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

When patients need a go-to, you're there.

So are we.

An overview of ALYGLO and administration guidance for infusion nurses

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

WARNING: THROMBOSIS, RENAL DYSFUNCTION and ACUTE RENAL FAILURE

- **Thrombosis may occur with immune globulin intravenous (IGIV) products, including ALYGLO. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.**
- **Renal dysfunction, acute renal failure, osmotic nephropathy, and death may occur with the administration of IGIV products in predisposed patients.**
- **Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. ALYGLO does not contain sucrose.**
- **For patients at risk of thrombosis, renal dysfunction or renal failure, administer ALYGLO at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.**

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

Caring with knowledge and compassion is where you shine

As an infusion nurse, you play a unique role in a patient's journey with IVIG therapy. For many, you're a trusted guide and the first call for clinical questions, reassurance, and practical guidance. Educating patients early and often can improve outcomes.

Patients starting ALYGLO® may have questions throughout their journey:

- How does IG therapy work?
- How will I feel?
- What reactions might occur?
- What are the most serious side effects?
- How can I manage side effects before, during, and after infusion?

This guide is meant to help provide you with key administration guidance, tips from IVIG experts, and information about ALYGLO you can share with your patients.

Clear, supportive conversations before, during, and after each infusion can help set expectations, ease anxiety, and promote long-term treatment success.

Some topics to cover before treatment begins:

- Identify risk factors, including medical conditions, allergies, sensitivities, vaccine history, and current medications, including herbal supplements
- Explain potential reactions or adverse events and what to do if they occur
- Set expectations for infusion time
- Stress the importance of therapy adherence

IMPORTANT SAFETY INFORMATION (CONT.)

Contraindications: ALYGLO is contraindicated in patients who have a history of anaphylactic or severe systemic reaction to the administration of human immune globulin and in IgA-deficient patients with antibodies to IgA and a history of hypersensitivity.

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When patients are counting on you, count on ALYGLO

Extra purification: Manufactured with G-XI™ Technology, an extra step that removes >99% of activated coagulation factor XI (FXIa).[1]

Sugar and sodium-free formulation: ALYGLO is a glycine-stabilized formula that contains no sugar or sodium, which can be important for patients managing other health conditions.[2,3]*

Proven protection: In a clinical trial, ALYGLO demonstrated its ability to protect against infection and its impact on daily living.[2]*

Demonstrated tolerability: In a clinical trial, most side effects were mild—and no patients needed to stop treatment due to adverse events.[2,4]*

*Based on a prospective, open-label, 12-month study of 33 adults ages 17-70 in North America.[2]

Alyglo Assist *YOUR ALLY IN IVIG*

Support for you and your patients, every step of the way.

IMPORTANT SAFETY INFORMATION (CONT.)

Hypersensitivity: In case of hypersensitivity, discontinue infusion immediately and institute appropriate treatment. Epinephrine should be available for immediate treatment of severe acute hypersensitivity reactions.

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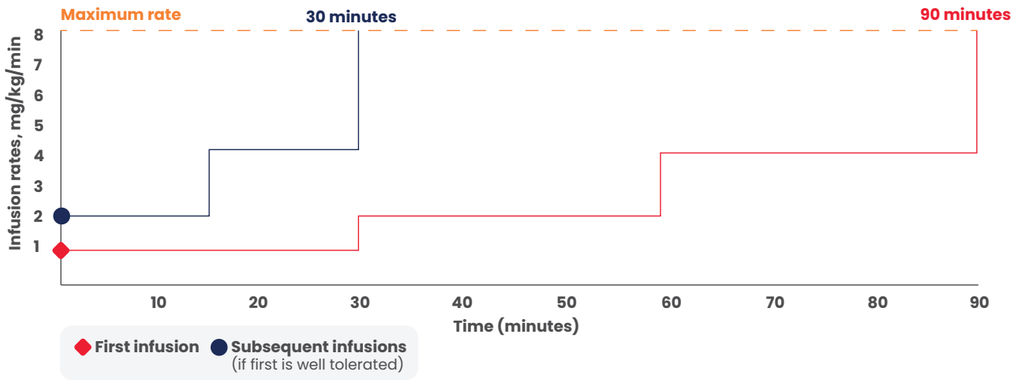
Alyglo® *immune globulin intravenous, human-stwk 10% liquid*

ALYGLO dosing and administration[2]

Allow ALYGLO to reach room temperature prior to administration. After the initial infusion, the maintenance infusion rate of ALYGLO can be doubled every 15 minutes to reach the maximum rate if well tolerated. This can help shorten the overall infusion time for your patients.

