



Product characteristics and clinical considerations for Ig therapies.

Ig therapies are not generic, and are not interchangeable.

Characteristics between the formulations of Ig products differ and can impact patients in different ways. When prescribing an Ig therapy, consider how these factors may contribute to each patient's individual treatment experience.¹ Refer to the respective manufacturers for the Full Prescribing Information for the products referenced herein.



Taking subcutaneous immune globulin (SCIG) product characteristics into consideration.

When prescribing a SCIG therapy, it's important to understand how the product characteristics vary. The following charts will allow you to differentiate product features but they *do not imply clinical outcomes*.

[See the data](#)





Facilitated SCIG Conventional SCIG

Facilitated SCIG product characteristics		
	Takeda	
	HyQvia® [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution	
Formulation		
	Recombinant Human Hyaluronidase ³	Immune Globulin Infusion 10% (Human) ³
Form	Liquid	Liquid
IgA content	0 µg/mL	Average 37 µg/mL
IgG purity	N/A	≥98%
Sugar content	No added sugar	No added sugar
Sodium content	175 mEq/L	No added sodium
Stabilizer	Human albumin (1.0 mg/mL)	Glycine (250 mM)
pH	-7.4	4.6-5.1
Viscosity	1 mPa-second ⁴	3 mPa-second ⁴
Osmolality <small>(physiologic range: 285-295 mOsmol/kg)²</small>	290-350 mOsmol/kg	240-300 mOsmol/kg
Dedicated viral inactivation/removal steps*	<ul style="list-style-type: none"> Comprehensive virus testing at the Master Cell Bank, Working Cell Bank, and bulk harvest stage Effective virus reduction during the purification process 	<ul style="list-style-type: none"> S/D treatment 35 nm nanofiltration Incubation at low pH at elevated temperature

Dosage		
Dose adjustment factor	For people with PI	For people with CIDP
	<ul style="list-style-type: none"> Use the same dose and frequency as previous IV treatment after the initial ramp-up For patients switching from Immune Globulin Subcutaneous (Human) [IGSC]: Administer HyQvia at 300 to 600 mg/kg at 3- to 4-week intervals after ramp-up 	<ul style="list-style-type: none"> A dose ramp-up schedule is recommended by gradually increasing the SC infusion volume until the full dose is reached to ensure the patients' tolerability† The starting dose and dosing frequency of HyQvia is the same as the patient's previous IGIV treatment. The typical dosing interval range in the clinical trial for HyQvia was 4 weeks. The typical dosing interval for HyQvia is 2, 3, or 4 weeks
Packaging		
	Recombinant Human Hyaluronidase ³	Immune Globulin Infusion 10% (Human) ³
Latex content in packaging	Not made with natural rubber latex	Not made with natural rubber latex
Shelf life/storage requirements	<ul style="list-style-type: none"> 36 months at refrigerated temperature from the date of manufacture: 2-8 °C (36-46 °F) 3 months at room temperature during the first 24 months from date of manufacture: 25 °C (77 °F) HyQvia must be used within 3 months after removal to room temperature but before the expiration date Keep vials in carton in order to protect from light Do not freeze 	
Vial sizes in grams of protein <small>(total volume in mL)</small>	1.25 mL (200 Units) 2.5 mL (400 Units) 5.0 mL (800 Units)	10.0 mL (1600 Units) 15.0 mL (2400 Units) 20 g (200 mL) 30 g (300 mL)

* Dedicated inactivation/removal steps are introduced into the manufacturing process for the sole purpose of reducing pathogens. Critical parameters can be optimized and standardized to ensure reliable and constant performance across many production runs.

† For patients switching from IVIG to HyQvia, a ramp-up period can take up to 9 weeks, depending on the dosing interval and tolerability.

CIDP=chronic inflammatory demyelinating polyradiculoneuropathy; PI=primary immunodeficiency.

Please see full Indication, Important Safety Information, including **BOXED WARNING regarding Thrombosis for HYQVIA on pages 13-14.** Please click for Full Prescribing Information for [HYQVIA](#).



Facilitated SCIG

Conventional SCIG

Higher concentration (≥16.5%) conventional SCIG product characteristics				
	Takeda	CSL Behring	Grifols	Octapharma
	CUVITRU® [Immune Globulin Subcutaneous (Human)] 20% Solution ⁵⁻⁷	HIZENTRA® Immune Globulin Subcutaneous (Human), 20% Liquid ⁸⁻¹⁰	XEMBIFY™ (immune globulin subcutaneous, human-klhw) 20% solution ¹¹⁻¹³	CUTAQUIG® (Immune Globulin Subcutaneous [Human] - hipp, 16.5% solution) ¹⁴⁻¹⁶
Formulation				
Form	Liquid	Liquid	Liquid	Liquid
IgA content	Average 80 µg/mL	≤50 µg/mL	49-87 µg/mL ¹²	≤600 µg/mL
IgG purity	≥98%	≥98%	≥98%	≥96%
Sugar content	No added sugar	No sucrose or maltose	No added sugars ¹³	Maltose (7.9 g/dL)
Sodium content	No added sodium	Trace amounts	Trace amounts ¹³	≤30 mEq/L
Stabilizer	Glycine (250 mM)	L-proline (210-290 mM)	Glycine (160-260 mM)	Maltose (230 mM)
Polysorbate 80	None detected ¹⁶	8-30 µg/mL	10-40 µg/mL	≤40 µg/mL ¹⁵
pH	4.6-5.1	4.6-5.2	4.1-4.8	5.0-5.5
Viscosity	14.4 mPa-second ⁷	14.7±1.2 mPa-second ⁹	Unknown	11.6±0.6 mPa-second ¹⁶
Osmolality <small>(physiologic range: 285-295 mOsmol/kg)²</small>	280-292 mOsmol/kg	380 mOsmol/kg ¹⁰	280-404 mOsmol/kg	310-380 mOsmol/kg
Dedicated viral inactivation/removal steps*	<ul style="list-style-type: none"> S/D treatment 35 nm nanofiltration Incubation at low pH at elevated temperature 	<ul style="list-style-type: none"> pH 4 incubation Virus filtration Depth filtration 	<ul style="list-style-type: none"> Caprylate precipitation Column chromatography Nanofiltration Incubation at low pH in final container 	<ul style="list-style-type: none"> Cold ethanol fractionation S/D treatment pH 4 treatment

