

INTRAVENOUS CANCER TREATMENT EDUCATION



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INOTUZUMAB OZOGAMICIN

Name of the regimen and cancer drugs

Inotuzumab ozogamicin (ih noh TOO zoo mab OH zoh ga MIH sin): Besponsa®

Common uses

Inotuzumab ozogamicin is most commonly used to treat B-cell Acute Lymphoblastic Leukemia (B-ALL) but may be used for other treatments.

Treatment schedule

Your treatment will be given into your vein through an intravenous (IV) line. This may be into a short, flexible temporary catheter in your arm, or through a central venous catheter. A central venous catheter, or central line is a long, flexible IV tube that empties into a very large vein next to the heart. Talk with your care team to see which will be best for you and your treatment.

Each inotuzumab ozogamicin treatment is repeated every 28 days. This is known as one cycle. Your treatment may be given for a set number of cycles, or it will keep going until the drug stops working or you have side effects which stop you from continuing treatment.

- Inotuzumab ozogamicin IV infusion is given over 1 hour on days 1, 8, and 15 in cycle one and then every 28 days.

Drug	Cycle 1	Day 1	2	3	4	...	8	9	10	11	12	13	14	15	...	28	Cycle 2 Day 1
Inotuzumab ozogamicin																	

Other medications

Other medications may be ordered for you to prevent or treat certain side effects. These include:

	Instructions:
Anti-nausea medications	<p>You will receive medications to prevent nausea just before your cancer treatment. You may also get prescriptions for other medications to take at home, as below:</p> <p>_____</p> <p>_____</p> <p>_____</p>
Infection prevention	<p>There is a risk of serious infections during treatment. You may receive medications to prevent infection in the hospital, and may also get prescriptions for medications to take at home for infection prevention, as below:</p> <p>_____</p> <p>_____</p> <p>_____</p>

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Possible drug interactions

- Inotuzumab ozogamicin may interact with other drugs you are taking. Please inform your care providers of all prescription medicine, over-the-counter medications, vitamins, and herbal products that you take.
- Talk with your care provider or pharmacist before taking new medications, supplements, or receiving any vaccines.

Common Side Effects

Common side effects that have been known to happen in patients receiving inotuzumab ozogamicin are listed in the left side of this table. In some instances, the side effects may be reported less often but are still important to discuss. This table does not list all the known side effects for this therapy, only the ones that are experienced most often. Not every patient experiences every known side effect of a drug; even if you are taking the same drug as another patient, you may experience different side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
<p>Decreased white blood cells (WBCs) and increased risk for infection</p>	<p>Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection.</p> <ul style="list-style-type: none"> • Wash your hands often, especially before eating and after using the bathroom. • Avoid crowds and people with fevers, flu, or other infection. • Bathe often for good personal hygiene. <p>Contact your care team if you experience any signs or symptoms of an infection such as: Fever (temperature more than 100.4°F or 38°C)</p> <ul style="list-style-type: none"> • Chills • Sore throat • Burning when peeing • Tiredness that is worse than normal • A sore that becomes red, is draining, or does not heal. <p>Check with your care team before taking any medicine for a fever or chills.</p>
<p>Decreased platelet count and increased risk of bleeding</p>	<p>Your platelets should be monitored by a simple blood test. When they are low, you may bruise or bleed more easily than usual.</p> <ul style="list-style-type: none"> • Use caution to avoid bruises, cuts, or burns. • Blow your nose gently and do not pick your nose • Brush your teeth gently with a soft toothbrush and maintain good oral hygiene • When shaving use an electric razor instead of razor blades • Use a nail file instead of a nail clippers <p>Call your care team if you have bleeding that won't stop. Examples include:</p> <ul style="list-style-type: none"> • A bloody nose that bleeds for more than 5 minutes despite pressure • A cut that continues to ooze despite pressure • Gums that bleed a lot when you floss or brush

