

Generic Name: **Obinutuzumab**

Brand Name: **Gazyva**

Drug Classification: Anti-CD20 Monoclonal Antibody (mAb)

INDICATIONS FOR USE

- Obinutuzumab can be given alone or in combination with many other medications to treat CLL or SLL.
- **For CLL or SLL without 17p deletion or TP53 mutation:** For those requiring treatment for the first time (front-line therapy), obinutuzumab can be given alone or in combination with many other medications. These include acalabrutinib, venetoclax, chlorambucil, methylprednisolone, bendamustine, or ibrutinib as a first-line therapy. Obinutuzumab administered alone is generally not the preferred treatment when a second round of treatment is needed (second-line therapy), but it can be added to other second-line combination therapies.
- **For CLL or SLL with 17p deletion or TP53 mutation:** Obinutuzumab can be given alone, or in combination with other medications (such as acalabrutinib or venetoclax) as a front-line therapy. For patients with 17p and or TP53 mutation, it is not recommended as a second-line or subsequent therapy option.

ADMINISTRATION ROUTE

This medication is infused through a vein intravenously (IV).

LENGTH OF TIME ADMINISTERED

Obinutuzumab is given for a pre-determined limited amount of time (also called limited-duration, fixed-duration, or time-limited therapy).

DOSING

Dose and frequency of dosing are dependent upon what other drugs obinutuzumab is given with. However, it is typically administered only on specific days within a pre-determined 28-day treatment cycle.

MISSED DOSE

Call your healthcare provider if you miss an appointment for your infusion.

HOW TO TAKE THIS MEDICATION

This medication is administered IV by your healthcare team, typically in an infusion center or other outpatient healthcare setting.

COMBINATION THERAPIES

Can be used in combination with multiple other

medications (ibrutinib, acalabrutinib, venetoclax, fludarabine, chlorambucil, or methylprednisolone) and with various combinations of other medications being studied in clinical trials.

COMMON SIDE EFFECTS

Side effects can occur as a result of any medication, some of which may go away with time as your body adjusts to the new medication. Please notify your healthcare provider if any of the following side effects occur:

- Infusion-related reactions can happen, especially after the first reaction (symptoms include hives, rash, itching, swelling of lips, tongue or throat, sudden cough, shortness of breath, weakness, dizziness, feeling faint, heart palpitations, or chest pain)
- Low white blood cell count, low red blood cell count, or low platelet count
- Any symptoms of infection (fever, stuffy nose, cough, sore throat, etc.)
- Call your doctor immediately if you have dizziness, balance difficulty, problems with speech, thought or vision or loss of coordination.
- Generalized body aches, muscle spasms, or aching joints
- Fatigue or tiredness
- Diarrhea
- Constipation

Other side effects not mentioned above may also occur. Notify your healthcare provider of any other unusual symptoms, as they may be able to tell you about ways to prevent or reduce certain side effects.

MANAGING COMMON SIDE EFFECTS

Some side effects are more common than others, many of which will go away after a short period of time after staying on the medication. It is important to talk to your healthcare provider to discuss if you might be able to manage side effects in the short term to stay on the therapy until your body has time to adjust to the new medication. Here are some possible ways to help manage some of the most common side effects of obinutuzumab in consultation with your healthcare provider.

Fatigue or Tiredness

- Ensure you are eating a well-rounded diet that includes a balance of lean meats, fruits, vegetables, whole grains, and limited amounts of processed foods.
- Incorporate light types of exercise (such as walking).
- If you are able, take one short twenty-minute nap during the day. Frequent or longer naps during the day can affect the amount of sleep you are getting during the night and increase fatigue/tiredness.

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Muscle, Joint, or Bone Pain

- Take acetaminophen (i.e., Tylenol) per package instructions.
- It is important to avoid taking anti-inflammatories (such as ibuprofen) for mild pain while taking venetoclax due to the slightly increased risk of bleeding.
- Antihistamines may help with bone pain.
- Magnesium supplements may help muscle cramping.
- Gentle stretching, application of heat or ice to affected area(s).
- If you are experiencing more severe joint pain, your healthcare provider may prescribe a short course of steroids.

Diarrhea

- Increase your fluid intake.
- Take anti-diarrheal medications (such as Imodium) per package instructions.
- Eat a bland diet (such as bananas, rice, apples/ applesauce, toast, or plain pasta).

Constipation

- Increase your fluid intake.
- Consume more foods that are high in fiber (such as vegetables and whole grain bread).
- Consider over-the-counter fiber supplements (such as Fibercon, Miralax, or Metamucil).
- Move around more, as walking and other forms of exercise can help.
- Take over the counter stool softeners (such as Colace) to help soften bowel movements.

REASONS TO TALK TO YOUR HEALTHCARE PROVIDER

The presence of other medical problems may affect the use of obinutuzumab. Make sure you share with your healthcare provider if you have any of the following health conditions:

- Heart, lung, or kidney problems
- Current, recent, or recurring infections (including hepatitis B, hepatitis COVID-19, cytomegalovirus, herpes simplex virus, parvovirus B19, varicella zoster virus/shingles, or West Nile virus)
- If you have recently been vaccinated or are scheduled to receive any vaccinations
- Pregnant or breastfeeding (or if you plan to become pregnant/breastfeed)

Always tell your healthcare provider about all the medications you take, including prescription and over the counter medicines, vitamins, and herbal supplements.

SPECIAL CONSIDERATIONS

- You should undergo a blood test for hepatitis B virus before receiving obinutuzumab, as it can reactivate the dormant virus. This can result in active infection requiring protective medication.
- A rare and potentially life-threatening event called tumor lysis syndrome (TLS) can occur due to the rapid killing of cancer cells, which happens so quickly that the body doesn't have time to clear out all the debris released from inside the cancer cells when they break open. This rapid uncontrolled release of the cell contents can potentially cause cardiovascular, renal, and neurological dysfunction. Your healthcare provider will assess your risk for TLS prior to initiating obinutuzumab. With close monitoring and preventative therapy, the incidence of TLS can be greatly reduced.
- Following each infusion, severe reactions may occur on mucous membranes or the skin. Tell your healthcare provider if you develop ulcers on your skin, lips, mouth or develop blisters, peeling skin, rash, or pustules.
- Obinutuzumab may cause low levels of antibodies that help to fight off infections and can potentially cause serious bacterial, viral, and fungal infections.
- Obinutuzumab may cause your body to not mount an immune response to vaccinations for some time after treatments are complete. This can decrease their effectiveness to fight off infection and can lead to potentially serious bacterial, viral, and fungal infections. Talk to your healthcare provider about getting up to date on all of the recommended vaccinations prior to starting this therapy.
- Although it is rare, a brain infection caused by a virus can occur known as Progressive Multifocal Leukoencephalopathy (PML). It is important to report any symptoms such as confusion, dizziness, loss of balance, difficulty talking or walking, decreased strength, or weakness on one side of the body, or vision problems to your healthcare provider immediately.
- Obinutuzumab can result in late-onset neutropenia (low neutrophil blood count) which can result in serious life-threatening complications, although most cases appear to resolve without issue. Your healthcare provider will be carefully monitoring your lab results.