Higher concentration (≥16.5%) conventional SCIG product characteristics				
	Takeda	CSL Behring	Grifols	Octapharma
	CUVITRU® [Immune Globulin Subcutaneous (Human)] 20% Solution ⁵⁻⁷	HIZENTRA® Immune Globulin Subcutaneous (Human), 20% Liquid ⁸⁻¹⁰	XEMBIFY™ (immune globulin subcutaneous, human-klhw) 20% solution ¹¹⁻¹³	CUTAQUIG® (Immune Globulin Subcutaneous [Human] - hipp, 16.5% solution) ¹⁴⁻¹⁶
Dosage				
Weekly dose adjustment factor[†]	PI: x 1.3 ⁹	PI and CIDP: x 1.37 ⁴	PI: 1.37	PI: 1.4
Packaging				
Latex content in packaging	Not made with natural rubber latex	Not made with natural rubber latex	Not made with natural rubber latex	Not made with natural rubber latex
Shelf life/storage requirements	<ul style="list-style-type: none"> 36 months at refrigerated temperature from the date of manufacture: 2-8 °C (36-46 °F) 24 months at room temperature from the date of manufacture: not to exceed 25 °C (77 °F) Do not use past expiration date printed on label Do not freeze 	<ul style="list-style-type: none"> 30 months at room temperature, up to 25 °C (77 °F) until expiration date Protect from light Do not shake Do not freeze 	<ul style="list-style-type: none"> Store in refrigerator at 2-8 °C (36-46 °F) 6 months at room temperature from date of manufacture: not to exceed 25 °C (77 °F) 	<ul style="list-style-type: none"> 24 months at refrigerated temperature from date of manufacture: 2-8 °C (36-46 °F) 6 months at room temperature from date of manufacture: not to exceed 25 °C (77 °F)
Vial sizes in grams of protein <small>(total volume in mL)</small>	1 g (5 mL) 2 g (10 mL) 4 g (20 mL) 8 g (40 mL) 10 g (50 mL)	1 g (5 mL) 2 g (10 mL) 4 g (20 mL) 10 g (50 mL)	1 g (5 mL) 2 g (10 mL) 4 g (20 mL) 10 g (50 mL)	1 g (6 mL) 1.65 g (10 mL) 2 g (12 mL) 3.3 g (20 mL) 4 g (24 mL) 8 g (48 mL)

*Dedicated inactivation/removal steps are introduced into the manufacturing process for the sole purpose of reducing pathogens. Critical parameters can be optimized and standardized to ensure reliable and constant performance across many production runs.

¹ Polysorbate 80 is used in the manufacturing process in the virus deactivation/removal step, but is removed from the final formulation to undetectable levels.

[†] Initial SCIG dose=previous IVIG dose ÷ number of weeks between IVIG doses x dose adjustment factor.

⁹ When switching from IVIG or HyQvia to CUVITRU.

⁴ For biweekly use in PI, administer twice the calculated weekly dose.

Please see full Indication, Important Safety Information, including BOXED WARNING regarding Thrombosis for CUVITRU on pages 13-14. Please click for Full Prescribing Information for CUVITRU.

Ig therapies are not interchangeable. Understanding product formulation matters.¹

Taking intravenous immune globulin (IVIG) product characteristics into consideration

When prescribing an IVIG therapy, it's important to understand how the product characteristics vary. The following charts will allow you to differentiate product features but they *do not imply clinical outcomes*.

[See the data](#)





Formulation Packaging

No comparisons or implications regarding efficacy or safety of listed treatments can or should be made on the basis of this information.

