

Inotuzumab Ozogamicin (Besponsa®)

Pronounce: in-oh-TOOZ-ue-mab oh-zoe-ga-MYE-sin

Classification: Monoclonal Antibody/Antibody Drug Conjugate

About Inotuzumab Ozogamicin (Besponsa®)

Monoclonal antibodies are made in a lab to attach to the targets found on specific types of cancer cells. The antibody "calls" the immune system to attack the cell it is attached to, resulting in the immune system killing the cell. These antibodies can work in different ways, including stimulating (revving up) the immune system to kill the cell, blocking cell growth, or other functions necessary for cell growth.

This medication is an anti-CD22 antibody combined with a calicheamicin and a drug linker, which helps attach the antibody part to the targeted cells, causing DNA damage to the cancer cell and killing it.

How to take Inotuzumab Ozogamicin

This medication is given by an intravenous (IV, into a vein) infusion. The dose is based on your height and weight. It will most likely be given weekly. The number of cycles will be decided by your care team. Before each dose, you will be given acetaminophen (tylenol), diphenhydramine (Benadryl), and possibly a corticosteroid, to help prevent any reactions.

Possible Side Effects

There are a number of things you can do to manage the side effects of inotuzumab ozogamicin. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

Liver Problems

This medication can cause liver toxicity, which your oncology care team may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown, or you have pain in your abdomen, as these can be signs of liver toxicity.

This medication may also potentially cause a serious side effect called veno-occlusive disease, also known as hepatic sinusoidal obstruction syndrome. This is caused by blockage of the blood flow through the small veins of the liver. Symptoms that should be reported to your care team right away include yellowing of the skin or eyes, an enlarged liver which can lead to discomfort in the upper abdomen (belly), weight gain, and fluid buildup in the belly. The chance of having this side effect is higher if you are planning to receive a stem cell transplant after receiving this medication.

Low White Blood Cell Count (Leukopenia or Neutropenia)

White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

Tips to preventing infection:

- Washing hands, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever, or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bathe daily and perform frequent mouth care.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with has any vaccinations.

Low Platelet Count (Thrombocytopenia)

Platelets help your blood clot, so when the count is low you are at a higher risk of bleeding. This medication can cause serious bleeding called hemorrhage so you should let your oncology care team know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums, or blood in your urine or stool. If the platelet count becomes too low, you may receive a transfusion of platelets.

- Do not use a razor (an electric razor is fine).
- Avoid contact sports and activities that can result in injury or bleeding.
- Do not take aspirin (salicylic acid), non-steroidal, anti-inflammatory medications (NSAIDs) such as Motrin/Advil (ibuprofen), Aleve (naproxen), Celebrex (celecoxib), etc. as these can all increase the risk of bleeding. Please consult with your healthcare team regarding the use of these agents and all overthe-counter medications/supplements while on therapy.
- Do not floss or use toothpicks and use a soft-bristle toothbrush to brush your teeth.

Low Red Blood Cell Count (Anemia)

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the red cell count is low, you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing or pain in your chest. If the count gets too low, you may receive a blood transfusion.

Fatigue

Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

Nausea and/or Vomiting

Talk to your oncology care team so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

Pain and Headache

Your healthcare provider can recommend medications and other strategies to help relieve pain.

Important but Less Common Side Effects

- *Infusion-Related Side Effects*: The infusion can cause a reaction that may lead to chills, fever, rash, and breathing issues. You will receive medications prior to the infusion to help prevent these reactions. You will be monitored closely during the infusion and for one hour after the infusion is complete. Notify your nurse of any changes in how you are feeling.
- **Heart Problems**: This medication can cause slow or abnormal heartbeats or an abnormal heart rhythm called QT prolongation. Tell your oncology care team right away if you feel abnormal heartbeats or if you feel dizzy or faint. You will be monitored with an electrocardiogram (ECG) prior to starting treatment and as needed.

Reproductive Concerns

This medication may affect your reproductive system, resulting in the menstrual cycle or sperm production becoming irregular or stopping permanently. Women may experience menopausal effects including hot flashes and vaginal dryness. In addition, the desire for sex may decrease during treatment. You may want to consider sperm banking or egg harvesting if you may wish to have a child in the future. Discuss these options with your oncology team.

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control is necessary during treatment and for at least 8 months after treatment for women and for 5 months for men. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should not breastfeed while taking this medication and for 2 months after the last dose.

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