

Alyglo[®]
immune globulin
intravenous, human-stwk
10% liquid

Less sick time. More you time.

It's
glo
time

[Patient Guide](#)

ALYGLO[®] is indicated for the treatment of primary humoral immunodeficiency (PI) in adults aged 17 years and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency (CVID), Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

IMPORTANT SAFETY INFORMATION

- **Thrombosis (blood clot formation) can happen with ALYGLO.** Factors that increase this risk include advanced age, prolonged immobility, certain medical conditions, and cardiovascular risk factors.
- **ALYGLO may affect the kidneys.** In some cases, it can lead to acute renal failure or death.
- **If you're at risk for blood clots or kidney problems, your doctor should give you ALYGLO at the lowest effective dose and infusion rate.** Staying well-hydrated before treatment is essential.

For more information about ALYGLO, please see accompanying Product Information, including Boxed Warning, or talk to your doctor.



What is

glo

time?

Glo Time starts the moment you stop letting PI define your day—so you can enjoy less sick time and more you time. Whether you're getting started or looking for a treatment that fits with your life, **ALYGLO® is here to help.**

- **ALYGLO is an IVIG therapy for adults 17+** with PI, including CVID and other antibody deficiencies. Delivered by IV infusion, ALYGLO helps replace missing antibodies so your body can better fight infections.³
- **The name ALYGLO reflects our purpose**—to be an ally in your care journey, and to deliver the immunoglobulin (glo) to help support your body.

How PI is treated

People living with PI (primary immunodeficiency) are missing important antibodies that play a critical role in protecting the body.¹ This can make fighting off infections much harder than it should be.¹

IG replacement therapy helps by providing antibodies, or immunoglobulins called IgG, giving the immune system extra support to recognize and fight infections more effectively.²



IgG (the helpful antibodies your body needs)

IMPORTANT SAFETY INFORMATION (CONT.)

- ALYGLO is not suitable for people who have had severe allergic reactions to immune globulin or those with IgA deficiency and a history of hypersensitivity.
- If you experience any signs of hypersensitivity during the infusion, treatment should be stopped and epinephrine (an emergency medication) should be administered immediately.

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How IG treatments are made— and why that’s important

Immunoglobulin (IG) treatments start with donated human plasma—the part of blood that contains important antibodies to help fight infection.¹

- To create the medication, plasma is pooled from thousands of carefully screened donors¹
- Each manufacturer uses a unique purification process, and that can directly impact a treatment’s quality and purity



IMPORTANT SAFETY INFORMATION (CONT.)

- ALYGLO may cause hyperproteinemia, increased serum viscosity, and hyponatremia (low sodium levels).
- Aseptic Meningitis Syndrome (AMS) is a rare condition that can occur after receiving ALYGLO, especially with high doses or rapid infusion. Symptoms usually start within a few hours to 2 days after treatment. If AMS occurs, stopping ALYGLO usually leads to improvement within several days without lasting effects.

