

INTRAVENOUS CANCER TREATMENT EDUCATION



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OBINUTUZUMAB (21 DAY REGIMEN)

Name of the regimen and cancer drugs

- Obinutuzumab (OH bin yoo TOO zoo mab): Gazyva®

Common uses

Obinutuzumab is most commonly used for chronic lymphocytic leukemia (CLL) and follicular lymphoma (FL) but may be used for other diagnoses. Obinutuzumab may be used as alone or in combination with other medications.

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 obinutuzumab treatment is repeated every 21 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, or drugs, stop working or you have side effects which stop you from continuing treatment.

Cycle 1:

- Obinutuzumab IV given on days 1, 2, 8, 15 for CLL OR days 1, 8, 15 for FL

Drug (diagnosis)	Cycle 1	Day 1	2	3	...	8	...	15	...	21	Cycle 2 Day 1
Obinutuzumab (CLL)											
Obinutuzumab (FL)											

Cycles 2-6:

- Obinutuzumab IV given on day 1

Drug	Cycles 2-6	Day 1	2	3	...	8	...	15	...	21	Cycle 3 Day 1
Obinutuzumab											

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Other medications

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

	Instructions:
Medications to prevent side effects	<p>You will receive your medications to prevent side effects just before your cancer treatment. You may get prescriptions for other medications to take at home, as below:</p> <hr/> <hr/> <hr/> <hr/>
Medications to prevent allergic reactions	<p>You will receive medications to prevent infusion related reactions prior to starting your cancer treatment.</p> <hr/> <hr/> <hr/> <hr/>
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> <hr/> <hr/> <hr/> <hr/>

Possible drug interactions

- Obinutuzumab 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. Do not receive any live vaccines while on treatment with obinutuzumab.

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Common Side Effects

Common side effects that have been known to happen in patients receiving obinutuzumab 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 infections. • Bathe often for good personal hygiene. <p>Contact your care team if you experience any signs or symptoms of an infection such as:</p> <ul style="list-style-type: none"> • Fever (temperature more than 100.4°F or 38°C) • 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 <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. 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>

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Possible Side Effect	Management
<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>Infusion reactions</p>	<p>Obinutuzumab can cause an infusion reaction. During your treatment, let the nurse know right away if any of these symptoms happen:</p> <ul style="list-style-type: none"> • Chills or shaking • Dizziness • Fever • Itchiness or rash • Flushing • Sweating • Difficulty breathing • Face or throat swelling • Wheezing • Sudden back pain • Feeling faint
<p>Changes in liver function</p>	<p>Your liver function will be checked regularly 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>	<p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none"> • 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.

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Possible Side Effect	Management
<p>Fatigue (continued)</p>	<ul style="list-style-type: none"> Avoid operating heavy machinery if you feel too tired. <p>Contact your care team if you experience extreme fatigue that prevents you from doing your normal daily activities.</p>
<p>Lung (respiratory tract) infection or cough</p>	<p>Wash your hands often, especially before eating and after using the bathroom</p> <ul style="list-style-type: none"> Avoid people with fevers, flu, or other infections Bathe often to keep good personal hygiene Report symptoms of a lung infection like a cough, sneezing, runny nose, fever, and scratchy or sore throat to your provider
<p>Constipation</p>	<p>Keep track of how many bowel movements you have each day.</p> <ul style="list-style-type: none"> Drink 8-10 (8-ounce) glasses of water or fluid each day unless your care team has asked you to limit your fluid intake. Stay active and exercise, if possible. Eat foods high in fiber like raw fruits and vegetables. <p>Contact your care team if you have not had a bowel movement in 3 or more days.</p> <p>Your care team may recommend over-the-counter medications to help with constipation. A daily stool softener such as docusate (Colace®) and/or laxative such as senna (Senakot®) may be helpful. If these do not help within 48 hours, tell your care team.</p>
<p>Diarrhea</p>	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> Drink 8-10 (8-ounce) glasses of water or fluid each day unless your care team has asked you to limit your fluid intake. Eat small, frequent meals throughout the day rather than a few large meals. Eat bland, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast). Avoid high fiber foods, such as raw vegetables and fruits and whole grains. Avoid foods that cause gas, such as broccoli and beans. Avoid foods with lactose, such as yogurt and milk. Avoid spicy, fried, and greasy foods. <p>Contact your care team if:</p> <ul style="list-style-type: none"> The number of bowel movements you have in a day increases by 4 or more. You feel dizzy or lightheaded. <p>Your care team may recommend an over-the-counter medication or prescribe something to help manage your symptoms.</p>

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Possible Side Effect	Management
Changes in electrolytes and other laboratory values: <ul style="list-style-type: none">• High uric acid levels• High potassium levels• High phosphorus levels• Low calcium levels	<p>Changes in some lab values may occur and will be monitored by a simple blood test.</p> <ul style="list-style-type: none">• You may not feel any symptoms if the changes are mild and they usually are not a sign of a serious problem• More severe changes may occur which can be a sign of a serious problem <p>Notify your care team if you have any of the following:</p> <ul style="list-style-type: none">• Shortness of breath• Chest discomfort• Weakness or fatigue• New aches and pains• Headaches• Dizziness• Swelling of your legs or feet• Red or brown colored urine

Rare but serious side effects

- Obinutuzumab can cause hepatitis B virus (HBV) reactivation in patients previously infected with HBV. You may be tested for HBV prior to beginning treatment with this medication. Be sure your healthcare provider is aware of any previous HBV diagnosis and treatment, if known. Patients with past HBV infection may need preventative antiviral medication while receiving and for months after completing this medication. Additional routine monitoring of HBV levels may be needed in patients who were previously infected with HBV.
- Obinutuzumab may cause a condition called tumor lysis syndrome when starting treatment. This results from the rapid destruction of cancer cells in the body during the initial cycles of treatment. Your care team may do blood tests to check for this side effect.
- Obinutuzumab can cause progressive multifocal leukoencephalopathy (PML). Please contact your healthcare team for any changes in vision, speech, or behavior.
- Obinutuzumab may cause harm to the fetus if administered to pregnant women. Please contact your healthcare professional if you are or suspect that you are pregnant, as this may result in an alternative treatment plan.

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 obinutuzumab, 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 obinutuzumab. 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

Product website: <https://www.Gazyva.com>

Prescribing information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125486s017s018lbl.pdf

Additional instructions

Updated – March 1, 2023

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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