Infusion details	1st infusion	Subsequent infusions
Dose	**300-800 mg/kg** every 21 or 28 days	**300-800 mg/kg** every 21 or 28 days
Initial infusion rate	**1 mg/kg/min** (0.01 mL/kg/min)	**2 mg/kg/min** (0.02 mL/kg/min)
Maintenance infusion rate	**Double the infusion rate every 30 minutes (if tolerated)** up to 8 mg/kg/min (0.08 mL/kg/min)	**Double the infusion rate every 15 minutes (if tolerated)** up to 8 mg/kg/min (0.08 mL/kg/min)



Adverse reactions may stem from ramping up the infusion speed too quickly. If this happens, slow or pause the infusion, wait for symptoms to subside, then restart at the last tolerated rate.

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IMPORTANT SAFETY INFORMATION (CONT.)

Hyperproteinemia, Increased Serum Viscosity, and Hyponatremia: Hyperproteinemia, increased serum viscosity, and hyponatremia may occur.

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

Mitigating adverse reactions

Immunoglobulin National Society (IgNS) hydration recommendations for all IVIG treatments[5]:

- The degree to which the patient is hydrated going into and coming out of the infusion may reduce the risk and severity of many systemic adverse reactions[6]
- Oral hydration can start 24 hours before infusion and continue during and after
- Fluid overload is a consideration for patients with certain comorbidities—consult the prescriber for patient-specific recommendations

Age	Sex	Recommended daily fluid intake
17	M/F	48 oz (1,420 mL)
>18	F	92 oz (2,700 mL)
>18	M	124 oz (3,700 mL)

Patients should be instructed to report potential serious reactions, such as[5]:

- Unusual weight gain
- Edema
- Shortness of breath
- Decrease in urine output
- Dark urine
- Neck pain or stiffness
- Fatigue
- Hives
- Rash
- Unresolved nausea
- Vomiting
- Unremitting headache
- Yellowing of the skin or whites of the eyes
- Increased heart rate

If you would like to speak to a **Medical Affairs representative**, have an inquiry related to drug safety, or to report adverse events, please call 1-833-426-6426, email medicalinfo@gcbiopharmausa.com, e-fax 1-866-728-7855, visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

This overview does not replace best clinical judgment. If a patient experiences any of the adverse reactions listed above, stop the infusion and consult the prescriber or emergency department.

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200 mL/20 g	*100 mL/10 g*	*50 mL/5 g*
NDC: 61476-0104-20	**NDC:** 61476-0104-10	**NDC:** 61476-0104-05

KEY PRODUCT CHARACTERISTICS[1,2]

- G-XI™ Technology reduces activated coagulation factor XI to below detection limits[1]
- ≤ 20 mcg/mL IgA
- Osmolality 240-360 mOsmol/kg, which is similar to physiological osmolality (average 275 to 295 mOsmol/kg)
- Stabilized with glycine
- No added sugars, sodium, or preservatives

AVAILABLE IN 3 VIAL SIZES[2]

- No natural rubber latex
- Integral suspension band for hanging

STORING AND HANDLING[2]

- Keep ALYGLO in its original carton to protect it from light
- Store ALYGLO in the refrigerator or at room temperature
  - Refrigeration: 2-8 °C [36-46 °F] for up to 36 months. Do not freeze
  - Room temperature: 8-25 °C [46-77 °F] for up to 24 months
  - Do not return to refrigeration after ALYGLO has been stored at room temperature

ALYGLO CAN BE SAFELY POOLED[2]

ALYGLO may be pooled under aseptic conditions into sterile infusion bags.

Important reminders:

1. Always use an aseptic technique while preparing the product for infusion.
2. Always administer ALYGLO at room temperature.
3. Keep an infusion log of lot numbers and expiration dates.