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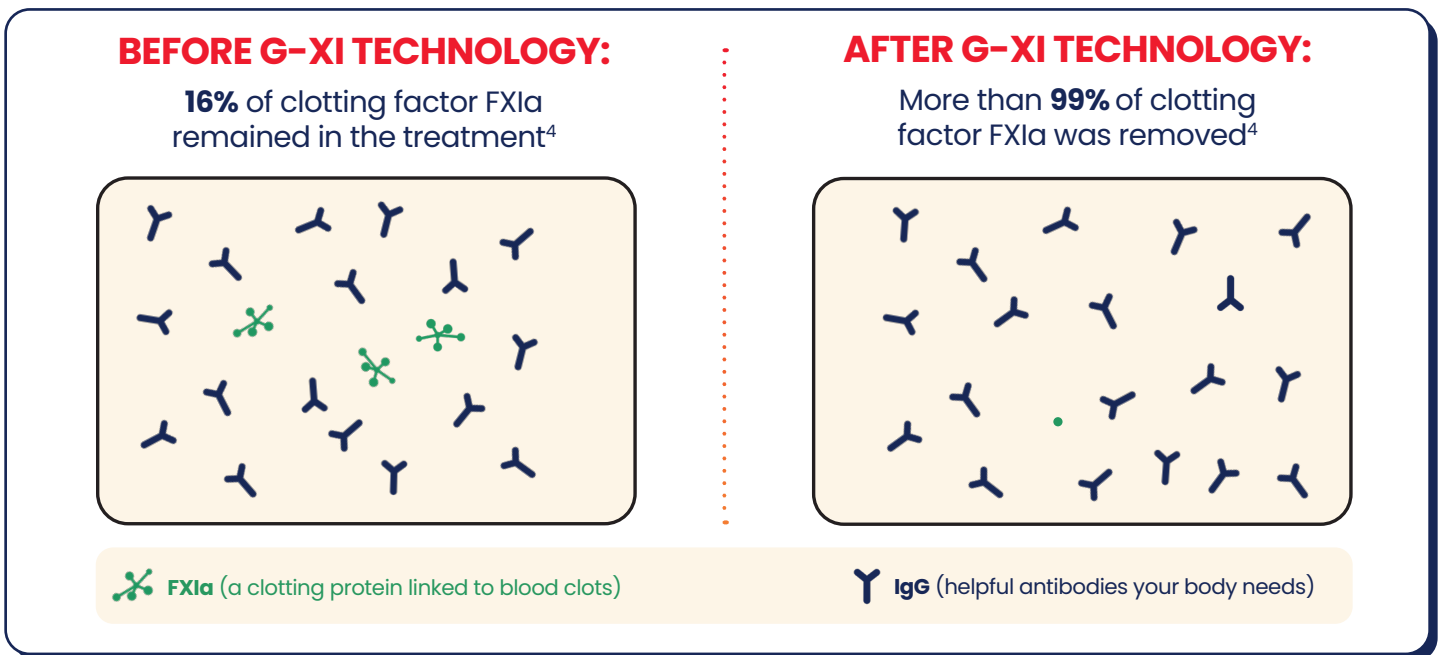
Designed with safety in mind

Like all IVIG treatments, ALYGLO goes through multiple purification steps. But thanks to an added step called G-XI™ Technology, ALYGLO also removes over 99% of **activated clotting factor XI (FXIa)**, which has been linked to rare but serious blood clots (thrombosis).⁴

- 1 **Donor plasma collected** from carefully screened, healthy US donors¹
- 2 **Standard IVIG purification process**, including multiple stages of virus inactivation, removal, and filtration to eliminate unwanted elements⁴
- 3 **Extra purification**, an additional step that targets and removes FXIa⁴

An extra step: G-XI Technology

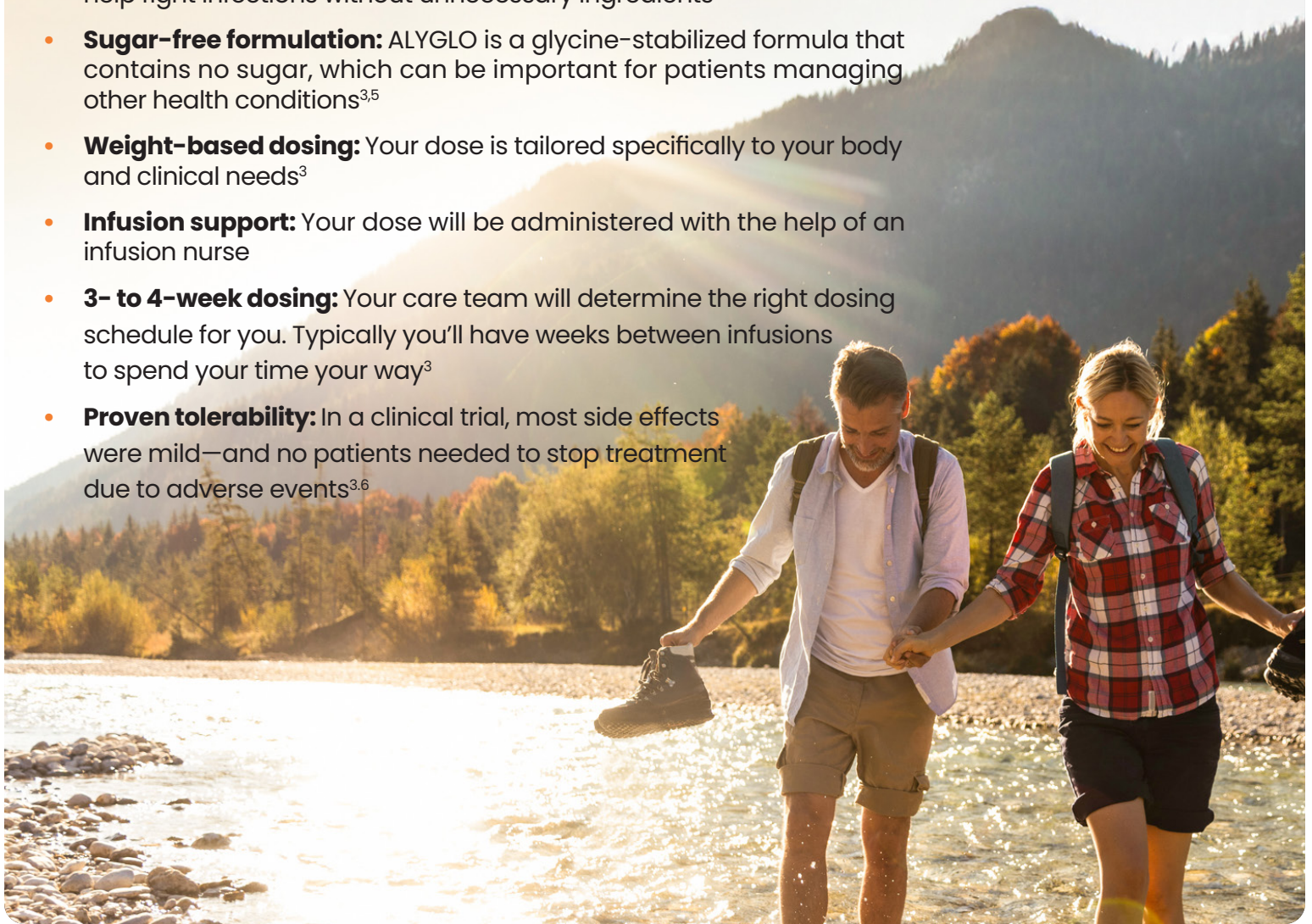
A study showed that most of the clotting factors in plasma are removed from IgG treatment during standard purification steps. However, activated FXIa required an extra step.⁴