	Takeda		Grifols			CSL Behring	Bio Products Laboratory		ADMA Biologics	Octapharma		
	GAMMAGARD LIQUID® [Immune Globulin Infusion (Human)] 10% Solution ²	GAMMAGARD S/D [Immune Globulin Intravenous (Human)] IgA <1 µg/mL in a 5% solution ^{17,18}	FLEBOGAMMA® 5% DIF [Immune Globulin Intravenous (Human)] ¹⁹	FLEBOGAMMA® 10% DIF [Immune Globulin Intravenous (Human)] ²⁰	GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified) ^{21-23†}	PRIVIGEN® [Immune Globulin Intravenous (Human)] 10% ^{24,25}	GAMMAPLEX 5% [Immune Globulin Intravenous (Human)], 5% Liquid ²⁶	GAMMAPLEX 10% [Immune Globulin Intravenous (Human)], 10% Liquid ²⁷	BIVIGAM® [Immune Globulin Intravenous (Human)], 10% Liquid ^{21,28}	OCTAGAM [Immune Globulin Intravenous (Human)] 5% Liquid ²⁹	OCTAGAM 10% [Immune Globulin Intravenous (Human)] ³⁰	PANZYGA® (immune globulin intravenous, human - ifas) 10% Liquid Preparation ³¹
Formulation												
Form	Liquid	Lyophilized	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid
IgA content	Average 37 µg/mL	<1 µg/mL	Typically <50 µg/mL	Typically <100 µg/mL	46 µg/mL	≤25 µg/mL	<10 µg/mL	<20 µg/mL	≤200 µg/mL	≤200 µg/mL	Average 106 µg/mL	Average 100 µg/mL
IgG purity	≥98%	≥90%	≥97%	≥97%	≥98%	≥98%	>95%	≥98%	≥96%	≥96%	≥96%	≥96%
Sugar content	No added sugar	Glucose (2 g/dL)	D-sorbitol (5 g/dL)	D-sorbitol (5 g/dL)	None ²¹	No added sugar ²⁵	D-sorbitol (5 g/dL)	No sucrose or maltose	No added sugar	Maltose (10 g/dL)	Maltose (9 g/dL)	No sucrose
Sodium content	No added sodium	145 mEq/L	Trace amounts	Trace amounts	Trace amounts ²¹	Trace amounts	76 mEq/L	<30 mEq/L	100-140 mEq/L	≤30 mEq/L	≤30 mEq/L	Trace amounts
Stabilizer	Glycine (250 mM)	Glycine (300 mM); Glucose (2 g/dL)	D-sorbitol (5 g/dL)	D-sorbitol (5 g/dL)	Glycine (160-240 mM)	L-proline (250 mM)	Glycine (80 mM); D-sorbitol (5 g/dL)	Glycine (200-300 mM)	Glycine (200-290 mM)	Maltose (10 g/dL)	Maltose (9 g/dL)	Glycine (200-260 mM)
Polysorbate 80	None reported [†]	100 µg/mL	None specified	None specified	None specified	None specified	~50 µg/mL	10-60 µg/mL	1500-2500 µg/mL	None specified	None specified	None specified
pH	4.6-5.1	6.4-7.2 (6.8±0.4)	5.0-6.0	5.0-6.0	4.0-4.5	4.6-5.0	4.8-5.1	4.9-5.2	4.0-4.6	5.1-6.0	4.5-5.0	4.5-5.0
Osmolality <small>(physiologic range: 285-295 mOsmol/kg)²</small>	240-300 mOsmol/kg	636 mOsmol/kg ¹⁸	240-370 mOsmol/kg	240-370 mOsmol/kg	258 mOsmol/kg	-320 mOsmol/kg (240-440 mOsmol/kg)	Typically 420-500 mOsmol/kg (≥240 mOsmol/kg)	Typically 280 mOsmol/kg (≥240 mOsmol/kg)	370-510 mOsmol/kg ²⁸	310-380 mOsmol/kg	310-380 mOsmol/kg	240-310 mOsmol/kg
Dedicated viral inactivation/removal steps*	<ul style="list-style-type: none"> S/D treatment 35 nm nanofiltration Incubation at low pH at elevated temperature 	<ul style="list-style-type: none"> Cold ethanol fractionation S/D treatment 	<ul style="list-style-type: none"> Pasteurization S/D treatment 20 nm nanofiltration Low pH treatment 	<ul style="list-style-type: none"> Pasteurization S/D treatment 20 nm nanofiltration Low pH treatment 	<ul style="list-style-type: none"> Caprylate precipitation Depth filtration Low pH incubation 	<ul style="list-style-type: none"> pH 4 incubation Virus filtration Depth filtration 	<ul style="list-style-type: none"> S/D treatment Virus filtration Low pH incubation 	<ul style="list-style-type: none"> S/D treatment Virus filtration Low pH incubation 	<ul style="list-style-type: none"> Precipitation and removal of fraction III during cold ethanol fractionation S/D treatment 35 nm virus filtration 	<ul style="list-style-type: none"> Cold-ethanol fractionation S/D treatment pH 4 treatment 	<ul style="list-style-type: none"> Cold-ethanol fractionation S/D treatment pH 4 treatment 	<ul style="list-style-type: none"> S/D treatment Ion-exchange chromatography 20 nm nanofiltration

*Dedicated inactivation/removal steps are introduced into the manufacturing process for the sole purpose of reducing pathogens. Critical parameters can be optimized and standardized to ensure reliable and constant performance across many production runs.

† Polysorbate 80 is used in the dedicated viral inactivation/removal steps during the S/D treatment process, which renders it below detection limits.

‡ Also distributed by Kedrion as GAMMAKED™ [Immune Globulin Injection (Human)], 10% Caprylate/Chromatography Purified.²³

Please see full Indication, Important Safety Information, including **BOXED WARNINGS** regarding **Thrombosis, Renal Dysfunction, and Acute Renal Failure, for GAMMAGARD S/D and GAMMAGARD LIQUID on pages 13-14. Please click for Full Prescribing Information for GAMMAGARD LIQUID and GAMMAGARD S/D.**



Formulation

Packaging

No comparisons or implications regarding efficacy or safety of listed treatments can or should be made on the basis of this information.

