

Inotuzumab ozogamicin

The possible benefits of treatment vary; for some people this Systemic Anti Cancer Treatment (SACT) may reduce the risk of the cancer coming back, for others it may control the cancer and its symptoms. Your doctor will explain to you whether you will receive SACT or another type of treatment, or a combination of both. Your doctor or nurse will be happy to answer any questions you have about your treatment. You will find it useful to refer to the booklet 'Chemotherapy, a guide' which gives general information on chemotherapy and side effects.

Your treatment

Inotuzumab ozogamicin (inotuzumab) is a monoclonal antibody which is combined with an anti-cancer chemotherapy drug. It targets and binds to CD-22 which is found on the surface of B cells. Once bound, it releases the chemotherapy drug which causes cancer cell death. You may sometimes hear this medication referred to as Besponsa. Inotuzumab is used to treat B Cell Acute Lymphoblastic Leukaemia (B-ALL) which has relapsed or is refractory to treatment.

This treatment is given in cycles, each cycle lasting 21-28 days.

It is given into the vein on days 1,8 and 15. Inotuzumab is given for 2 cycles for patients proceeding to stem cell transplant.

For patients not proceeding to stem cell transplant, a maximum of 6 cycles can be administered.

You will be given some medications before each infusion to reduce the risk of infusion related reactions. Inotuzumab is most commonly given as an outpatient but you will come to the day unit regularly for review.

We will ask you to come to clinic every 4 weeks before each course of treatment. You will have a blood test at these appointments to assess whether you are fit to start your next cycle of inotuzumab. Sometimes we may need to delay your next cycle because of low blood counts.

This treatment can have serious or possibly life-threatening side effects. It is very important that you report side effects straight away. Don't delay, if you feel unwell, please ring The Christie Hotline on **0161 446 3658**. The lines are open 24 hours a day.

Increased risk of serious infection

You are vulnerable to infection while you are having chemotherapy. Minor infections can become life-threatening in a matter of hours if left untreated. Symptoms of infection include fever, shivering, sweats, sore throat, diarrhoea, discomfort when passing urine, cough or breathlessness. We recommend that you use a thermometer so you can check your temperature. You can buy one from your local chemist.

If your temperature is 37.5°C or above, or below 36°C or you have symptoms of an infection, contact The Christie Hotline straight away.



Possible side effects

Chemotherapy can cause many different side effects. Some are more likely to occur than others. We are all different, so we may get different side effects with varying severity. Most side effects are usually temporary, but in some rare cases they can be life-threatening. It is important to tell your hospital doctor or nurse about any side effects so they can be monitored and, where possible, treated.

Common side effects (more than 1 in 10)

- **Low white count**

When your white cells are low you will be at an increased risk of infections. If your white cells are very low you may need extra antibiotics and/or GCSF growth-factor injections.

- **Bruising or bleeding**

This treatment can reduce the production of platelets which help the blood to clot. Tell your doctor if you have unexplained bruising or bleeding, such as nosebleeds, bloodspots or rashes on the skin and bleeding gums. You may need a platelet infusion.

- **Anaemia (low number of red blood cells)**

While having this treatment you may become anaemic. This may make you feel tired and breathless. Let your doctor or nurse know if these symptoms are a problem. You may need a blood transfusion and/or an erythropoietin growth-factor injection.

- **Fatigue**

Tiredness and fatigue can happen during and after treatment. Doing gentle exercises each day can help keep your energy up but make sure to take plenty of rest if you need it and ask others for help.

- **Fever**

Please let your healthcare professional know urgently if you have a temperature greater than 37.5°C

- **Altered liver enzymes**

You will have regular blood tests to check on the enzymes in your liver.

Uncommon side effects (less than 1 in 10)

- **Venous occlusive disease (VOD)**

A serious, but uncommon side effect of inotuzumab is veno-occlusive disease (VOD). Your team will keep a close eye on you for signs of a painful enlarged liver, rapid weight gain from fluid retention, and rising bilirubin levels.

The following symptoms require medical attention, but are not an emergency. Contact your health care provider within 24 hours of noticing any of the following:

- Nausea (interferes with ability to eat and unrelieved with prescribed medication)
- Vomiting (vomiting more than 4 - 5 times in a 24 hour period)
- Diarrhoea (4 - 6 episodes in a 24-hour period)
- Constipation unrelieved by laxative use.
- Extreme fatigue (unable to carry out self-care activities)
- Mouth sores (painful redness, swelling and ulcers)
- Yellowing of the skin or eyes
- Swelling of the feet or ankles. Sudden weight gain.
- Signs of infection such as redness or swelling, pain on swallowing, coughing up mucus, or painful urination.
- Unable to eat or drink for 24 hours or have signs of dehydration: tiredness, thirst, dry mouth, dark and decreased amount of urine, or dizziness.

Serious and potentially life threatening side effects

In a small proportion of patients chemotherapy can result in very severe side effects which may rarely result in death. The team caring for you will discuss the risk of these side effects with you.

Late side effects

Some side effects may become evident only after a number of years. In reaching any decision with you about treatment, the potential benefit you receive from treatment will be weighed against the risks of serious long term side effects to the heart, lungs, kidneys and bone marrow. With some drugs there is also a small but definite risk of developing another cancer. If any of these problems specifically applies to you, the doctor will discuss these with you and note this on your consent form.

Sex, contraception and fertility

Women of childbearing potential should avoid becoming pregnant while receiving inotuzumab.

Women should use effective contraception during treatment and for at least 8 months after the last dose. Men with female partners of childbearing potential should use effective contraception during treatment and for at least 5 months after the last dose.

Pregnancy

Inotuzumab must not be used during pregnancy unless the potential benefit to the mother outweighs the potential risks to the foetus. Pregnant women, or patients becoming pregnant while receiving inotuzumab, or treated male patients as partners of pregnant women, must be apprised of the potential hazard to the foetus.

Breast feeding

There is no data on the presence of inotuzumab or its metabolites in human milk; the effects on the breast fed child, or the effects on milk production. Because of the potential for adverse reactions in breast fed children, women must not breast feed during treatment with inotuzumab and for at least 2 months after the final dose.

Fertility

Based on non-clinical findings, male and female fertility may be compromised by treatment with inotuzumab. Both men and women must seek advice for fertility preservation before treatment.

Contacts

If you have any general questions or concerns about your treatment, please contact the Haematology team.

- Lisa Jeffrey, Emma Whitham and Decima Govett, **0161 918 7962**
Haematology nurse specialists
- Haematology and transplant day unit **0161 446 3924**
- General enquiries **0161 446 3000**
- For urgent advice ring The Christie Hotline **0161 446 3658** (24 hours)

Your consultant is:

Your hospital number is:

Your key worker is:

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The Christie is committed to producing high quality, evidence based information for patients. Our patient information adheres to the principles and quality statements of the Information Standard. If you would like to have details about the sources used please contact **the-christie.patient.information@nhs.net**

For information and advice visit the cancer information centres at Withington, Oldham or Salford. Opening times can vary, please check before making a special journey.



Contact The Christie Hotline for
urgent support and specialist advice
The Christie Hotline: 0161 446 3658
Open 24 hours a day, 7 days a week