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Possible Side Effect	Management
<p>Decreased platelet count and increased risk of bleeding (continued)</p>	<p>Seek medical help right away if you have any severe headaches, blood in your urine or stool, coughing up blood, or bleeding that you cannot stop or lasts a long time.</p> <p>You may need to take a break or “hold” your medication for medical or dental procedures. Talk to your care team or dentist before any scheduled procedures.</p>
<p>Decreased hemoglobin, part of the red blood cells that carry iron and oxygen</p>	<p>Your hemoglobin should be checked by a simple blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.</p> <ul style="list-style-type: none"> • Try to get 7 to 8 hours of sleep per night • Avoid operating heavy machinery if you feel too tired • Find a balance between “work” and “rest” • Stay as active as possible, but know that it is okay to rest as needed, too • You might notice that you are more pale than usual <p>Let your care team know right away if you have:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Fast or abnormal heartbeat
<p>Changes in liver function</p>	<p>Your liver function will be checked every so often by a simple blood test. Contact your care team if you notice any of the following.</p> <ul style="list-style-type: none"> • Yellowing of the skin or whites of your eyes • Dark or brown urine • Bleeding or bruising
<p>Fatigue</p>	<ul style="list-style-type: none"> • You may be more tired than usual or have less energy. • Stay as active as possible, but know it is okay to rest as needed. • Try to do some type of moderate activity every day. • Conserve your energy. Plan your activities and do them at a time of day when you feel a bit more energetic. • Follow a healthy diet and stay hydrated. • Accept help from family and friends • Find healthy ways to manage stress, such as meditation, journaling, yoga, and guided imagery • Develop good sleeping habits, limit napping during the day to help you sleep better at night. • Avoid operating heavy machinery if you feel too tired. • Contact your care team if you experience extreme fatigue that prevents you from doing your normal daily activities.
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Possible Side Effect	Management
Nausea or vomiting	<ul style="list-style-type: none">• Take all medications as prescribed to help prevent and lessen symptoms of nausea and vomiting• Eat and drink slowly• Drink 8-10 (8-ounce) glasses of water and/or fluid (soup or broth) each day unless your care team has instructed you to limit your fluid intake• Eat small, frequent meals throughout the day rather than a few large meals• Eat bland foods; avoid spicy, fried, and greasy foods
Fever	<p>You may feel hot, cold and shivery, achy or dizzy. This usually starts during the first month of therapy but could happen at any time.</p> <ul style="list-style-type: none">• Call your doctor immediately if you have a fever 100.4° F• Ask your doctor if you can take medicine to help with the fever

Rare but serious side effects

- Infusion reaction: Inotuzumab ozogamicin can cause infusion reactions. During your treatment, let the nurse know right away if any of these symptoms happen: chills or shaking, dizziness, fever, itchiness or rash, flushing, difficulty breathing, wheezing, sudden back pain, or feeling faint.
- QTc prolongation: Inotuzumab ozogamicin may cause changes to the electrical activity of your heart. Tell your care team right away if you feel faint, lightheaded, or dizzy, or if you feel your heart beating irregularly or fast, while taking Inotuzumab ozogamicin.

If you experience ANY new, worsening, or uncontrolled side effects, call your care team immediately.

(INSTITUTIONAL CONTACT INFO)

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Handling body fluids and waste

Some of the drugs you receive may be present in urine, stool, sweat, or vomit for many days after treatment. Many cancer drugs are toxic, your bodily waste may also be toxic and can be dangerous to come into contact with. Once you have started inotuzumab ozogamicin, follow the instructions below for at least two days after your treatment. This is to keep you, your loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure that all waste has been discarded.
- If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surface after every use before other people use the toilet.
- Wash hands with soap and water after using the toilet for at least 20 seconds.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Intimacy, sexual activity, contraception, and fertility

This treatment may cause changes that can affect intimacy and sexuality, including desire and body image. Maintaining physical closeness and/or intimacy with loved ones can be continued during treatment. Holding hands, hugging, and kissing can be done safely. It is recommended that you talk to your care team about any restrictions or questions you may have.

Some treatments can influence the ability to have children, also known as fertility. If you're interested in preserving fertility, talk to your care team before treatment. Ask your healthcare provider to determine when it is safe to become pregnant after your treatment. Patients of reproductive ability should not become pregnant or get their partners pregnant while receiving inotuzumab ozogamicin. Some of the drugs you receive may be present in semen and vaginal secretion for many days after treatment. You should use barrier devices, such as condoms, during sexual activity to limit exposure to body fluids.

- Talk to your care team about birth control. Not all options may be right for your treatment or cancer. Effective contraception could include one or more of the following: barrier methods (e.g. condoms), hormone methods (e.g. birth control pills), or surgery.
- Tell your care team if you become pregnant or plan to breastfeed.

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Additional resources

Besponsa prescribing information link: <http://labeling.pfizer.com/ShowLabeling.aspx?id=9503>

Besponsa product resources: <https://www.besponsa.com/resources>

Additional instructions

Updated – March 20, 2022

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the therapy derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this therapy and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this therapy by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual receiving therapy. All decisions related to receiving this therapy should be made with the guidance and under the direction of a qualified healthcare professional.

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