	Takeda		Grifols			CSL Behring	Bio Products Laboratory		ADMA Biologics	Octapharma		
	GAMMAGARD LIQUID® [Immune Globulin Infusion (Human)] 10% Solution ²	GAMMAGARD S/D [Immune Globulin Intravenous (Human)] IgA <1 µg/mL in a 5% solution ^{17,18}	FLEBOGAMMA® 5% DIF [Immune Globulin Intravenous (Human)] ¹⁹	FLEBOGAMMA® 10% DIF [Immune Globulin Intravenous (Human)] ²⁰	GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified) ^{21-23*}	PRIVIGEN® [Immune Globulin Intravenous (Human)] 10% ^{24,25}	GAMMAPLEX 5% [Immune Globulin Intravenous (Human)], 5% Liquid ²⁶	GAMMAPLEX 10% [Immune Globulin Intravenous (Human)], 10% Liquid ²⁷	BIVIGAM® [Immune Globulin Intravenous (Human)], 10% Liquid ^{21,28}	OCTAGAM [Immune Globulin Intravenous (Human)] 5% Liquid ²⁹	OCTAGAM 10% [Immune Globulin Intravenous (Human)] ³⁰	PANZYGA® (immune globulin intravenous, human - ifas) 10% Liquid Preparation ³¹
Packaging												
Latex content in packaging	Not made with natural rubber latex	Not made with natural rubber latex	Not made with natural rubber latex	Not made with natural rubber latex	Not made with natural rubber latex	The components used in packaging are not made with natural rubber latex	The components used in packaging are not made with natural rubber latex	The components used in packaging are latex free	The components used in packaging are not made with natural rubber latex	The components used in packaging are not made with natural rubber latex	The components used in packaging are not made with natural rubber latex	The components used in packaging are not made with natural rubber latex
Shelf life/storage requirements	<ul style="list-style-type: none"> 36 months at refrigerated temperature from the date of manufacture: 2-8 °C (36-46 °F) 24 months at room temperature from the date of manufacture: not to exceed 25 °C (77 °F) Do not use past expiration date printed on label Do not freeze 	<ul style="list-style-type: none"> 24 months at room temperature, not to exceed 25 °C (77 °F) Do not use past expiration date printed on label Do not freeze 	<ul style="list-style-type: none"> 24 months at room temperature, 2-25 °C (36-77 °F), until expiration date Do not freeze Protect from light 	<ul style="list-style-type: none"> 24 months at room temperature, 2-25 °C (36-77 °F), until expiration date Do not freeze Protect from light 	<ul style="list-style-type: none"> 36 months at refrigerated temperature, 2-8 °C (36-46 °F), from the date of manufacture Up to 6 months not to exceed 25 °C (77 °F) during the 36-month shelf life Do not freeze 	<ul style="list-style-type: none"> 36 months at room temperature, not to exceed 25 °C (77 °F), until expiration date Do not freeze Protect from light 	<ul style="list-style-type: none"> 36 months at temperature from 2-25 °C (35.6-77 °F) until expiration date Protect from light Do not freeze 	<ul style="list-style-type: none"> 36 months at temperature from 2-25 °C (35.6-77 °F) until expiration date Protect from light Do not freeze 	<ul style="list-style-type: none"> Refrigerate from 2-8 °C (36-46 °F) until expiration date Do not freeze or heat 	<ul style="list-style-type: none"> 24 months at 2-25 °C (36-77 °F) from date of manufacture Do not freeze 	<ul style="list-style-type: none"> 24 months at 2-8 °C (36-46 °F) from date of manufacture Within the first 12 months of this shelf life, the product may be stored up to 9 months at ≤25 °C (77 °F) Do not freeze 	<ul style="list-style-type: none"> 36 months at temperature from 2-8 °C (36-46 °F) from date of manufacture 12 months at temperature of up to 25 °C (77 °F) within shelf-life; use immediately or discard following Do not use past expiration date Do not freeze
Vial sizes in grams of protein (total volume in mL)	1 g (10 mL) 2.5 g (25 mL) 5 g (50 mL) 10 g (100 mL) 20 g (200 mL) 30 g (300 mL)	2.5 g 5 g 10 g	0.5 g (10 mL) 2.5 g (50 mL) 5 g (100 mL) 10 g (200 mL) 20 g (400 mL)	5 g (50 mL) 10 g (100 mL) 20 g (200 mL)	1 g (10 mL) 2.5 g (25 mL) 5 g (50 mL) 10 g (100 mL) 20 g (200 mL) 40 g (400 mL)	5 g (50 mL) 10 g (100 mL) 20 g (200 mL) 40 g (400 mL)	5 g (100 mL) 10 g (200 mL) 20 g (400 mL)	5 g (50 mL) 10 g (100 mL) 20 g (200 mL)	5 g (50 mL) 10 g (100 mL)	1 g (20 mL) 2.5 g (50 mL) 5 g (100 mL) 10 g (200 mL) 25 g (500 mL)	2 g (20 mL) 5 g (50 mL) 10 g (100 mL) 20 g (200 mL) 30 g (300 mL)	1 g (10 mL) 2.5 g (25 mL) 5 g (50 mL) 10 g (100 mL) 20 g (200 mL) 30 g (300 mL)

*Polysorbate 80 is used in the dedicated viral inactivation/removal steps during the S/D treatment process, which renders it below detection limits.
 †Also distributed by Kedrion as GAMMAKED™ [Immune Globulin Injection (Human)], 10% Caprylate/Chromatography Purified.²³

Please see full Indication, Important Safety Information, including **BOXED WARNINGS** regarding **Thrombosis, Renal Dysfunction, and Acute Renal Failure, for GAMMAGARD S/D and GAMMAGARD LIQUID** on pages 13-14. Please click for Full Prescribing Information for **GAMMAGARD LIQUID** and **GAMMAGARD S/D**.

