

## Inotuzumab Ozogamicin (Besponsa®)

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### About This Drug

Inotuzumab ozogamicin is used to treat cancer. It is given in the vein (IV).

### Possible Side Effects

- Bone marrow suppression. This is a decrease in the number of white blood cells, red blood cells, and platelets. This may raise your risk of infection, make you tired and weak (fatigue), and raise your risk of bleeding.
- Fever or fever in the setting of decreased white blood cells, which can be life-threatening
- Nausea
- Pain in your abdomen
- Abnormal bleeding – symptoms may be coughing up blood, throwing up blood (may look like coffee grounds), red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds or any other unusual bleeding.
- Tiredness
- Infection
- Changes in your liver function
- Headache

**Note:** Each of the side effects above was reported in 20% or greater of patients treated with inotuzumab ozogamicin. Not all possible side effects are included above.

### Warnings and Precautions

- Severe changes in your liver function and blockage of small veins in the liver, which can cause liver failure and be life-threatening
- Abnormal heart beat
- Increased risk of complications and death in patients who will undergo a stem cell transplant after receiving inotuzumab ozogamicin
- Severe bone marrow suppression which can be life-threatening
- While you are getting this drug in your vein (IV), you may have a reaction to the drug. Sometimes you may be given medication to stop or lessen these side effects. Your nurse will check you closely for these signs: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble

breathing, rash, itching, chest tightness, or chest pain. **These reactions may happen after your infusion. If this happens, call 911 for emergency care.**

**Note:** *Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.*

## Important Information

- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.

## Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your doctor or nurse tells you, and whenever you feel like you may have a fever.
- To help decrease bleeding, use a soft toothbrush. Check with your nurse before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- If you throw up or have loose bowel movements, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- Infusion reactions may occur after your infusion. If this happens, call 911 for emergency care.

## Food and Drug Interactions

- There are no known interactions of inotuzumab ozogamicin with food.
- This drug may interact with other medicines. Tell your doctor and pharmacist about all the prescription and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs and others) that you are taking at this time. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

## When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4 F (38 C) or higher
- Chills
- Tiredness that interferes with your daily activities
- Feeling dizzy or lightheaded
- Easy bleeding or bruising
- Feeling that your heart is beating fast or in a not normal way (palpitations)
- Blood in your urine, vomit (bright red or coffee-ground) and/or stools ( bright red, or black/tarry)
- Coughing up blood
- Signs of a local infection such as pain, redness, tenderness, warmth and/or swelling
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Signs of infusion reaction: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, rash, itching, chest tightness, or chest pain.
- Signs of possible liver problems: dark urine, pale bowel movements, bad stomach pain, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Pain in your abdomen that does not go away
- If you think you may be pregnant or may have impregnated your partner

## Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of child bearing potential should use effective methods of birth control during your cancer treatment and for at least 8 months after treatment. Men with female partners of child bearing potential should use effective methods of birth control during your cancer treatment and for at least 5 months after your cancer treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for at least 2 months after treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men and women both, this drug may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

Revised April 2019