

# Intravenous Immune Globulins



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PRODUCT SPECIFICS	Privigen®	Carimune® NF Nanofiltered	Flebogamma® 5% DIF	Flebogamma® 10% DIF	Gamunex-C®	Gammaked®	Octagam®	Gammagard Liquid
INDICATIONS	Primary Immunodeficiency (PI), Chronic Immune Thrombocytopenic Purpura (ITP)	Primary Immune Deficiency (PID), Acute ITP, Chronic ITP	Primary Immune Deficiency (PID)	Primary Immune Deficiency (PID)	CIDP, PI, ITP	Intravenous (IV): CIDP, PI, ITP. Subcutaneous (SC): PI	Primary humoral immunodeficiency (PI)	Replacement therapy for PI in adult and pediatric patients two years of age or older
CONTRAINDICATIONS	Patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin. Patients with hyperproliferemia. Patients with selective IgA deficiency with antibodies to IgA.	Contraindicated in patients with selective IgA deficiency, who possess antibody to IgA. It may also be contraindicated in patients who have had severe systemic reactions to intravenous or intramuscular administration of 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.	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.	Acute severe hypersensitivity reactions to human immunoglobulin. IgA deficient patients with antibodies against IgA and history of hypersensitivity. Patients with acute hypersensitivity reaction to com.	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
IG A CONTENT	≤ 25 mcg/mL	720 mcg/mL (~2%) for concentrations from 3% to 12%	Average: 2.9±0.1 mcg/mL (Specification Value: <50 mcg/mL)	Average: 6 mcg/mL (Specification Value: <100 mcg/mL)	Average 46 mcg/mL	Average 46 mcg/mL	≤ 200 mcg/mL	The average immunoglobulin A (IgA) concentration is 37mcg/mL (in a 10% solution)
OSMOLALITY	Approximately 320 mOsmol/kg (range: 240-440)	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	240-370 mOsm/kg	258 mOsmol/kg	258 mOsmol/kg	310-380 mOsmol/kg	240 to 300 mOsmol/kg,
SUGAR CONTENT	None. L-Proline, a nonessential amino acid, is used as a stabilizer.	5% Sucrose	5% D-sorbitol (polyol)	5% D-sorbitol (polyol)	No sugar	No sugar	Maltose	No sugar added
SODIUM CONTENT	Trace	0% water; 0.9% saline	Trace (<3.2 mmol/L)	Trace (<3.2 mmol/L)	Trace amounts	Trace amounts	<30 mmol/L	No sodium added
pH OF LIQUID PRODUCT	4.8 (range is 4.6 - 5.0)	After reconstitution with a neutral buffered diluent, the pH is 6.4 - 6.8	5.6±0.1	5.0-6.0	4.0-4.5	4.0-4.5	5.1 - 6.0	4.6-5.1
PRODUCT HALF LIFE	36.6 days	21 days	3-week dosing interval: 30±9 days; 4-week dosing interval: 32±5 days	3-week dosing interval: 34±10 days; 4-week dosing interval: 37±13 days	Approximately 35 days	Approximately 35 days	40 days	35 days Median value
VIRAL SAFETY PROCESS	pH 4 incubation, 20nm virus filtration, and depth filtration; TSE validation and removal	pH 4.0 + trace pepsin, nanofiltration, fractionation, depth filtration, TSE reduction	Flebogamma® 5% DIF has seven validated steps: 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	Flebogamma® 10% DIF has seven validated steps: 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, Low pH Incubation	Caprylate Precipitation/Depth Filtration, Caprylate Incubation, Depth Filtration, Column Chromatography, Low pH Incubation	Cold ethanol fractionation Solvent-detergent treatment pH4 treatment	Solvent Detergent, 35 nm filtration, incubation (elevated temp) at low pH
ROUTE OF ADMINISTRATION	Intravenous (IV)	Intravenous (IV)	IV	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. Subcutaneous (SC): PI.	IV	IV or SC
FORMULATION & CONCENTRATION	10% Liquid	Lyophilized powder	5% Liquid	10% Liquid	10% Liquid	10% Liquid	5% 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.	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.	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°C (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.	Do not freeze. Frozen product should not be used. Do not use after expiration date.	36 months refrigerated 2°-8°C (36°-46°F), 12 months room temperature 25°C (77°F) within the first 24 months of the date of manufacture; Do not freeze
SHELF LIFE FROM DATE OF MANUFACTURE	36 months	24 months	24 months	24 months	36 months. Do not use after the labeled expiration date	36 months. Do not use after the labeled expiration date	24 months at +2°C to + 25°C (36°F to 77°F) from the date of manufacture	36 months or until expiration date
AVAILABLE SIZES	5 g (50 mL), 10 g (100 mL), 20 g (200 mL)	3 g, 6 g, and 12 g vials	2.5 g (50 mL), 5 g (100 mL) 10 g (200 mL) and 20 g (400 mL)	5 g (50 mL), 10 g (100 mL), and 20 g (200 mL)	1g (10 mL), 2.5g (25 mL), 5g (50 mL), 10g (100 mL), 20g (200 mL)	1g (10 mL), 2.5g (25 mL), 5g (50 mL), 10g (100 mL), 20g (200 mL)	1.0 g, 2.5 g, 5 g, 10 g or 25 g single use bottles	1.0, 2.5, 5.0, 10.0, 20.0, 30.0 grams

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