Evaluating Ig product characteristics

Not all Ig products are biologically equivalent, and your patients' tolerance can differ based on their formulation.¹

The information provided here can be used for reference when selecting an Ig therapy, but it is not an all-inclusive list, and it is not intended to recommend a particular treatment or provide medical advice.

[See the data](#)



Stabilizer content³²

Different Ig products use different sugars or amino acids as stabilizers, contributing to safety and tolerability in various ways.

- **MALTOSE** should be avoided in people with corn allergies as it's derived from corn syrup. Maltose does not increase glucose levels in blood, but it can cause false-positive readings with certain glucometers. Precaution should be used in people with diabetes as these readings may lead to inappropriate insulin administration and hypoglycemia^{1,33}
- **L-PROLINE** is an amino acid, contraindicated in people with hyperprolinemia³³
- **GLUCOSE** should be avoided in people with diabetes; it may raise serum glucose and insulin levels, causing risk for hyperglycemia^{1,32}
- **D-SORBITOL** should be avoided in people with hereditary fructose intolerance (HFI) because it can metabolize to fructose. It is found naturally in stone fruits (eg, apricots, cherries, peaches) and berries³²
- **GLYCINE** is an amino acid used as an alternative to sugar. The most commonly used stabilizer, it does not increase glucose blood levels, nor has it been reported to cause acute renal failure due to osmotic nephrosis^{1,32,33}
- **POLYSORBATE 80** is contraindicated in patients who have had anaphylactic or severe systemic reactions to human immune globulin or components such as polysorbate 80. It has been associated with nonimmunologic anaphylactoid reactions^{8,34,35}

Sodium content^{1,18,36}

Sodium concentrations can vary (0%-1.8%) between products. Those who may be sensitive to higher concentrations, and therefore at risk for adverse events, include those who are:

- Elderly
- Cardiac impaired
- Renal dysfunctional
- At risk for thromboembolic reactions

Lyophilized preparations can increase sodium concentration and may also be associated with a higher rate of adverse events and thromboembolic complications.

IgA content^{1,37}

Different Ig products contain varying amounts of IgA, ranging from <1 µg/mL to 600 µg/mL. Most Ig products are contraindicated in patients who have selective IgA deficiency with antibodies against IgA and a history of hypersensitivity.

All Ig preparations carry the risk of inducing potentially severe hypersensitivity and anaphylactic reactions to IgA, in patients with antibodies against IgA, regardless of the IgA concentration.

Osmolality^{1,25}

Osmolality ranges between products, but most products lie within the range of physiologic osmolality of 280 to 296 mOsmol/kg. If this range is exceeded, there is a possible association of aseptic meningitis and thrombotic events such as stroke or myocardial infarction. Those especially at risk include the:

- Elderly
- Neonatal/pediatric
- Cardiometabolic impaired
- Renal dysfunctional

Formulation/concentration¹

Ig therapies are available as both liquid and lyophilized powders. Their individual concentrations range from ~5% to 20% and determine their infusion volumes.

Assessing patients' clinical considerations

Remember, not all Ig therapies are interchangeable. To ensure an appropriate treatment is selected, product characteristics should be assessed in conjunction with your patients' clinical considerations.¹

[See the data](#)



