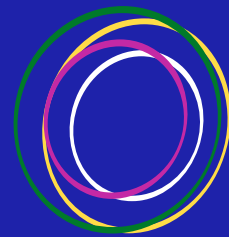


Inotuzumab ozogamicin



Inotuzumab ozogamicin is a medicine used to treat some people with B-cell acute lymphoblastic leukaemia (ALL) that has come back or not responded after treatment. Find out more about what inotuzumab ozogamicin is, how you have it, and what side effects you may get.

This information is aimed at people in the UK. We do our best to make sure it is accurate and up to date but it should not replace advice from your health professional.

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This leaflet includes addresses and QR codes that link to webpages for further support. If you cannot access the webpages, please email information@leukaemiacare.org.uk or call **08088 010 444**.



Summary

- Inotuzumab ozogamicin is a medicine used to treat some people with B-cell acute lymphoblastic leukaemia (ALL).
- Before having it, you'll have tests and scans to make sure it's suitable for you and that you're fit enough to have it.
- You have treatment in cycles. Each cycle is usually 3 to 4 weeks. You have three doses of inotuzumab ozogamicin in each cycle.
- You have between one and six cycles of treatment.
- You may need to stay in hospital for your first cycle. You usually have the rest of your treatment on a hospital day unit.
- You have a steroid, antihistamine and paracetamol before each dose. This helps prevent your body reacting to it. Then you have your treatment through a drip into a vein.
- You may get some side effects from your treatment. Some people have very few side effects. A small number of people may experience more serious side effects.
- Some side effects can be serious if they are not treated promptly. Most people do **not** get these but it's important to know what to look out for. Seek urgent medical help if you have:
 - Pain in your tummy or sides.
 - A swollen tummy or rapid weight gain.
 - Yellowing of the whites of your eyes or your skin. This may be harder to see on black or brown skin.
 - Blood in your pee or you are not peeing as often as usual.
 - A fast or irregular heart rate.
 - Muscle cramps, spasms or weakness.
 - Confusion.
 - Sickness or diarrhoea.
 - Fever or chills.
 - Wheezing or difficulty breathing.
- Tell your haematology team about any side effects you have. They may be able to suggest things you can do or give you medicines to help.

What is inotuzumab ozogamicin?

Inotuzumab ozogamicin is a type of medicine called an antibody-drug conjugate. This means it is a lab-made antibody joined to a chemotherapy drug.

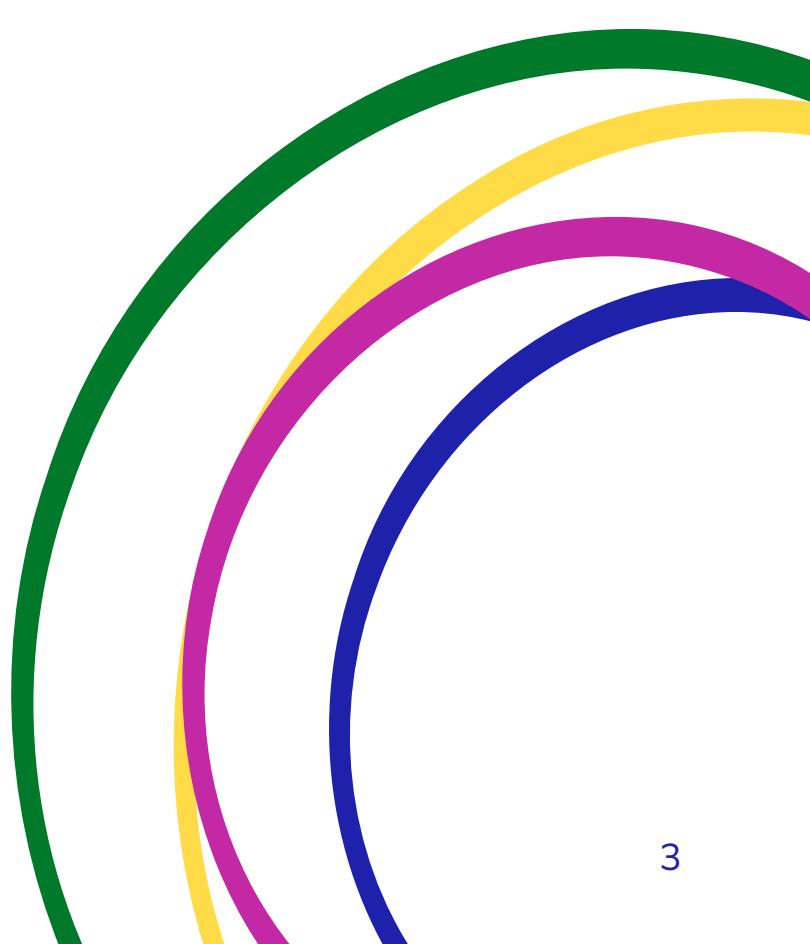
- Inotuzumab is the antibody part. It's designed to stick to a protein called CD22. This protein is on the surface of some types of leukaemia cell.
- Ozogamicin is the chemotherapy part. Once the antibody sticks to a leukaemia cell, the chemotherapy part can then kill the cell.

