vitalcare® of SOUTH DALLAS

Comparison of IVIG

P: 945.212.3707
F: 945.212.3708

IG Medication Name														
MEDICATION DETAILS	**ASCENIV ™ 10%**	**BIVIGAM® 10%**	**FLEBOGAMMA® 5% DIF**	**FLEBOGAMMA® 10% DIF**	**GAMMAGARD LIQUID**	**GAMMAGARD S/D** IgA less than 1ug/mL in a 5% solution	**GAMMAKED®**	**GAMMAPLEX® 5%**	**GAMMAPLEX® 10%**	**GAMUNEX-C®**	**OCTAGAM® 5%**	**OCTAGAM® 10%**	**PANZYGA**	**PRIVIGEN®**
PHARMACEUTICAL MANUFACTURER	ADMA Biologics, Inc.	ADMA Biologics, Inc.	Grifols	Grifols	Takeda	Takeda	Grifols (distributed by Kedrion Biopharma)	BioProducts Labs	BioProducts Labs	Grifols	Octapharma	Octapharma	Octapharma/Pfizer	CSL Behring
INDICATIONS	Primary Humoral Immunodeficiency (PI) in adults and adolescents (12 years of age). This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congential agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies	Primary Humoral Immunodeficiency (PI)	Primary Immune Deficiency (PID)	Primary Immune Deficiency (PID) and ITP in 2 years 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).	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.	Intravenous (IV): CIDP, PI, ITP. Subcutaneous (SC): PI	Primary Humoral Immunodeficiency (PI) in ages >/= 2 years old, Chronic Immune Thrombocytopenic Purpura (ITP)	Primary Humoral Immunodeficiency (PI) in Adults, Chronic Immune Thrombocytopenic Purpura (ITP)	Intravenous (IV): CIDP, PI, ITP Subcutaneous (SC): PI	Primary humoral immunodeficiency (PI)	Chronic ITP	Primary humoral immunodeficiency (PI) in patients 2 years of age and older, Chronic immune thrombocytopenia (ITP) in adults, Chronic inflammatory demyelinating polyneuropathy (CIDP) in adults	Primary humoral immunodeficiency (PI), Chronic immune thrombocytopenic purpura (ITP), and CIDP
CONTRAINDICATIONS	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 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 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.	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.	History of anaphylactic or severe systemic hypersensitivity reactions to human immune globulin; IgA-deficient patients with antibodies against IgA and a history of hypersensitivity.	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. Hereditary intolerance to fructose. Hereditary intolerance to fructose, also in infants and neonates for whom sucrose or fructose tolerance has not been established.	In patients who have had an anaphylactic or sever systemic reaction to the administration of human immune globulin; IgA-deficient patient 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.	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.	Anaphylactic or severe systemic reactions to human immunoglobulin. IgA deficient patients with antibodies against IgA and history of hypersensitivity. Patients with acute hypersensitivity reaction to corn.	Anaphylactic or severe reaction to human immunoglobulin. IgA deficient patients with antibodies against IgA and history of hypersensitivity. Warning/ Precaution for patients with corn allergy.	History of anaphylactic or severe systemic reactions to human immune globulin IgA-deficient patients with antibodies against IgA and a history of hypersensitivity	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	≤ 200mcg/mL	≤ 200 mcg/mL	Average: < 3.2 mcg/mL	Average: < 3.2 mcg/mL	Average: 37 mcg/mL in a 10% solution	< 1 mcg/mL in a 5% solution	Average: 46 mcg/mL	< 10 mcg/mL	< 20 mcg/ml	Average: 46 mcg/mL	≤ 200 mcg/mL	Average 106 ug/ml	100 µg/ml	≤ 25 mcg/mL
OSMOLALITY	370 - 510 mOsmol/kg	370 - 510 mOsm/kg	240 - 370 mOsm/kg	240 - 370 mOsm/kg	240 - 300 mOsmol/kg	5% - 636 mOsm/kg 10% - 1250 mOsm/kg	258 mOsmol/kg	Not less than 240 (typically 420 - 500 mOsmol/kg)	Not less than 240mOsmol/kg (typically 280 mOsmol/kg)	258 mOsmol/kg	310 - 380 mOsmol/kg	310-380 mOsmol/kg	240-310 mOsmol/kg	Approximately 320 mOsmol/kg (range: 240 - 440 mOsmol/kg)
SUGAR CONTENT	No sugar – stabilized with glycine and polysorbate 80	No sugar	5% D-sorbitol (polyol)	5% D-sorbitol (polyol)	No sugar	20 mg/mL glucose in a 5% solution	No sugar	D-sorbitol (a sugar alcohol) - stabilized with glycine and polysorbate 80	No Sugar – stabilized with glycine and polysorbate 80	No sugar	Maltose	Maltose	No sugar stabilized with glycine	None. L-Proline, a nonessential amino acid is used as a stabilizer.
SODIUM CONTENT	0.100 - 0.140 M Sodium chloride	0.100 - 0.140 M Sodium chloride	Trace (< 3.2 mmol/L)	Trace (< 3.2 mmol/L)	No sodium	Approximately 0.85% NaCL at a 5% concentration	Trace amounts	30 - 50 mmol/L	<30 mmol/L	Trace amounts	< 30 mmol/L	< 30 mmol/L	Trace amounts	Trace amounts
PH OF MEDICATION	4.0 – 4.6	4.0 – 4.6	Average: 5.6 ± 0.1	Average: 5.5 ± 0.1	4.6 - 5.1	6.8 ± 0.4 in a 5% solution	4.0 - 4.5	4.8 - 5.1	4.9-5.3	4.0 - 4.5	5.1 - 6.0	4.5 - 5.0	4.5 - 5.0	4.6 - 5.0