The differences in Ig formulations matter.¹

Clinical considerations <small>(not an all-inclusive list)</small>	Product characteristics
<p>Predisposition for renal insufficiency³⁶</p> <ul style="list-style-type: none"> • Diabetes mellitus • >65 years of age • Volume depletion (dehydration or hypovolemia) • Hypertension • Sepsis • Paraproteinemia • Concomitant therapy with nephrotoxic drugs 	<p>IVIG products have Boxed Warnings indicating that renal dysfunction, acute renal failure, osmotic nephropathy and death may occur with use in predisposed patients. SCIG products list renal failure as a warning and precaution with at-risk patients. Patients with a predisposition for renal insufficiency should be identified prior to treatment.³⁶</p> <p>Osmolality: Hyperosmolality of the product, as well as sensitivities to sugar and salt content, may be among the factors that can increase the risk of renal complications.³²</p>
<p>Predisposition for thrombotic events^{38,39}</p> <ul style="list-style-type: none"> • Atherosclerosis • Heart failure • Hypertension • Hypertriglyceridemia • Vascular disease • Cardiovascular risk factors • Diabetes mellitus • MI, CVT, PE, or other thrombotic disorders • Obesity • Prolonged immobilization • Known or suspected hyperviscosity • Elderly and pediatric patients 	<p>IgG has been associated with thrombotic events (TEs) in at-risk patients, with rates anywhere from 1% to 16.9%. In a retrospective cohort of 11,785 individuals, 1% experienced a TE on the day of Ig administration, while rates ranged from 6.1% to 20.5% for different Ig product groups per 1000 persons. In another cohort of 303 individuals treated with IVIG, 16.9% experienced TEs.^{38,39}</p> <p>Results suggest that elevated TE rates exist in different products and may be due to factors such as differences in dosage, infusion rates, or manufacturing processes. To increase awareness, the FDA requires all Ig products to have information on Thrombosis in their Boxed Warning.^{38,40}</p> <p>For patients at risk of thrombosis, administer Ig at the minimum dose and infusion rate practicable. Ensure adequate hydration and monitor for signs and symptoms. Assess blood viscosity in patients at risk of hyperviscosity.⁴⁰</p> <p>Osmolality: Hyperosmolar products may be related to an increased risk of thrombosis. Other causes of TEs have been attributed to platelet aggregation, arterial vasospasm, and patients with significant risk factors related to age, lifestyle, and disease.^{41,42}</p>
<p>Diabetes mellitus³³</p> <ul style="list-style-type: none"> • Type 1 and Type 2 	<p>Acute renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with IVIG products in patients with diabetes mellitus.³² The biggest concern in patients with diabetes mellitus is the stabilizer used to prevent IgG aggregation.³³</p> <p>Glucose: Ig products stabilized with glucose may increase insulin requirements and should be avoided or accounted for.³³</p> <p>Maltose: Maltose doesn't increase glucose levels, but it can trigger false-positive readings on certain devices. Case reports of fatal iatrogenic hypoglycemia resulting from falsely elevated glucometer readers have been associated with maltose-stabilized IVIG. Therefore, glucose-specific monitoring systems should be used in patients with diabetes receiving maltose.^{32,43}</p>
<p>IgA deficiency³³</p>	<p>Ig products are contraindicated in IgA-deficient patients with antibodies against IgA and a history of hypersensitivity, because all Ig products contain some form of IgA.^{33,44}</p> <p>IgA concentration: The IgA concentration threshold for anaphylactic risk is unknown, but patients with true selective IgA deficiencies have the potential to develop anaphylactic reactions.⁴⁵</p>



Clinical considerations <small>(not an all-inclusive list)</small>	Product characteristics
Previous Ig administration^{2,17} <ul style="list-style-type: none"> • Experience with Ig • History of reactions to certain brands 	ARs may occur more frequently in patients receiving Ig therapy for the first time, upon switching products, or if there has been a long interval since the time of their last infusions. ^{2,17,46}
Hemolytic anemia⁴⁷	Though rare, hemolytic anemia can occur with use of any Ig product. Factors that can increase risk include: non-O blood type, high dosage of Ig (with high titration of anti-A or B antibodies), and high cumulative Ig doses given during a short period of time. ⁴⁷
Patients with sodium or volume-intake restrictions^{18,45} <ul style="list-style-type: none"> • Cardiac impairment • Renal impairment • Hypertension 	<p>Sodium concentration: Sodium concentration varies widely between products, from trace amounts to 1.8%, dependent on the final solution concentration. Increased sodium concentrates may be associated with a higher rate of ARs and TEs.¹⁸</p> <p>Ig concentration: Ig concentrations vary between products. The higher the concentration, the lower the volume required to administer a dose.¹⁸</p> <p>Osmolality: Hyperosmolar solutions can contribute to hemodynamic changes and infusion-related ARs. Reconstituted lyophilized products can result in a hyperosmolar solution and should be monitored.⁴⁸</p>
Elderly patients³³ <ul style="list-style-type: none"> • ≥65 years of age 	Elderly patients have an increased risk for developing renal failure or TEs, such as acute renal failure and arterial and venous thrombosis, and require close monitoring for ARs. ^{33,49} Sensitivities to volume load, sugar and sodium content, and osmolality, can increase risk and Ig intolerance. Ensure proper hydration prior to infusions, do not exceed the recommended dose, and infuse the chosen product at the slowest practical rate. ^{33,49}
Pediatrics³³ <ul style="list-style-type: none"> • Fructose intolerance 	D-sorbitol: Sorbitol metabolizes to fructose, so patients with HFI should avoid Ig products with this stabilizer. There is potential for severe, and often fatal, hepatic failure. Babies and young children should also not receive sorbitol as it's possible their HFI is not yet diagnosed. ^{32,50}
Hyperprolinemia³³	L-proline: Ig products stabilized with L-proline are contraindicated in patients with hyperprolinemia. ³³
Corn allergy³³	Maltose: Ig products stabilized with maltose should be avoided in patients with corn allergies, as it is derived from corn syrup. ³³
Latex allergy⁵¹	Latex: Ig treatments that are manufactured with rubber latex in their product, container, and/or packaging should be used with caution in patients with a hypersensitivity to latex. ⁵¹



INDICATIONS

CUVITRU® [Immune Globulin Subcutaneous (Human)] 20% Solution, GAMMAGARD LIQUID® [Immune Globulin Infusion (Human)] 10% Solution, and GAMMAGARD S/D® [Immune Globulin Intravenous (Human)] IgA less than 1 µg/mL in a 5% solution are indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients ≥2 years.

HYQVIA® [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution is indicated for the treatment of primary immunodeficiency (PI) in adults and pediatric patients two years of age and older and for chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment in adults.

