

# Intravenous Immune Globulin (10%)

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Product Specifics	BIVIGAM® NF ADMA Biologics	Flebogamma® 10% DIF Grifols	GAMMAGARD LIQUID Shire	Gammaked® Kedrion
Indications	BIVIGAM® is an Immune Globulin Intravenous (Human), 10% Liquid, indicated for the treatment of primary humoral immunodeficiency (PI)	Primary Immune Deficiency (PID), Chronic Primary Immune Thrombocytopenia (ITP) in patients 2 years of age and older.	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].	Gammaked is an immune globulin injection (human), 10% liquid indicated for treatment of: Primary Humoral Immunodeficiency (PI) in patients 2 years of age and older, Idiopathic Thrombocytopenic Purpura (ITP) in adults and children, Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) in adults. Gammaked may also be administered subcutaneously for the treatment of PI.
Contraindications	BIVIGAM® is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin.  BIVIGAM® is contraindicated in IgA deficiency 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.	<ol style="list-style-type: none"> <li>In patients who have had a history of anaphylactic or severe systemic hypersensitivity reaction to the administration of human immune globulin.</li> <li>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.</li> </ol>	Gammaked is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin. Gammaked is contraindicated in IgA deficient patients with antibodies against IgA and history of hypersensitivity.
IgA Content	≤ 200 mcg/mL	Flebogamma 10% DIF contains trace amounts of IgA (typically less than 100 µg/mL) Average: 3.1 µg/mL	The average immunoglobulin A (IgA) concentration is 37 mcg/mL (in a 10% solution).	Average 46 mcg/mL
Osmolality	370-510 mOsm/kg	240-370 mOsm/kg	240 - 300 mOsmol/kg	258 mOsmol/kg
Sugar Content	BIVIGAM® does not contain sucrose	5% D-sorbitol (polyol)	No sugar added	Gammaked does not contain sucrose
Sodium Content	0.100-0.140 M sodium chloride	Trace (< 3.2 mmol/L)	No sodium added	Trace amounts
pH of Product	4.0 - 4.6	The pH of the solution ranges from 5 to 6. Average: 5.5 ± 0.1	4.6 - 5.1	4.0 - 4.5
Product Half Life	The median terminal half-life of BIVIGAM® was 30 days	3-week dosing interval: 34 ± 10 days; 4-week dosing interval: 37 ± 13 days	26 – 35 days for Intravenous use	Approximately 35 days
Viral Safety Process	Precipitation and removal of fraction III removes both enveloped and nonenveloped viruses, solvent/detergent treatment represents a virus inactivation step for enveloped viruses, and 35 nm virus filtration removes both enveloped and nonenveloped viruses by size exclusion	Pasteurization at 60 °C, 10 hours, solvent-detergent treatment for 6 hours and nanofiltration down to 20 nm Planova filters. Fraction I precipitation, Fraction II+III precipitation, 4% PEG precipitation and pH treatment for 4 hours at 37 °C).	Solvent Detergent, 35 nm filtration, incubation (elevated temp) at low pH	Gammaked is made from large pools of human plasma by a combination of cold ethanol fractionation, caprylate precipitation and filtration, and anion-exchange chromatography. Isotonicity is achieved by the addition of glycine. Gammaked is incubated in the final container (at the low pH of 4.0–4.3).
Route of Administration	Intravenous (IV)	Intravenous (IV)	Intravenous (IV) or Subcutaneous (SC)	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.
Formulation & Concentration	10% Liquid	10% Liquid	10% Liquid	10% Liquid
Storage Requirements	Refrigerate between 2 to 8°C (36 to 46°F) Do not freeze or heat. Do not use any solutions that have been frozen or heated. Allow refrigerated product to come to room temperature before use. Do not use after expiration date.	Room temperature storage: + 2° to + 25°C (36° F to 77° F). Do not freeze.	<ul style="list-style-type: none"> <li>Do not freeze.</li> <li>Store GAMMAGARD LIQUID in the refrigerator or at room temperature.</li> <li>Refrigeration: 2° to 8°C [36° to 46°F] for up to 36 months.</li> <li>Room Temperature: up to 25°C [77°F] for up to 24 months.</li> <li>Expiration dates for both storage conditions are printed on the outer carton and vial label.</li> <li>Do not use past the applicable expiration date.</li> </ul>	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.
Shelf Life from Date of Manufacture	24 months	24 months	24 months at room temperature, 36 months when refrigerated, or until expiration date.	36 months. Do not use after the labeled expiration date.
How Supplied	5 g protein in (50 mL) single-use, tamper-evident vial 10 g protein in (100 mL) single-use, tamper-evident vial	5 g (50 mL), 10 g (100 mL), and 20 g (200 mL)	1.0 g, 2.5 g, 5 g, 10 g, 20 g, 30 g	1 g (10 mL), 2.5 g (25 mL), 5 g (50 mL), 10 g (100 mL), 20 g (200 mL)

