



It's time to rethink GAZYVA

Eight FDA-Approved Regimens Across FL & CLL¹⁻⁴

Indications

GAZYVA is a CD20-directed cytolytic antibody indicated:

- In combination with chlorambucil, for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL)
- In combination with bendamustine followed by GAZYVA monotherapy, for the treatment of patients with follicular lymphoma who relapsed after, or are refractory to, a rituximab-containing regimen
- In combination with chemotherapy followed by GAZYVA monotherapy in patients achieving at least a partial remission, for the treatment of adult patients with previously untreated stage II bulky, III or IV follicular lymphoma (FL)

Select Important Safety Information

BOXED WARNINGS: HEPATITIS B VIRUS REACTIVATION AND PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY

- **Hepatitis B Virus (HBV) reactivation**, in some cases resulting in fulminant hepatitis, hepatic failure, and death, can occur in patients receiving CD20-directed cytolytic antibodies, including GAZYVA. Screen all patients for HBV infection before treatment initiation. Monitor HBV-positive patients during and after treatment with GAZYVA. Discontinue GAZYVA and concomitant medications in the event of HBV reactivation
- **Progressive Multifocal Leukoencephalopathy (PML)** including fatal PML, can occur in patients receiving GAZYVA

→ [Click here](https://www.gene.com/download/pdf/gazyva_prescribing.pdf) for full prescribing information and throughout for additional important safety information, including Boxed Warning.

https://www.gene.com/download/pdf/gazyva_prescribing.pdf


GAZYVA[®]
obinutuzumab
injection | 1,000mg/40mL

8

Eight FDA-Approved Regimens Across FL & CLL, With Many Studies Ongoing¹⁻⁴

Approved in 2013
1L CLL

GAZYVA + chlorambucil¹

GAZYVA in combination with chlorambucil is indicated for the treatment of patients with previously untreated CLL.

Approved in 2016
R/R FL

GAZYVA + bendamustine¹

GAZYVA in combination with bendamustine followed by GAZYVA monotherapy, for the treatment of patients with FL who relapsed after, or are refractory to, a rituximab product-containing regimen.

Approved in 2017
1L FL

GAZYVA + bendamustine¹

followed by GAZYVA monotherapy.

GAZYVA + CHOP¹

followed by GAZYVA monotherapy.

GAZYVA + CVP¹

followed by GAZYVA monotherapy.

In patients achieving at least a partial remission, for the treatment of adult patients with previously untreated stage II bulky, III or IV follicular lymphoma (FL).

Approved in 2019
1L CLL/SLL

GAZYVA + ibrutinib^{2,*}

Ibrutinib is indicated for the treatment of adult patients with CLL/SLL.

GAZYVA + venetoclax tablets^{3,*}

Venetoclax tablets are indicated for the treatment of adult patients with CLL/SLL.

GAZYVA + acalabrutinib^{4,*}

Acalabrutinib is indicated for the treatment of adult patients with CLL/SLL.

***Refer to the full Prescribing Information for ibrutinib, venetoclax tablets, and acalabrutinib for additional information including Indications, Safety, and Dosing.**

2020+

GAZYVA continues to be studied in CLL and FL.

Important Safety Information

Contraindications

- GAZYVA is contraindicated in patients with known hypersensitivity reactions (e.g. anaphylaxis) to obinutuzumab or to any of the excipients, or serum sickness with prior obinutuzumab use

Additional Warnings and Precautions

- Infusion-Related Reactions:** Premedicate patients with glucocorticoid, acetaminophen, and antihistamine. Monitor patients closely during infusions. Interrupt, reduce rate, or discontinue for infusion-related reactions based on severity
- Hypersensitivity Reactions Including Serum Sickness:** Discontinue GAZYVA permanently
- Tumor Lysis Syndrome (TLS):** Premedicate with antihyperuricemics and adequate hydration, especially for patients with high tumor burden, high circulating lymphocyte count or renal impairment. Correct electrolyte abnormalities, provide supportive care, and monitor renal function and fluid balance

Click here for full prescribing information and throughout for additional important safety information, including Boxed Warning.

https://www.gene.com/download/pdf/gazyva_prescribing.pdf

Important Safety Information (cont'd)

Additional Warnings and Precautions (cont'd)

- Infections:** Do not administer GAZYVA to patients with an active infection. Patients with a history of recurring or chronic infections may be at increased risk of infection
- Neutropenia:** In patients with Grade 3 to 4 neutropenia, monitor laboratory tests until resolution and for infection. Consider dose delays and infection prophylaxis, as appropriate
- Thrombocytopenia:** Monitor platelet counts and for bleeding. Transfusion may be necessary
- Immunization:** Avoid administration of live virus vaccines during GAZYVA treatment and until B-cell recovery
- Embryo-Fetal Toxicity:** Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and use effective contraception



Important Safety Information (cont'd)

Additional Important Safety Information

The most common adverse reactions (incidence $\geq 20\%$ and $\geq 2\%$ greater in the GAZYVA treated arm) were:

- CLL were infusion-related reactions (66%), neutropenia (38%)
- Relapsed or refractory NHL: infusion-related reactions (67%), fatigue (40%), neutropenia (37%), upper respiratory tract infection (36%), cough (31%), and musculoskeletal pain (28%)
- Previously untreated NHL: infusion-related reactions (72%), neutropenia (53%), upper respiratory tract infection (50%), cough (35%), constipation (32%), diarrhea (30%)

You are encouraged to report side effects to Genentech and the FDA. You may contact Genentech by calling 1-888-835-2555. You may contact the FDA by visiting www.fda.gov/medwatch, or calling 1-800-FDA-1088.

Click [here](#) for full prescribing information and please see additional important safety information throughout, including BOXED WARNINGS.

CHOP, cyclophosphamide, doxorubicin hydrochloride, vincristine, and prednisone; CLL, chronic lymphocytic leukemia; CVP, cyclophosphamide, vincristine sulfate, and prednisone; FL, follicular lymphoma; SLL, small lymphocytic lymphoma.

References: **1.** GAZYVA® (obinutuzumab) full Prescribing Information. South San Francisco, CA: Genentech, Inc.; 2020. **2.** IMBRUVICA® (ibrutinib) Prescribing Information. Horsham, PA: Janssen Biotech, Inc.; 2019. **3.** VENCLEXTA® (venetoclax tablets) Prescribing Information. North Chicago, IL: AbbVie Inc.; 2019. **4.** CALQUENCE® (acalabrutinib) Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2019.

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