GAMMAGARD LIQUID is also indicated as a maintenance therapy to improve muscle strength and disability in adult patients with Multifocal Motor Neuropathy (MMN) and as a therapy to improve neuromuscular disability and impairment in adult patients with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).

LIMITATIONS OF USE (CIDP): **GAMMAGARD LIQUID** has not been studied in immunoglobulin-naïve patients with CIDP. **GAMMAGARD LIQUID** maintenance therapy in CIDP has not been studied for periods longer than 6 months. After responding during an initial treatment period, not all patients require indefinite maintenance therapy with **GAMMAGARD LIQUID** in order to remain free of CIDP symptoms. Individualize the duration of any treatment beyond 6 months based upon the patient's response and demonstrated need for continued therapy.

GAMMAGARD S/D is also indicated for the prevention of bacterial infections in hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell chronic lymphocytic leukemia (CLL), prevention and/or control of bleeding in adult chronic idiopathic thrombocytopenic purpura (ITP) patients, and prevention of coronary artery aneurysms associated with Kawasaki syndrome in pediatric patients.

CUVITRU and **HYQVIA** are for subcutaneous use only.

GAMMAGARD LIQUID for PI is for intravenous or subcutaneous use.

GAMMAGARD LIQUID for MMN and CIDP is for intravenous use only.

GAMMAGARD S/D is for intravenous use only.

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS

CUVITRU, HYQVIA, GAMMAGARD LIQUID, and GAMMAGARD S/D

- **Thrombosis may occur with immune globulin (IG) products, including CUVITRU, HYQVIA, GAMMAGARD LIQUID, and GAMMAGARD S/D. 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. Thrombosis may occur in the absence of known risk factors.**

- **For patients at risk of thrombosis, administer CUVITRU, HYQVIA, GAMMAGARD LIQUID, and GAMMAGARD S/D 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 of hyperviscosity.**

WARNING: RENAL DYSFUNCTION and ACUTE RENAL FAILURE

GAMMAGARD LIQUID and GAMMAGARD S/D

- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients with immune globulin intravenous (IGIV) products, including GAMMAGARD LIQUID and GAMMAGARD S/D. Patients predisposed to renal dysfunction include those with any degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. GAMMAGARD LIQUID and GAMMAGARD S/D do not contain sucrose.**

Contraindications

- **CUVITRU, HYQVIA, and GAMMAGARD LIQUID** are contraindicated in patients with a history of anaphylactic or severe systemic hypersensitivity reactions to human IG, and IgA-deficient patients with antibodies to IgA and a history of hypersensitivity to human IG. Anaphylaxis has been reported with intravenous (IV) use of **GAMMAGARD LIQUID**.

- Additionally, **HYQVIA** is contraindicated in patients with known systemic hypersensitivity to hyaluronidase including Recombinant Human Hyaluronidase of **HYQVIA**, and known systemic hypersensitivity to human albumin (in the hyaluronidase solution).

- **GAMMAGARD S/D** is contraindicated in patients with a history of anaphylactic or severe systemic hypersensitivity reactions to the administration of **GAMMAGARD S/D**.

Warnings and Precautions

Hypersensitivity: Severe hypersensitivity reactions may occur, even in patients who have tolerated previous treatment with human IG. Severe hypersensitivity reactions and anaphylactic reactions with a fall in blood pressure have occurred in patients receiving **GAMMAGARD S/D**, including patients who tolerated previous treatments with **GAMMAGARD S/D**, even though it contains low levels of IgA. If a hypersensitivity reaction occurs, discontinue infusion immediately and institute appropriate treatment. IgA-deficient patients with antibodies to IgA are at greater risk of developing potentially severe hypersensitivity reactions, including anaphylaxis.

Renal Dysfunction/Failure: Acute renal dysfunction/failure, acute tubular necrosis, proximal tubular nephropathy, osmotic nephrosis, and death may occur with IV use of IG products, especially those containing sucrose. Acute renal failure has been reported in association with **GAMMAGARD LIQUID** and **GAMMAGARD S/D**. Ensure patients are not volume depleted prior to infusion. In patients at risk due to pre-existing renal insufficiency or predisposition to acute renal failure, assess renal function before initiation and throughout treatment, and consider lower, more frequent dosing. If renal function deteriorates, consider discontinuation.

Thrombosis: Has been reported to occur following treatment with IG products, including **HYQVIA** and in the absence of known risk factors. In patients at risk, administer at the minimum dose and infusion rate practicable. Ensure adequate hydration before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Aseptic Meningitis Syndrome: Has been reported with use of IG, including **CUVITRU** and **HYQVIA** and may occur more frequently in females. Conduct a thorough neurological exam on patients exhibiting signs and symptoms, to rule out other causes of meningitis. Discontinuing IG treatment has resulted in remission within several days without sequelae. The syndrome usually begins within several hours to two days following IG treatment.

Hemolysis: **CUVITRU, HYQVIA, GAMMAGARD LIQUID, and GAMMAGARD S/D** contain blood group antibodies, which may cause a positive direct antiglobulin reaction and hemolysis. Monitor patients for signs and symptoms of hemolysis and delayed hemolytic anemia and, if present, perform appropriate confirmatory lab testing.

Transfusion-Related Acute Lung Injury: Non-cardiogenic pulmonary edema has been reported with IV-administered IG, including **GAMMAGARD LIQUID**. Monitor patients for pulmonary adverse reactions. If suspected, perform appropriate tests for presence of anti-neutrophil and anti-HLA antibodies in both product and patient serum. May be managed using oxygen therapy with adequate ventilatory support.

