Intravenous Immune Globulin (10%)

Product Specifics	Privigen® CSL Behring	Flebogamma® 10% DIF Grifols	Gamunex-C® Grifols	Gammaked® Kedrion	BIVIGAM® NF Kedrion	Octagam® 10% Octapharma	Gammagard Liquid Shire
Indications	Primary Humoral Immunodeficiency (PI), Chronic Immune Thrombocytopenic Purpura (ITP)	Primary Immune Deficiency (PID)	Intravenous (IV): CIDP, PI, ITP. Subcutaneous (SC): PI	Intravenous (IV): CIDP, PI, ITP. Subcutaneous (SC): PI	Primary Humoral Immunodeficiency (PI)	Chronic immune thrombocytopenic purpura (ITP) in adults.	Replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age or older. Maintenance therapy to improve muscle strength and disability in adult patients with Multifocal Motor Neuropathy [MMN].
Contraindications	Patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin. Patients with hyperprolinemia. Patients with selective IgA deficiency with antibodies to IgA and a history of hypersensitivity.	Individuals who have had a history of anaphylactic or severe systemic reactions to the administration of human immune globulin and IgA deficient patients with antibodies to IgA and a history of hypersensitivity.	Individuals with known anaphylactic or severe systemic response to IG. Individuals with known antibodies against IgA should receive Gamunex-C® with utmost cautionary measures due to risk of severe immediate hypersensitivity reactions including anaphylaxis.	Individuals with known anaphylactic or severe systemic response to IG. Individuals with known antibodies against IgA should receive Gammaked® with utmost cautionary measures due to risk of severe immediate hypersensitivity reactions including anaphylaxis.	History of anaphylactic or severe systemic reactions to human immunoglobulin. IgA deficient patients with antibodies to IgA and a history of hypersensitivity.	History of anaphylactic or severe systemic reactions to human immunoglobulin. IgA deficient patients with antibodies against IgA and a history of hypersensitivity.	1. In patients who have had a history of anaphylactic or severe systemic hypersensitivity reaction to the administration of human immune globulin. 2. In IgA-deficient patients with antibodies to IgA and a history of hypersensitivity. Anaphylaxis has been reported with intravenous use of GAMMAGARD LIQUID and is theoretically possible following subcutaneous use.
IgA Content	≤ 25 mcg/mL	Average: < 3.2 mcg/mL	Average 46 mcg/mL	Average 46 mcg/mL	200 mcg/mL	Trace amounts (average 106 µg/mL in a 10% solution).	The average immunoglobulin A (IgA concentration is 37 mcg/mL in a 10% solution).
Osmolality	Approximately 320 mOsmol/kg (range: 240-440)	240-370 mOsm/kg	258 mOsmol/kg	258 mOsmol/kg	510 mOsm/kg	310 - 380 mosmol/kg.	240 - 300 mOsmol/kg
Sugar Content	None. L-Proline, a nonessential amino acid, is used as a stabilizer.	5% D-sorbitol (polyol)	No sugar	No sugar	No sugar	Maltose (90 mg/mL), no sucrose.	No sugar added
Sodium Content	Trace	Trace (< 3.2 mmol/L)	Trace amounts	Trace amounts	0.100-0.140 M sodium chloride	Not more than 30 mmol/L.	No sodium added
pH of Product	4.8 (range is 4.6 - 5.0)	Average: 5.5 ± 0.1	4.0 - 4.5	4.0 - 4.5	4.0 - 4.6	4.5 - 5.0.	4.6 - 5.1
Product Half Life	36.6 days	3-week dosing interval: 34 ± 10 days; 4-week dosing interval: 37 ± 13 days	Approximately 35 days	Approximately 35 days	The median terminal half-life of BIVIGAM® was 30 days	Not tested in primary humoral immunodeficiency (PI) patients.	26 – 35 days for Intravenous use.