# Intravenous Immune Globulin (10%) Continued

Product Specifics	Gammaplex® 10% BPL	Gamunex-C® Grifols	Octagam® 10% Octapharma	Privigen® CSL Behring
Indications	Primary Humoral Immunodeficiency (PI) in adults, Chronic Immune Thrombocytopenic Purpura (ITP) in adults	GAMUNEX-C is an immune globulin injection (human), 10% liquid indicated for treatment of: Primary Humoral Immunodeficiency (PI) in patients 2 years of age and older, Idiopathic Thrombocytopenic Purpura (ITP) in adults and children, Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) in adults. GAMUNEX-C may also be administered subcutaneously for the treatment of PI.	Chronic immune thrombocytopenic purpura (ITP) in adults.	Primary Humoral Immunodeficiency (PI), Chronic Immune Thrombocytopenic Purpura (ITP), Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
Contraindications	Patients who have a history of anaphylactic or severe systemic reactions to human immune globulin and IgA-deficient patients with antibodies to IgA and a history of hypersensitivity.	GAMUNEX-C is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin. GAMUNEX-C is contraindicated in IgA deficient patients with antibodies against IgA and 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.	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.
IgA Content	< 20 mcg/mL	Average 46 mcg/mL	Trace amounts (average 106 µg/mL in a 10% solution).	≤ 25 mcg/mL
Osmolality	Typically 280 mOsmol/kg	258 mOsmol/kg	310 - 380 mOsmol/kg.	Approximately 320 mOsmol/kg (range: 240-440)
Sugar Content	No sugar	GAMUNEX-C does not contain sucrose	Maltose (90 mg/mL), no sucrose.	None. L-Proline, a nonessential amino acid, is used as a stabilizer.
Sodium Content	< 5 mM	Trace amounts	Not more than 30 mmol/L.	Trace
pH of Product	4.9 - 5.2	4.0 - 4.5	4.5 - 5.0	4.8 (range is 4.6 - 5.0)
Product Half Life	4-week dosing: 34.8 days	Approximately 35 days	Not tested in primary humoral immunodeficiency (PI) patients	Mean 3-week dosing interval = 27.6 ± 5.9 days Mean 4-week dosing interval = 45.4 ± 18.5 days
Viral Safety Process	Solvent detergent, nanofiltration, terminal low pH incubation	GAMUNEX-C is made from large pools of human plasma by a combination of cold ethanol fractionation, caprylate precipitation and filtration, and anion-exchange chromatography. Isotonicity is achieved by the addition of glycine. GAMUNEX-C is incubated in the final container (at the low pH of 4.0–4.3).	Cold-ethanol fractionation, S/D treatment, and pH 4 treatment.	pH 4 incubation, 20nm virus filtration, depth filtration; TSE validation and removal
Route of Administration	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)	Intravenous (IV)
Formulation & Concentration	10% Liquid	10% Liquid	10% Liquid	10% Liquid
Storage Requirements	When stored between 2 °C [35.6 °F] and 25 °C [77 °F]), GAMMAPLEX 10% has a shelf life of 36 months. Do not freeze. Keep GAMMAPLEX 10% in its original carton to protect it from light.	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.	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.
Shelf Life from Date of Manufacture	36 months	36 months. Do not use after the labeled expiration date.	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).	36 months
How Supplied	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)	Supplied in 2 g, 5 g, 10 g or 20 g single use bottles.	5 g (50 mL), 10 g (100 mL), 20 g (200 mL), 40 g (400 mL)