The brand name for inotuzumab ozogamicin is Besponsa.

Who might have it?

Your haematology team might recommend it for you if:

- You have B-cell ALL that has not responded or has come back after treatment **and**
- Your leukaemia cells make the CD22 protein



Before having your treatment

Before having inotuzumab ozogamicin, you'll have tests and scans to make sure it's suitable for you and that you're fit enough to have it. This might include:



Blood tests to check your blood cell counts, liver and kidney function and to check for any infections that could flare up during treatment



Bone marrow tests to check the level of leukaemia cells



Lab tests to look for genetic changes in your leukaemia cells and check what proteins they make



A lumbar puncture to check for leukaemia cells in the fluid around your brain or spinal cord



A pregnancy test



A heart tracing (ECG)

Your team will tell you if there are any other tests or scans they recommend.

Fertility

Inotuzumab ozogamicin may affect your fertility. If you might want to have children in the future, tell your doctor or nurse. They can talk to you about your options. Your haematology team may refer you to a fertility specialist. This may not be possible for everyone.

Things to tell your haematology team

Before starting treatment, you should tell your haematology team if you:

- Have any allergies or have ever had an allergic reaction
- Have or have ever had any problems with your liver, kidneys, pancreas, gallbladder or bile ducts
- Have or have ever had any problems with your heart
- Have or think you have an infection
- Have recently had or are due to have any vaccines, including travel vaccines
- Are pregnant or breastfeeding

Some medicines or drugs may interact with inotuzumab ozogamicin. It is important to tell your haematology team about any medicines or supplements you're taking. This includes prescribed medicines and any medicines, drugs, supplements or herbal medicines you've bought without a prescription.

Having a central line fitted

You have inotuzumab ozogamicin through a drip into a vein. If you don't already have one, your haematology team may fit a central line. This is a long, thin plastic tube that enters the skin in your arm, chest, neck or groin and ends in a large vein near your heart.



A central line can stay in throughout your treatment. It makes it easier to have the treatment, but it is not essential. There are different types, such as a PICC line, Hickman line or port-a-cath. Your team will explain what type they recommend and what fitting it involves.

Treatment to lower your leukaemia cell count

Before starting inotuzumab ozogamicin, you might have treatment to lower your leukaemia cell count. This may include steroids or chemotherapy. If you need it, your team will tell you what they recommend and what to expect.

Having your treatment

You have inotuzumab ozogamicin through a drip into a vein. You have treatment in cycles.



You may need to stay in hospital to have your first dose or cycle



You usually have the rest of your treatment on a hospital day unit and go home afterwards

Treatment cycles

You have treatment in cycles. Each cycle is usually 3 to 4 weeks. You have three doses of inotuzumab ozogamicin in each cycle. These are on:

- Day 1
- Day 8
- Day 15

After this, you have time to recover before starting the next cycle.

You may have between one and six cycles. It depends on:

- How you respond to the treatment
- If you're having it as your only treatment, or as preparation for a different treatment

Having your dose

- About 30 to 60 minutes before having inotuzumab ozogamicin, you have medicine to help prevent reactions to the treatment. These may include:
 - A steroid
 - An antihistamine
 - Paracetamol
- You might also have medicine and fluids to help prevent a complication called tumour lysis syndrome, if you need it.
- Then you have inotuzumab ozogamicin through a drip into a vein. It usually takes around an hour.
- Your team monitor you for any side effects or reactions during your treatment. And for at least an hour after the drip finishes.

Monitoring your treatment



You'll have blood tests during treatment to check your blood cell counts and liver and kidney function. These check how your body is coping with treatment.



You may also have heart tracings (ECGs) or other tests to monitor side effects from treatment.

Tell your team if you have any side effects, worries or concerns about your treatment.

Measuring your response to treatment

During treatment you will have regular blood tests and occasional bone marrow tests to check how well your ALL is responding to treatment. What tests you have and how often depends on your individual situation.