Viral Safety Process	pH 4 incubation, 20nm virus filtration, depth filtration; TSE validation and removal	Pasteurization (60° C, 10 h), solvent detergent, dual sequential nanofiltration (35 nm and 20 nm), Fraction I precipitation, Fraction II + III incubation, 4% PEG precipitation and acid pH 4 treatment	Caprylate Precipitation/Depth Filtration, Caprylate Incubation, Depth Filtration, Column Chromatography, Nanofiltration, Low pH Incubation. Manufacturing process includes steps that provide significant removal (≥ 6.6 log10) of TSE infectivity.	Caprylate Precipitation/Depth Filtration, Caprylate Incubation, Depth Filtration, Column Chromatography, Nanofiltration, Low pH Incubation. Manufacturing process includes steps that provide significant removal (≥ 6.6 log10) of TSE infectivity.	Three steps: "Precipitation and removal of fraction III" during cold ethanol fractionation, Classical "Solvent/detergent treatment", and "35 nm virus filtration".	Cold-ethanol fractionation, S/D treatment, and pH 4 treatment.	Solvent Detergent, 35 nm filtration, incubation (elevated temp) at low pH
Route of Administration	Intravenous (IV)	Intravenous (IV)	Intravenous (IV): CIDP, PI, ITP. Check prescribing information for initial and maintenance infusion rates. Subcutaneous (SC): PI. Initial rate 20 mL/hr/site. Over time, the dose may need to be adjusted to achieve the desired clinical response and serum IgG trough level.	Intravenous (IV): CIDP, PI, ITP. Check prescribing information for initial and maintenance infusion rates. Subcutaneous (SC): PI. Initial rate 20 mL/hr/site. Over time, the dose may need to be adjusted to achieve the desired clinical response and serum IgG trough level.	Intravenous (IV)	Intravenously (IV)	Intravenous (IV) or Subcutaneous (SC)
Formulation & Concentration	10% Liquid	10% Liquid	10% Liquid	10% Liquid	10% Liquid	10% Liquid	10% Liquid
Storage Requirements	Store at room temperature up to 25°C (77°F) for up to 36 months, as indicated by the expiration date printed on the outer carton and vial label. Do not freeze. Protect from light.	Room temperature storage: + 2° to + 25°C (36° F to 77° F) Do not freeze.	36 months at refrigerated temperature 2°-8°C (36°-46°F). Do not freeze. 6 months at temperatures not to exceed 25° (77°F) anytime during the 36-month shelf life.	36 months at refrigerated temperature 2°-8°C (36°-46°F). Do not freeze. 6 months at temperatures not to exceed 25° (77°F) anytime during the 36-month shelf life.	Refrigerate between 2 to 8°C (36 to 46°F)	Do not freeze. Frozen product should not be used. Do not use after expiration date.	• Do not freeze. • Store GAMMAGARD LIQUID in the refrigerator or at room temperature • Refrigeration: 2° to 8°C [36° to 46°F] for up to 36 months. • Room Temperature: up to 25°C [77°F] for up to 24 months. • Expiration dates for both storage conditions are printed on the outer carton and vial label. • Do not use past the applicable expiration date.
Shelf Life from Date of Manufacture	36 months	24 months	36 months. Do not use after the labeled expiration date.	36 months. Do not use after the labeled expiration date.	BIVIGAM® may be stored until expiration date on vial packaging at 2 to 8°C (36 to 46°F).	24 months at +2°C to + 8°C (36°F to 46°F) from the 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).	24 months at room temperature, 36 months when refrigerated, or until expiration date.
How Supplied	5 g (50 mL), 10 g (100 mL), 20 g (200 mL), 40 g (400 mL)	5 g (50 mL), 10 g (100 mL), and 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)	1 g (10 mL), 2.5 g (25 mL), 5 g (50 mL), 10 g (100 mL), 20 g (200 mL)	5 g (50 mL) 10 g (100 mL)	Supplied in 2 g, 5 g, 10 g or 20 g single use bottles.	1.0 g, 2.5 g, 5 g, 10 g, 20 g, 30 g