

## Patient and Product Risk Factors<sup>1-5</sup>

Patient Risk Factor	Concern	Ig Product Parameter Affecting Use	Appropriate Intervention	Risk Mitigation Strategies
Risk of thrombosis (See full prescribing information for complete Boxed Warning)	Thrombosis may occur with any immune globulin product.	Risk factors include advanced age, prolonged immobilization, hypercoagulable conditions, history of venous catheters, hyperviscosity, and cardiovascular risk factors.	Monitor for signs and symptoms of thrombosis.	Administer at the lowest infusion rate practicable. Administer large doses over several days or non-consecutive days. Consider concomitant anti-thrombotic therapy in high-risk patients. Ensure hydration prior to and during infusion. Consider SCIG.
Renal impairment/renal failure (See full prescribing information for complete Boxed Warning)	Fluid overload Increased plasma viscosity	Volume Osmolality/osmolality	Consider IVIG 10% vs IVIG 5% Consider SCIG Choose products with physiologic osmolality (~300 mOsm/L)	Administer at the lowest infusion rate practicable. Administer large doses over several days or on non-consecutive days. Monitor fluid status. Ensure adequate hydration while considering fluid restriction.
Cardiac/pulmonary insufficiency	Potential for fluid overload Sodium Altered hemodynamics	Volume Sodium content Osmolality/osmolality	Consider IVIG 10% vs IVIG 5% Avoid products with high sodium content Select products with physiologic osmolality (~300 mOsm/L)	Administer at the lowest infusion rate practicable. Administer large doses over several days or on alternate days Monitor fluid status
IgA deficiency	Potential for anaphylaxis in IgA deficient patients with antibodies to IgA.	IgA content	In patients with IgA deficiency and IgG antibodies to IgA, consider IVIG or SCIG products with the lowest IgA content. In patients with a history of anaphylaxis to Ig or blood products, or with IgE antibodies to IgA, it is strongly advised to use an IgA-depleted IVIG or a low IgA containing SCIG.	Correlation of product IgA content and risk for anaphylaxis is not well established but caution is recommended. Monitor all patients closely for signs and symptoms of anaphylaxis and ensure an anaphylaxis kit is readily available.
Obesity	Adipose tissue is poorly perfused, and higher doses of IVIG increase the risk of serious adverse events.	Potential for higher Ig dose-related adverse events	Consider adjusted body weight dosing initially.	Optimal dosing must be adjusted based on clinical response
Diabetes	Potential for elevated blood glucose levels with glucose-stabilized products. Potential for glucometer interference with maltose-stabilized products. Greater risk for renal complications.	Glucose used as stabilizer Maltose used as stabilizer Volume, sodium content, osmolality	Avoid glucose-containing products if possible. If using maltose-stabilized product, ensure glucometer and test strip accuracy are not affected. Select Ig products with best parameters; Consider IVIG 10% vs IVIG 5% Consider SCIG	Administer at the lowest infusion rate practicable. Administer large doses over several days or on non-consecutive days. Monitor fluid status
Non-O blood type	Potential for hemolysis/hemolytic anemia with high doses of IVIG (≥2gm/kg).	anti-A, anti-B antibody levels	Consider products containing the lowest anti-A, anti-B antibody titers.	Be knowledgeable of patient blood type to identify patients at risk. Administer at the lowest infusion rate practicable. Closely monitor for signs of hemolysis/hemolytic anemia with large doses
Hereditary fructose intolerance	Sorbitol presents a risk to patients with hereditary fructose intolerance (HFI). In patients <2 years old, HFI may not yet be diagnosed and may be fatal.	D-sorbitol used as stabilizer	Products stabilized with d-sorbitol are contraindicated in patients with hereditary intolerance to fructose, and in infants and neonates for whom sucrose or fructose tolerance has not been established.	Products stabilized with d-sorbitol are contraindicated in patients with hereditary intolerance to fructose, and in infants and neonates for whom sucrose or fructose tolerance has not been established.
Hyperproliferemia	A dysfunction of proline metabolism may lead to seizures or other neurological abnormalities. Additional exposure of these patients to proline should be limited.	L-proline used as a stabilizer	In patients suffering from hyperproliferemia, a dysfunction of proline metabolism may lead to seizures or other neurological abnormalities. Additional exposure of these patients to proline should be limited. Avoid products with L-proline.	In patients suffering from hyperproliferemia, a dysfunction of proline metabolism may lead to seizures or other neurological abnormalities. Additional exposure of these patients to proline should be limited. Avoid products with L-proline.
Neonatal and geriatric patients	Potential for volume overload. Compromised acid-base compensatory mechanisms in neonates.	Volume Osmolality pH	Consider IVIG 10% vs IVIG 5% Consider SCIG Choose products with physiologic osmolality (~300 mOsm/L) Caution with products having low pH.	Administer at the lowest infusion rate practicable. Administer large doses over several days or on non-consecutive days. Monitor access site for irritation. Monitor appropriate blood chemistry.
Male patients of reproductive age	Development of non-neutralizing antibodies to recombinant human hyaluronidase (PH20) present in HyQvia <sup>®</sup> , and potential cross-reactivity with endogenous PH20 expressed in adult testes, epididymis, and sperm.	Recombinant human hyaluronidase (PH20) used in HyQvia <sup>®</sup>	Assess risk/benefit in male patients of child-bearing age and consider alternative products without PH20.	Clinical significance of anti-PH20 antibodies is unknown. Consider using products that do not contain PH20 in male patients of reproductive age.
Fluid restriction	Fluid overload	Volume of IV fluids infused	Consider IVIG 10% vs IVIG 5% Consider SCIG	Administer at the lowest infusion rate practicable. Administer large doses over several days or on non-consecutive days. Monitor fluid status.