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Is ALYGLO right for you?

- **Extra-purified formulation:** ALYGLO is carefully processed to remove unwanted elements, so you get the antibodies your body needs to help fight infections without unnecessary ingredients⁴
- **Sugar-free formulation:** ALYGLO is a glycine-stabilized formula that contains no sugar, which can be important for patients managing other health conditions^{3,5}
- **Weight-based dosing:** Your dose is tailored specifically to your body and clinical needs³
- **Infusion support:** Your dose will be administered with the help of an infusion nurse
- **3- to 4-week dosing:** Your care team will determine the right dosing schedule for you. Typically you'll have weeks between infusions to spend your time your way³
- **Proven tolerability:** In a clinical trial, most side effects were mild—and no patients needed to stop treatment due to adverse events^{3,6}



IMPORTANT SAFETY INFORMATION (CONT.)

- Hemolysis, a breakdown of red blood cells, may occur. Some patients may experience delayed hemolytic anemia due to increased sequestration of red blood cells. Severe hemolysis-related kidney dysfunction or disseminated intravascular coagulation has been reported.
- Transfusion-Related Acute Lung Injury (TRALI) is a rare complication characterized by severe respiratory distress, pulmonary edema, and fever. Patients with TRALI may need oxygen therapy and ventilator support.

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How effective is **ALYGLO**?

In a clinical study, patients treated with ALYGLO experienced low rates of infection and hospital stays.^{3,a}

Proven protection from infection³

One of the goals of the study was to measure how many acute serious bacterial infections (ASBIs) patients had over 1 year. ASBIs are short-term but serious infections that need immediate medical care. Examples include bacterial pneumonia and bacterial meningitis.^b The FDA standard for efficacy—that is, if an IG treatment works—is <1 ASBI per patient year.

PATIENTS RECEIVING ALYGLO IN THE CLINICAL STUDY EXPERIENCED AN AVERAGE OF ONLY **0.03** **SERIOUS INFECTIONS** per patient year

Upper one-sided 99% confidence limit was 0.31, which met the predefined success rate of <1 ASBI per patient year (intent-to-treat [ITT] population).

Reduced impact on daily living³

The study also evaluated the impact of ALYGLO in people's lives. Patients experienced an average of only:

2.4

OTHER INFECTIONS
per patient year

0.2

DAYS OF HOSPITALIZATION
per patient year

6

DAYS OF MISSED WORK OR SCHOOL
per patient year

14

DAYS ON ANTIBIOTICS
per patient year

The study also looked at how well people tolerated ALYGLO.³

The most common side effects people experienced during treatment included headache, nausea, fatigue, nasal congestion, rash, joint pain, diarrhea, muscle pain or aches, infusion site pain or swelling, abdominal pain or discomfort, cough, and dizziness.