The tests measure:

- Your blood cell counts. This is sometimes called your **haematological response**. It checks if your blood cell counts have returned to normal and whether specialists can see any leukaemia cells under a microscope.
- The level of leukaemia markers or leukaemia genetic changes in your blood cells. This is called your **molecular response**. It can detect very low levels of leukaemia cells in your bone marrow.

You might hear your doctor talk about measurable residual disease or MRD. If you are MRD negative, it means sensitive molecular tests cannot find any leukaemia cells in your body.

Precautions during treatment

There are some precautions to be aware of when you are having inotuzumab ozogamicin.

Contraception and pregnancy

Inotuzumab ozogamicin may harm unborn babies.

- If you could get pregnant, it is important to use effective contraception. You need to do this while you are having treatment, and for at least 8 months after you stop.
- If you could make someone pregnant, it is important to use effective contraception. You need to do this while you are having treatment, and for at least 5 months after you stop.
- If you think you might be pregnant during and up to 8 months after treatment, tell your haematology team as soon as possible. They will talk to you about your treatment options.
- If you are planning to get pregnant, or get someone pregnant, tell your haematology team before you start treatment. They can discuss your fertility and treatment options with you.

Breastfeeding

Scientists do not know if inotuzumab ozogamicin passes into breast milk. If it does, it could be a risk for breastfed babies or children.

You should not breastfeed when having inotuzumab ozogamicin and for at least 2 months after you stop.

During this time, you can keep your milk supply up by expressing but you must discard the breastmilk. You must **not** use it.

Driving or operating machinery

Inotuzumab ozogamicin can cause fatigue. You should avoid driving, or operating tools or heavy machinery if you feel tired or have a lack of energy.

Vaccinations

Vaccinations support your immune system and help protect against infections. There are two main types: live and non-live.

It is safe to have non-live vaccines if you are taking inotuzumab ozogamicin. But they might not work as well for you as they do in other people.

You should not have live vaccines:

- For at least 2 weeks before starting inotuzumab ozogamicin
- During inotuzumab ozogamicin treatment
- Until your level of white blood cells called B cells has recovered after treatment

Check with your doctor, nurse or pharmacist whether any vaccine they offer you is live or not.

Possible side effects

Like all medicines, inotuzumab ozogamicin can cause side effects. Some people have very few side effects, whereas others get more serious side effects. They may differ from day to day.

Your haematology team should tell you what side effects to look out for and who to contact if you need to.

If you are worried about any symptoms or side effects, contact your haematology team. You do not have to wait until your next appointment.

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

- Prescribe medicines to help manage some side effects
- Suggest things you can do to help you cope with side effects
- Recommend pausing or stopping treatment, if needed

Side effects you might notice

This is not a full list of all the side effects that can happen. The patient information leaflet your haematology team give you will have more information.

If you don't have the leaflet, you can find it at the [Electronic Medicines Compendium](#). Follow the link, scan the QR code or search 'inotuzumab ozogamicin' at [medicines.org.uk](https://www.medicines.org.uk)



Here, we list some of the more common side effects of inotuzumab ozogamicin. These affect at least 1 in every 100 people who take it.



Infections. Contact your team straight away if you think you have an infection. Look out for:

- A high temperature (37.5°C or 38°C or higher)
- Aching muscles, shivering or chills
- Sore throat, sneezing, blocked or runny nose or earache
- Cough, chest pain, shortness of breath, or wheezing
- Burning or stinging when you pee, or peeing more often than usual
- Sickness or diarrhoea
- Headache
- Pain or redness around any cuts, wounds, central lines or drips



Fatigue. You may have extreme tiredness or lack of energy that doesn't get better with rest.



Unexpected bruising or bleeding. You may have nosebleeds, bleeding gums or heavy periods. Look out for blood in your sick or poo, or red or purple spots under your skin. This may look different on black or brown skin. Tell your team if you notice any of these.



Mouth and tummy problems. You might get diarrhoea, constipation, tummy pain, swelling or bloating. You might feel sick or be sick. You may have mouth ulcers or a sore mouth. You may lose your appetite.



Liver problems. You might have yellowing of the whites of your eyes or your skin. This may be harder to see on black or brown skin.



Heart and circulation problems. You may have changes in the electrical activity in your heart. This might make you feel dizzy or faint.



Brain and nervous system problems. You may get headaches or insomnia or feel confused. You might get sudden weakness, numbness or paralysis.

Allergic reaction

Some people develop a reaction to the drip. This is most likely to happen in your first cycle of treatment, but it can happen in later cycles. It can sometimes be serious.

Reactions to the drip happen in around 10 in every 100 people having inotuzumab ozogamicin. Around 90 in every 100 people do **not** have a reaction to the drip.