Transmittable Infectious Agents: Because **CUVITRU, HYQVIA, GAMMAGARD LIQUID, and GAMMAGARD S/D** are made from human plasma, they may carry a risk of transmitting infectious agents (e.g., viruses, other pathogens). No confirmed cases of viral transmission of variant Creutzfeldt-Jakob disease (vCJD) have been associated with **CUVITRU** or **GAMMAGARD LIQUID**, and no cases have been associated with **HYQVIA**.

Interference with Lab Tests: False positive serological test results and certain assay readings, with the potential for misleading interpretation, may occur as the result of passively transferred antibodies.

Additional Warnings and Precautions for HYQVIA

Immunogenicity of Recombinant Human Hyaluronidase (rHuPH20): Non-neutralizing antibodies to the Recombinant Human Hyaluronidase component can develop. The clinical significance of these antibodies or whether they interfere with fertilization in humans is unknown.

Spread of Localized Infection: Do not infuse **HYQVIA** into or around an infected area due to potential risk of spreading a localized infection.

Additional Warnings and Precautions for GAMMAGARD LIQUID and GAMMAGARD S/D

Hyperproteinemia, increased serum viscosity, and hyponatremia may occur. It is critical to distinguish true hyponatremia from a pseudohyponatremia because certain treatments may lead to volume depletion, a further increase in serum viscosity, and a predisposition to thromboembolic events.

Alterations in serum sodium levels (i.e., acute hypernatremia, pseudohyponatremia) may occur with **GAMMAGARD S/D**. In patients on a low sodium diet, calculate the amount of sodium from **GAMMAGARD S/D** when determining dietary sodium intake.

Adverse Reactions

CUVITRU

The most common adverse reactions observed in ≥5% of patients in clinical trials were local adverse reactions including mild or moderate pain, erythema, and pruritus, and systemic adverse reactions including headache, nausea, fatigue, diarrhea, and vomiting.

HYQVIA

The most common adverse reactions observed in >5% of patients in clinical trials were:

PI: local adverse reactions including pain, erythema, edema, and pruritus, and systemic adverse reactions including headache, antibody formation against Recombinant Human Hyaluronidase (rHuPH20), fatigue, nausea, pyrexia, and vomiting.

CIDP: local reactions, headache, pyrexia, nausea, fatigue, erythema, pruritus, increased lipase, abdominal pain, back pain, and pain in extremity.

Please see additional Important Safety Information on page 14.



IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions (continued)

GAMMAGARD LIQUID

The serious adverse reactions observed in clinical studies in PI was aseptic meningitis, and in MMN were pulmonary embolism and blurred vision.

The most common adverse reactions observed in $\geq 5\%$ of patients were:

IV administration for PI: headache, fatigue, pyrexia, nausea, chills, rigors, pain in extremity, diarrhea, migraine, dizziness, vomiting, cough, urticaria, asthma, pharyngolaryngeal pain, rash, arthralgia, myalgia, oedema peripheral, pruritus, and cardiac murmur.

Subcutaneous administration for PI: infusion site (local) event (rash, erythema, edema, hemorrhage, and irritation), headache, fatigue, heart rate increased, pyrexia, abdominal pain upper, nausea, vomiting, asthma, blood pressure systolic increased, diarrhea, ear pain, aphthous stomatitis, migraine, oropharyngeal pain, and pain in extremity.

IV administration for MMN: headache, chest discomfort, muscle spasms, muscular weakness, nausea, oropharyngeal pain, and pain in extremity.

IV administration for CIDP: Headache, pyrexia, anemia, leukopenia, neutropenia, illness, blood creatinine increased, dizziness, migraine, somnolence, tremor, nasal dryness, abdominal pain upper, vomiting, chills, nasopharyngitis, and pain in extremity.

GAMMAGARD S/D

The most common adverse reactions observed in $\geq 5\%$ of clinical trial patients during or within 48 hours of infusion were headache, nausea, chills, fatigue, pyrexia, upper abdominal pain, diarrhea, back pain, infusion site pain, hyperhidrosis, and flushing.

The most serious adverse reactions reported postmarketing include renal failure, thrombotic events (myocardial infarction, cerebrovascular accidents, and pulmonary embolism), anaphylactic shock, aseptic meningitis, and hemolysis.

Drug Interactions

Passive transfer of antibodies may transiently interfere with the immune responses to live attenuated virus vaccines (e.g., measles, mumps, rubella, and varicella).

Use In Specific Populations

Pregnancy: Limited human data are available on the use of **HYQVIA** during pregnancy. The effects of antibodies to the Recombinant Human Hyaluronidase on the human embryo or fetal development are unknown. It is not known whether **HYQVIA** can cause fetal harm when administered to a pregnant woman or if it can affect reproductive capacity. **HYQVIA** should be given to a pregnant woman only if clearly needed.

Please click for Full Prescribing Information, including Boxed Warnings regarding Thrombosis, Renal Dysfunction, and Acute Renal Failure, for CUVITRU, HYQVIA, GAMMAGARD LIQUID, and GAMMAGARD S/D.

For more information please [click here](#) to contact Takeda Medical Information or call 1-877-TAKEDA-7 (1-877-825-3327).

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