

Product Specifics	Gammaplex® BPL	Flebogamma® 5% DIF Grifols	Octagam® 5% Octapharma	Carimune® NF CSL Behring	Gammagard S/D (IgA > 1 µg/mL) Shire
Indications	Primary Humoral Immunodeficiency in ages ≥ 2, Chronic ITP	Primary Immune Deficiency (PID)	Primary humoral immunodeficiency (PI).	Primary Immune Deficiency (PID) Acute ITP, Chronic ITP	Treatment of Primary Immunodeficiency (PI) in adults and pediatric patients two years of age or older. 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. Prevention of coronary artery aneurysms associated with Kawasaki syndrome in pediatric patients.
Contraindications	History of anaphylactic or severe systemic reactions to human immunoglobulin; IgA deficient patients with antibodies to IgA and history of hypersensitivity. Hereditary intolerance to fructose.	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.	Anaphylactic or severe systemic reactions to human immunoglobulin. IgA deficient patients with antibodies against IgA and a history of hypersensitivity. Patients with acute hypersensitivity reaction to corn.	Contraindicated in patients with selective IgA deficiency, who possess antibody to IgA or hypersensitivity to immunoglobulins. It is contraindicated in patients who have had anaphylactic or severe systemic reactions to human immune globulin.	History of anaphylactic or severe systemic hypersensitivity reactions to the administration of GAMMAGARD S/D <1µg/mL IgA in a 5 % solution.
IgA Content	IgA content lower than 10 mcg/mL	Average: < 3.2 mcg/mL	Trace amounts of IgA (not more than 0.2 mg/ml in a 5% solution).	Specification limit for IgA in Carimune NF is ≤ 2.4 g/L	IgA concentration less than 1 µg/mL
Osmolality	Not less than 240 (typically 420 - 500 mOsmol/kg)	240 - 370 mOsm/kg	310 - 380 mosmol/kg.	In sterile water: 3% - 192 mOsm/kg; 6% - 384 mOsm/kg; 9% - 576 mOsm/kg; 12% - 768 mOsm/kg. In 0.9% NaCl: 3% - 498 mOsm/kg 6% - 690 mOsm/kg; 9% - 882 mOsm/kg; 12% - 1074 mOsm/kg. In 5% Dextrose: 3% - 444 mOsm/kg 6% - 636 mOsm/kg; 9% - 828 mOsm/kg; 12% - 1020 mOsm/kg.	Information not provided
Sugar Content	D-sorbitol (a sugar alcohol) and glycine are used as stabilizers	5% D-sorbitol (polyol)	Maltose (100 mg/mL), no sucrose.	1.67 g sucrose per gram of protein	20 mg/mL glucose in a 5% solution
Sodium Content	30-50 mmol/L	Trace (< 3.2 mmol/L)	Not more than 30 mmol/L.	<20mg NaCl per gram of protein	The product, after reconstituted to 5% solution, contains a physiological concentration of sodium chloride (approximately 8.5 mg/mL)
pH of Product	4.8-5.1	Average: 5.6 ± 0.1	5.1-6.0.	After reconstitution with a neutral unbuffered diluent, the pH is 6.4 - 6.8	6.8 ± 0.4 in a 5% solution
Product Half Life	Mean 42 days	3-week dosing interval: 30 ± 9 days; 4-week dosing interval: 32 ± 5 days	40.7 days in immunodeficient patients.	21 days	37.7 ± 15 days
Viral Safety Process	3 dedicated steps: solvent/detergent, 20nm filtration, terminal low pH incubation	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	Cold-ethanol fractionation, S/D treatment, and pH 4 treatment.	pH 4.0 + trace pepsin, nanofiltration, fractionation, depth filtration, TSE reduction	Solvent Detergent Cohn-Onclay cold ethanol fractionation process Cation and anion exchange chromatography
Route of Administration	Intravenous (IV) only	Intravenous (IV)	Intravenous (IV)	Intravenous (IV)	Intravenous (IV)
Formulation & Concentration	5% Liquid	5% Liquid	5% Liquid	Lyophilized powder	Lyophilized powder
Storage Requirements	Do not freeze, store between 2-25°C (35-77°F)	Room temperature storage: + 2° to + 25°C (36° F to 77° F) Do not freeze.	Do not freeze. Frozen product should not be used. Do not use after expiration date.	Store at room temperature not exceeding 30°C (86°F).	Store at a temperature not to exceed 25°C (77° F)
Shelf Life from Date of Manufacture	36 months at room temperature as indicated by expiry date printed on label	24 months	24 months at +2°C to + 25°C (36°F to 77°F) from the date of manufacture.	36 months	24 months
How Supplied	5g in 100mL, 10g in 200mL, 20g in 400mL	2.5 g (50 mL), 5 g (100 mL) 10 g (200 mL) and 20 g (400 mL)	1 g, 2.5 g, 5 g, 10 g or 25 g single use bottles.	6 g, and 12 g vials	5 g and 10 g