Your haematology team monitor you closely for any signs of a reaction. If it happens, they'll stop inotuzumab ozogamicin for a while. They might give you steroids or antihistamines, if you need them.

Tell your haematology team immediately if you develop any of the following symptoms of a reaction during or shortly after the drip:

- Fever and chills
- Flushing or reddening of your face, neck or upper chest (this may be harder to see on black or brown skin)
- Wheezing, finding it hard to breathe

Sepsis

Inotuzumab ozogamicin can cause a severe response to an infection, called sepsis. This needs urgent treatment.

Sepsis affects around 2 in every 100 people having inotuzumab ozogamicin. Around 98 in every 100 people do **not** get it.

If it does happen, it can be serious, so it's sensible to know what to look out for.

Contact your doctor straight away if you get symptoms like:

- Confusion, slurred speech or not making sense
- Blue, grey or pale, blotchy skin, lips or tongue (on black or brown skin look on the palms of the hands or soles of the feet)
- A rash that doesn't fade when you roll a glass over it
- Breathing difficulties, such as breathlessness or rapid breathing

Side effects your team might notice

There might be some side effects that your haematology team find during regular checks and blood tests. These include:

- Low blood pressure
- Low levels of red blood cells, white blood cells or platelets
- Changes in your liver, kidney or pancreas function
- Changes in the balance of salts and uric acid in your body
- A rapid increase in your weight or tummy size
- Changes in the electrical activity in your heart, seen on an ECG

Serious side effects to know about

Some side effects of inotuzumab ozogamicin can be serious. Your team will monitor you closely for these so they can manage them promptly if they happen.

Most people do not experience these effects. But it's important to know about them so you can seek help quickly if you need it.

Liver problems

Inotuzumab ozogamicin can sometimes cause a problem with the blood vessels in your liver. This is called VOD/SOS. It can be serious.

VOD/SOS happens to around 3 in every 100 people having inotuzumab ozogamicin. Around 97 in every 100 people do **not** get it.

You'll have regular blood tests to check your liver function. Your team will also monitor you for any signs or symptoms so they can spot liver problems early. If you develop VOD/SOS, you may need to stop inotuzumab ozogamicin.

Tell your haematology team immediately if you notice any of the following symptoms of liver problems:

- Swelling of your tummy.
- Rapid weight gain.
- Pain in the top right-hand side of your tummy.
- Yellowing of the whites of your eyes or your skin. This may be harder to see on black or brown skin.

Tumour lysis syndrome

If lots of cancer cells die at once, they release a lot of chemicals into your blood. This can cause a condition called tumour lysis syndrome (TLS).

TLS affects around 2 in every 100 people having inotuzumab ozogamicin. Around 98 in every 100 people do **not** get it.

TLS can change the balance of salts and uric acid in your body. This can make you very unwell:

- Your kidneys may work less well
- Your heartbeat may become irregular
- You may have fits (seizures)

If you have a high leukaemia cell count before treatment, you might have medicine and fluids to prevent TLS. You'll have blood tests and your team will monitor how much you're drinking and peeing. They'll also closely monitor you for signs of TLS so they can treat it quickly if it happens. If it does, they'll give you fluids. They might pause inotuzumab ozogamicin for a while.

Tell your haematology team immediately if you develop any of the following symptoms of tumour lysis syndrome:

- Pain in your sides
- Blood in your pee or not peeing as often as usual
- Fast or irregular heart rate
- Muscle cramps, spasms or weakness
- Confusion
- Feeling or being sick, diarrhoea

If this treatment is not successful

If inotuzumab ozogamicin doesn't work well for you, or causes side effects that are serious or difficult to cope with, your doctor will discuss your options with you. They might suggest changing your dose, pausing or stopping treatment.

They will talk to you about other treatment options that might be suitable for you.

Finding out treatment hasn't worked as expected can be distressing. **We are here for you if you need support.** Scan the QR code or search 'support and community' at leukaemiacare.org.uk. Or call our Helpline on **08088 010 444**.



We have more **information on your feelings if blood cancer comes back or does not respond to treatment.** Follow the link, scan the QR code or search 'if cancer does not respond' at leukaemiacare.org.uk



We'd like to thank the expert reviewers and patient contributors who helped us with this information:

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Tell us what you think of our information.

Follow the link or scan the QR code to complete a **short survey** about how we can improve our information. You can also contact us for a list of the sources we used.

Email information@leukaemiacare.org.uk or call **08088 010 444**.



Need support or more information?

- Scan the QR code or visit leukaemiacare.org.uk
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