - Painful, hot, red swollen area of skin, blisters or peeling of skin (this may look different on black or brown skin)
    - Coldsores around your lips, mouth or tongue
    - Red patches, ulcers, loss of taste or pain, burning or swelling in your mouth
- Sepsis, which is a life-threatening reaction to an infection. You may get symptoms like:
    - Feeling confused, slurring your words, not making sense
    - Blue, grey, pale or blotchy skin, lips or tongue (this may look different on black or brown skin)

    - A rash that doesn't fade when you roll a glass over it
    - Difficulty breathing, shortness of breath or breathing very fast

- Bleeding
- Liver problems. This can cause symptoms like:
    - Tummy pain
    - Feeling sick or being sick
    - Dark coloured pee and light-coloured poo
    - Yellowing of your skin and the whites of your eyes (this may look different on black or brown skin)
    - Fatigue

- Tumour lysis syndrome. You may get symptoms like:
    - Feeling sick or being sick
    - Weight loss
    - Diarrhoea
    - Muscle weakness

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Very common side effects

Very common side effects affect more than 10 in every 100 people who are having daunorubicin + cytarabine + gemtuzumab ozogamicin.

Very common side effects include:

- Feeling tired, dizzy or short of breath due to a low red blood cell count (anaemia).
- A high blood sugar level, which can make you feel tired or thirsty. You may need to pee more often than usual, have a dry mouth or blurred vision.
- Changes in your liver function, found on blood tests.
- High levels of uric acid in your blood, which can cause gout or affect organs, such as the kidneys.

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Common side effects

Common side effects affect more than 1 but less than 10 out of every 100 people who are having daunorubicin + cytarabine + gemtuzumab ozogamicin.

Common side effects include:

- Blockage of the small veins in the liver. This can cause symptoms like:
  - Yellowing of your skin and the whites of your eyes (this may look different on black or brown skin)
  - A build up of fluid in your tummy, which can cause bloating
  - Sudden weight gain
  - Pain or discomfort under your ribs on the right-hand side

This is not a full list of side effects you might get. Your medical team can give you more information on what to expect from your treatment.

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What to do if you get side effects

Tell your haematology team if you get any side effects. They may be able to suggest things to help. This could include:

- Medicines like antibiotics, antifungals or antivirals to treat and prevent infections
- Blood thinners to help if you have blockages in your blood vessels
- Blood or platelet transfusions if you have low levels of blood cells
- Mouthwashes, rinses and gels to help with sore mouth
- Medicines to prevent and treat sickness and diarrhoea
- Medicines to reduce your uric acid level to prevent gout
- A drip if you're not getting enough fluid

You may need to stay in hospital to manage some of these side effects.

Blood Cancer UK and Macmillan have more information on coping with side effects and treatment.

Hair loss

You might experience hair loss. This is usually temporary. It happens gradually. Some people prefer to shave their hair or cut it short. This can give you a feeling of control and

reduce the emotional impact of it falling out. You could also cover your hair loss, if you choose to. There are lots of options like hats, headscarves, wraps, turbans or wigs.

Cancer Hair Care UK has more information on hair loss, including how to care for Afro-textured hair during chemotherapy

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If this treatment does not work

If daunorubicin + cytarabine + gemtuzumab ozogamicin are not working well, there are a number of different options. Your medical team will explain what they recommend for you.

If your AML does not respond to treatment, this is known as refractory AML. We have more information about relapsed and refractory AML.

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Sources we used to develop this information

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Need support?

You are not alone. We're here for you whether you have a diagnosis yourself or know someone who has. If you'd like advice, support, or a listening ear, call our freephone helpline on 08088 010 444 or send a WhatsApp message to 07500 068 065.

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