**Additional Notes**

- HyQvia<sup>®</sup> is available in prefilled syringes. All other products are available in vials. HyQvia<sup>®</sup> is available in a dual unit vial of two single use vials containing IgG and recombinant human hyaluronidase.
- Gammagard SD<sup>®</sup> is a lyophilized powder and must be reconstituted to a 5% or 10% concentration before administration.
- HyQvia<sup>®</sup> is a combination product containing Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase. See full prescribing information for complete details.
- Maximum IVG rate: Consult the product package insert for titration steps before reaching maximum rate and lower maximum rates when risk factors are present.
- SCIG rate/volume: Consult the product package insert for titration steps and number of doses at lower rates/volumes before reaching maximum rates/volumes.
- Switching IV to SC: Multiply the previous monthly IV dose by the appropriate dose adjustment factor (see package insert), then divide by the number of SC doses desired per month (e.g. for weekly SCIG, divide by 4).
- XembiF<sup>®</sup> Product characteristics. Website. Accessed September 26, 2023 at <https://www.xembi.com/en/cz/czech-characteristics>

**References**

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3. BIVIGAM<sup>®</sup> [Immune globulin intravenous (Human)], 10% Liquid, United States Prescribing Information. Manufactured by ADMA Biologics. Revised April 2019.
4. GAMMAGARD<sup>®</sup> [Immune Globulin Intravenous (Human)], 10% Liquid Preparation, United States Prescribing Information. Manufactured by Octapharma Pharmazeutika Produktionsges.m.b.H. Revised August 2018.
5. CUTAQIG<sup>®</sup> [Immune Globulin Subcutaneous (Human)], 20% Solution, United States Prescribing Information. Manufactured by Octapharma Pharmazeutika Produktionsges.m.b.H. Revised date not indicated.
6. CUVITRU<sup>®</sup> [Immune Globulin Subcutaneous (Human)], 20% Solution, United States Prescribing Information. Manufactured by Takeda. Revised May 2019.
7. FLEBOGAMMA<sup>®</sup> 5% IVP [Immune Globulin Intravenous (Human)], 5% Liquid Preparation, United States Prescribing Information. Manufactured by Instituto Grifols, S.A. Revised September 2019.
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9. GAMMAGARD<sup>®</sup> LIQUID [Immune Globulin Infusion (Human)], 5% Liquid, Intravenous and subcutaneous administration, United States Prescribing Information. Manufactured by Takeda. Revised January 2024.
10. GAMMAGARD<sup>®</sup> SD [Immune Globulin Infusion (Human)], 5% Liquid, Intravenous and subcutaneous administration, United States Prescribing Information. Manufactured by Takeda. Revised September 2019.
11. GAMMAREX<sup>®</sup> [Immune Globulin Injection (Human)], 10% Cryoprecipitated Chromatography Purified, United States Prescribing Information. Manufactured by Grifols Therapeutics LLC. Revised June 2018.
12. GAMMAREX<sup>®</sup> 5% [Immune Globulin Intravenous (Human)], 5% Liquid, Intravenous use, United States Prescribing Information. Manufactured by Bio Products Laboratory Ltd. Revised December 2018.
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15. XEMBITR<sup>®</sup> [Immune Globulin Subcutaneous (Human)], 20% Liquid, United States Prescribing Information. Manufactured by CSL Behring LLC. Revised March 2018.
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17. OCTAGAM<sup>®</sup> 5% [Immune Globulin Intravenous (Human)] liquid preparation, United States Prescribing Information. Manufactured by Octapharma Pharmazeutika Produktionsges.m.b.H. Revised May 2018.