No pre-medications were provided to patients ahead of infusions per study protocol.⁷

^aALYGLO was studied in 33 adults ages 17–70 in North America.

^bThe FDA defines ASBIs as: bacterial pneumonia, bacteremia/sepsis, bacterial meningitis, visceral abscesses, and osteomyelitis/septic arthritis.

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Your treatment journey

Starting ALYGLO can bring up a lot of questions—but that’s why we’re here. The process typically follows 5 simple stages, each designed to keep you informed, supported, and on track from Day 1.

1

Step 1: Your Healthcare Provider Prescribes ALYGLO

If your doctor decides that ALYGLO is right for your type of primary immunodeficiency and risk factors, your doctor will write a prescription to start the process.

2

Step 2: Your Infusion Provider Reaches Out

You’ll be contacted to confirm your information, discuss insurance coverage, and schedule your first infusion.

3

Step 3: Setting Up Your Coverage

Your infusion provider will work with your insurance to verify coverage, request prior authorization if needed, and explore co-pay support options to help you start therapy as soon as possible.

4

Step 4: Your First Infusion Is Scheduled

Once approved, your infusion is scheduled either in a clinic or in the comfort of your own home.

5

Step 5: Ongoing Treatment

ALYGLO is typically given every 3 to 4 weeks with the help of an infusion nurse. Your infusion schedule and dose are based on your weight and clinical needs.³

IMPORTANT SAFETY INFORMATION (CONT.)

- ALYGLO is made from human blood, which may carry a risk of transmitting infectious agents (such as viruses).
- After receiving ALYGLO, some antibodies from the treatment may temporarily show up in blood tests. This could lead to misleading results, so your healthcare provider will consider this when interpreting lab results.



Alyglo Assist **YOUR ALLY IN IVIG**

Support that goes beyond treatment

Navigating treatment shouldn't be overwhelming. ALYGLO ASSIST is here to help with co-pay assistance, insurance coordination, and personalized support throughout your treatment journey. From answering questions to helping manage out-of-pocket costs, we're with you every step of the way.

Scan to see how we can help cover the cost of ALYGLO



- Common side effects include headache, nausea/vomiting, fatigue, nasal/sinus congestion, rash, arthralgia, diarrhea, muscle pain/aches, infusion site pain/swelling, abdominal pain/discomfort, cough, and dizziness.

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Spend more
time on the
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make you

glo



**TALK TO YOUR DOCTOR TO LEARN MORE ABOUT
HOW ALYGLO CAN FIT INTO YOUR TREATMENT PLAN**



References: **1.** Immunoglobulin replacement therapy. Immune Deficiency Foundation. Accessed June 18, 2025. <https://primaryimmune.org/understanding-primary-immunodeficiency/treatment/immunoglobulin-replacement-therapy> **2.** Perez EE, Orange JS, Bonilla F, et al. Update on the use of immunoglobulin in human disease: a review of evidence. *J Allergy Clin Immunol.* 2017;139(3S):S1-S46. **3.** ALYGLO Prescribing Information. GC Biopharma; 2023. **4.** Kang GB, Huber A, Lee J, et al. Cation exchange chromatography removes FXIa from a 10% intravenous immunoglobulin preparation. *Front Cardiovasc Med.* 2023;10:1253177. **5.** Siegel J. IVIG medication safety: a stepwise guide to product selection and use. *Pharmacy Practice News.* Accessed June 13, 2025. https://pharmacypracticenews.com/download/IVIG_safety_ppn0910_wm.pdf **6.** Perez EE, Hébert J, Ellis AK, et al. Efficacy, safety and tolerability of a new 10% intravenous immunoglobulin for the treatment of primary immunodeficiencies. *Front Immunol.* 2021;12:707463. **7.** Data on file. GC Biopharma; 2019.

Please see additional Important Safety Information throughout, and accompanying full Prescribing Information.

You are encouraged to report negative side effects of prescription drugs.

Contact GC Biopharma medical affairs at **1-833-426-6426**,
or email medicalinfo@gcbiopharmausa.com, or e-fax **1-866-728-7855**,
or visit www.fda.gov/medwatch, or call **1-800-FDA-1088**.