For questions about **ALYGLO**, including storage, packaging or administration, please contact **GC Biopharma Medical Affairs** at **1-833-426-6426** or **medicalinfo@gcbiopharmausa.com**

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- **Hypersensitivity:** In case of hypersensitivity, discontinue infusion immediately and institute appropriate treatment. Epinephrine should be available for immediate treatment of severe acute hypersensitivity reactions.
- **Hyperproteinemia, Increased Serum Viscosity, and Hyponatremia:** Hyperproteinemia, increased serum viscosity, and hyponatremia may occur.
- **Aseptic Meningitis Syndrome (AMS):** Aseptic meningitis syndrome (AMS) may occur, especially with high doses or rapid infusion. AMS usually begins within several hours to 2 days following ALYGLO treatment. Discontinuation of treatment has resulted in remission of AMS within several days without sequelae.
- **Hemolysis:** Delayed hemolytic anemia due to enhanced red blood cell (RBC) sequestration and acute hemolysis consistent with intravascular hemolysis have been reported. Cases of severe hemolysis-related renal dysfunction/failure or disseminated intravascular coagulation have occurred following infusion of IGIV. Closely monitor patients for clinical signs and symptoms of hemolysis, particularly patients with risk factors.
- **Transfusion-Related Acute Lung Injury:** Noncardiogenic pulmonary edema (transfusion-related acute lung injury [TRALI]) may occur. TRALI is characterized by severe respiratory distress, pulmonary edema, hypoxemia, normal left ventricular function, and fever. Patients with TRALI may be managed using oxygen therapy with adequate ventilator support. Monitor patients for pulmonary adverse reactions.
- **Transmissible Infectious Agents:** Because ALYGLO is made from human blood, it may carry a risk of transmitting infectious agents (eg, viruses, the variant Creutzfeldt-Jakob disease [vCJD] agent and, theoretically, the Creutzfeldt-Jakob disease [CJD] agent).
- **Interference with Laboratory Tests:** After infusion of immunoglobulin, the transitory rise of the various passively transferred antibodies in the patient's blood may yield positive serological testing results, with the potential for a misleading interpretation.
- **Adverse reactions** (observed in ≥ 5% of study subjects) were headache, nausea/vomiting, fatigue, nasal/sinus congestion, rash, arthralgia, diarrhea, muscle pain/aches, infusion site pain/swelling, abdominal pain/discomfort, cough, and dizziness.
- It is recommended that ALYGLO be administered separately from other drugs or medications.

Please see accompanying full Prescribing Information.

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ALYGLO was proven effective in a clinical trial[2]

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The efficacy, safety, and tolerability of ALYGLO were evaluated in a prospective, open-label, multicenter, single-arm study in 33 adults with primary immunodeficiency, aged 17-70 years.

- Before enrollment, all subjects were receiving stable doses between 300 and 900 mg/kg of a commercially available IVIG treatment. (The approved dosing for ALYGLO is between 300 and 800 mg/kg)
- For 12 months, subjects received ALYGLO infusion administered every 21 or 28 days (both the dose and schedule depending on prior therapy)

PROVEN PROTECTION

Patients receiving ALYGLO experienced an average of the following (per patient year):

- **0.03** acute serious bacterial infections (ASBIs)
  - *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)*
- **14 days** on antibiotics
- **6 days** of missed work or school

DEMONSTRATED TOLERABILITY

- >98% of infusions were completed without discontinuation, interruption, or rate reductions[4]
- No pre-medications were provided to patients ahead of infusions per study protocol[7]
- The majority of adverse events reported during the study were mild in intensity[4]
- No adverse events (AEs) led to withdrawal from the study[2]

Sharing results from a clinical study can help boost confidence. **Encourage patients to keep a diary, so that they can track their own progress.**

Scan for more information on ALYGLO or clinical study results.

IMPORTANT SAFETY INFORMATION, cont.

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References: 1. 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. **2.** ALYGLO Prescribing Information. GC Biopharma; 2025. **3.** 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 **4.** 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. **5.** Immunoglobulin National Society. *Immunoglobulin Therapy Standards of Practice*. 3.1 ed. Ig Society, Inc.; 2023. **6.** Clarke A. Ig therapy foundational review: session 5: administration of IVIG and SCIG by the Standards. October 5, 2023. Accessed September 4, 2025. https://test.ig-ns.org/lessons/ig-therapy-foundational-review-session-5-administration-of-ivig-and-scig-by-the-standards **7.** Data on file. GC Biopharma; 2025.

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