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21. XEMBITR<sup>®</sup> [Immune Globulin Subcutaneous (Human)], 20% Solution, United States Prescribing Information. Manufactured by Grifols Therapeutics LLC. Revised July 2024.

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**Disclaimer**

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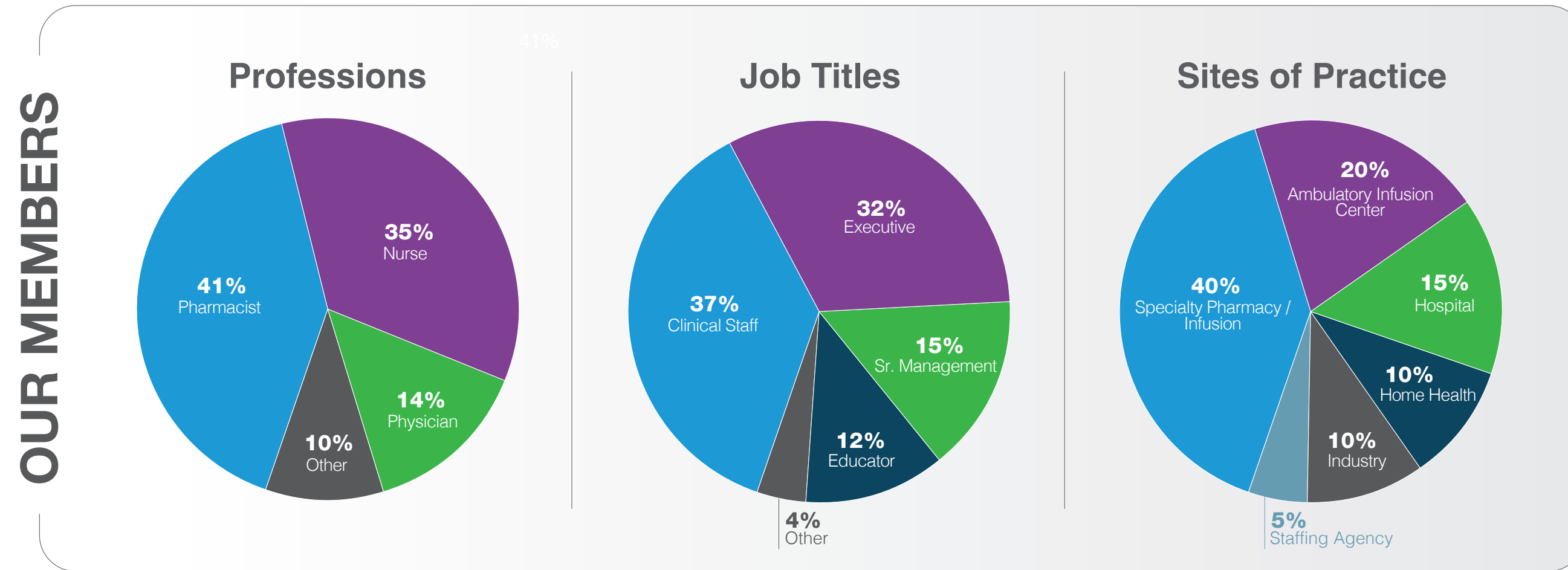
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Product & Risk Factors Chart