Intravenous Immune Globulin (5% & Lyophilized)

Product Specifics	**Carimune® NF** CSL Behring	**Flebogamma® 5% DIF** Grifols	**Gammagard S/D** (IgA > 1 µg/mL) Shire	**Gammaplex® 5%** BPL	**Octagam® 5%** Octapharma
Indications	Primary Immune Deficiency (PID) Acute ITP, Chronic ITP	The treatment of primary (inherited) immunodeficiency (PI) in adults and pediatric patients 2 years of age and older.	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.	Primary Humoral Immunodeficiency in adults and pediatric patients 2 years of age and older, Chronic Immune Thrombocytopenic Purpura (ITP)	Primary humoral immunodeficiency (PI).
Contraindications	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.	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.	History of anaphylactic or severe systemic hypersensitivity reactions to the administration of GAMMAGARD S/D <1µg/mL IgA in a 5 % solution.	History of anaphylactic or severe systemic reactions to human immunoglobulin; IgA-deficient patients with antibodies to IgA and a history of hypersensitivity. Hereditary intolerance to fructose, also in infants and neonates for whom sucrose or fructose tolerance has not been established.	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.
IgA Content	Specification limit for IgA in Carimune NF is ≤ 2.4 g/L	Contains trace amounts of IgA (typically less than 50 µg/mL). Average: 2.9 µg/mL	IgA concentration less than 1 µg/mL	IgA content less than 10 mcg/mL	Trace amounts of IgA (not more than 0.2 mg/ml in a 5% solution).
Osmolality	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.	240 - 370 mOsm/kg	Information not provided	Not less than 240 (typically 420 - 500 mOsmol/kg)	310 - 380 mOsmol/kg.
Sugar Content	1.67 g sucrose per gram of protein	5% D-sorbitol (polyol)	20 mg/mL glucose in a 5% solution	D-sorbitol and glycine	Maltose (100 mg/mL), no sucrose.
Sodium Content	<20mg NaCl per gram of protein	Trace (< 3.2 mmol/L)	The product, after reconstituted to 5% solution, contains a physiological concentration of sodium chloride (approximately 8.5 mg/mL)	30-50 mmol/L	Not more than 30 mmol/L.
pH of Product	After reconstitution with a neutral unbuffered diluent, the pH is 6.4 - 6.8	The pH of the solution ranges from 5 to 6. Average: 5.6 ± 0.1	6.8 ± 0.4 in a 5% solution	4.8 - 5.1	5.1 - 6.0
Product Half Life	21 days	3-week dosing interval: 30 ± 9 days; 4-week dosing interval: 32 ± 5 days	37.7 ± 15 days	4-week dosing: 41 ± 14 days	40.7 days in immunodeficient patients.
Viral Safety Process	pH 4.0 + trace pepsin, nanofiltration, fractionation, depth filtration, TSE reduction	The purification process includes cold ethanol fractionation, polyethylene glycol precipitation, ion exchange chromatography, low pH treatment, pasteurization, solvent detergent treatment, and Planova nanofiltration using 20 nanometer (nm) filters.	Solvent Detergent Cohn-Oncley cold ethanol fractionation process Cation and anion exchange chromatography	Solvent detergent, 20nm filtration, terminal low pH incubation	Cold-ethanol fractionation, S/D treatment, and pH 4 treatment.
Route of Administration	Intravenous (IV)	Intravenous (IV)	Intravenous (IV)	Intravenous (IV)	Intravenous (IV)
Formulation & Concentration	Lyophilized powder	5% Liquid	Lyophilized powder	5% Liquid	5% Liquid
Storage Requirements	Store at room temperature not exceeding 30°C (86°F).	Room temperature storage: + 2° to + 25°C (36° F to 77° F) Do not freeze.	Store at a temperature not to exceed 25°C (77° F)	Store between 2-25°C (35-77°F). Do not freeze. Keep GAMMAPLEX 5% in its original carton to protect it from light.	Do not freeze. Frozen product should not be used. Do not use after expiration date.
Shelf Life from Date of Manufacture	36 months	24 months	24 months	36 months at room temperature as indicated by expiration date printed on label.	24 months at +2°C to + 25°C (36°F to 77°F) from the date of manufacture.
How Supplied	6 g, and 12 g vials	0.5 g (10 mL), 2.5 g (50 mL), 5 g (100 mL) 10 g (200 mL) and 20 g (400 mL)	5 g and 10 g	5 g (100mL), 10 g (200mL), 20 g (400mL)	1 g, 2.5 g, 5 g, 10 g or 25 g single use bottles.