MEDICATION HALF LIFE	3 week dosing interval: 28.47 days ± 4.4 days 4 week dosing interval: 39.70 days ± 11.6 days	30 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.	35 Days	37.7 ± 15 Days	Approximately 35 days	119-132 hours	118-123 hours	Approximately 35 days	Approximately 40 days	Approximately 36 - 40 days	36.1 Days	36.6 Days
VIRAL SAFETY PROCESS	Cohn-Oncley fractionation, Precipitation and removal of fraction III during cold ethanol fractionation; Classical solvent/ detergent treatment; 35 nm virus filtration and low PH	Cohn-Oncley fractionation, Anion exchange chromatography; Precipitation and removal of fraction III during cold ethanol fractionation; Classical solvent/ detergent treatment; 35 nm virus filtration	Seven validated steps: Pasteurization (60°C, 10 h), solvent detergent, dual sequential nonofiltration (35nm and 20 nm), Fraction I precipitation, Fraction II + III incubation, 4% PEG precipitation and acid pH 4 treatment.	Seven validated steps: Pasteurization (60°C, 10 h), solvent detergent, dual sequential nonofiltration (35nm and 20 nm), Fraction I precipitation, Fraction II + III incubation, 4% PEG precipitation and acid pH 4 treatment.	Solvent detergent, 35 nm filtration, Incubation (elevated tempjat low pH	Solvent detergent, Cohn-Oncley cold ethanol fractionation process, Cation and anion exchange chromatography.	Caprylate preclpitation/ depth filtration, caprylate incubation, depth filtration, column chromatography, low pH incubation and TSE removal	Solvent/Detergent treatment; 18nm viral filtration; terminal low pH incubation	Solvent/Detergent treatment; 18nm viral filtration; terminal low pH incubation step	Caprylate preclpitation/depth filtration, caprylate incubation, depth filtration, column chromatography, low pH incubation.	Cold ethanol fractionation, solvent-detergent treatment, pH 4 treatment.	Cold ethanol fractionation, ultra filtration, chromatography solvent - detergent treatment, pH 4 treatment	Cold ethanol fractionation, solvent/detergent treatment, ion-exchange chromatography, nanofiltration (20nm)	pH4 tncubation, 20 nm virus filtration, depth filtration, TSE validation and removal
ROUTE OF ADMINISTRATION	Intravenous (IV)	Intravenous (IV)	Intravenous (IV)	Intravenous (IV)	Intravenous (IV) or Subcutaneous (SC)	Intravenous (IV)	Intravenous (IV): CIDP, PI, ITP. Subcutaneous (SC): PI	Intravenous (IV)	Intravenous (IV)	Intravenous (IV): CIDP, PI, ITP check prescribing information for intital and maintenance infusion rates. SCIG: Adult: 20 mL/hr/site. Pediatric: 10 mL/hr/site (< 25 kg) 15 mL/hr/site (≥ 25 kg).	Intravenous (IV)	Intravenous (IV)	Intravenous (IV)	Intravenous (IV)
FORMULATION & CONCENTRATION	10% Liquid	10% Liquid	5% Liquid	10% Liquid	10% Liquid	Lyophilized powder	10 % Liquid	5% Liquid solutions containing 5% IgG (50mg/ml)	10% Liquid solution containing 10% IgG (100mg/ml)	10% Liquid	5% Liquid	10% Liquid	10% Liquid	10% Liquid
STORAGE REQUIREMENTS	Refrigerate between 2°C to 8°C (36°F to 46° F). Don't freeze or heat.	Refrigerate between 2°C to 8°C (36°F to 46° F). Don't freeze or heat.	Room temperature storage: 2 to 25°C (36 to 77°F). Do NOT freeze. Protect from light.	Room temperature storage: 2 to 25°C (36 to 77°F). Do NOT freeze. Protect from light.	36 Months refrigerated at 2 to 8°C (36 to 46°F). 12 Months room temperature 25°C (77°F) within the first 24 months of the date of manufacture. Do NOT freeze. Protect from light. If removed from refrigerator and brought to room temperature, do not return to refrigerator.	Room temperature storage not to exceed 25°C (77°F). Protect from light. If removed from refrigerator and brought to room temperature, do not return to refrigerator.	36 Months at refrigerated temperature 2 to 8°C (36 to 46°F). Do NOT freeze. 6 months at temperatures not to exceed 25°C (77°F) anytime during the 36-month shelf-life.	Store between 2 to 25°C (35 to 77°F). Do NOT Freeze. Protect from light.	Store between 2°C (35.6°F) to 25°C (77°F). Do NOT Freeze. Protect from light.	36 Months at refrigerated temperature 2 to 8°C (36 to 46°F). Do not freeze. 6 months at temperatures not to exceed 25°C (77°F) anytime during the 36-month shelf-life. Protect from light.	Octagam 5% liquid may be stored for 36 months at +2°C to + 8°C (36°F to 46°F) from the date of manufacture. Within the first 24 months of this shelf life, the product may be stored at ≤ +25°C (77°F). After storage at ≤ +25°C (77°F) the product must be used or discarded. Do not freeze.	Store Octagam 10% for 36 months at +2°C to + 8°C (36°F to 46°F) from the date of manufacture. Within this shelf-life, the product may be stored up to 9 months at ≤+25°C (77°F). After storage at ≤ +25°C (77°F) the product must be used or discarded. Do not freeze.	For 36 months at +2°C to +8°C (36°F to 46°F) from the date of manufacture. Within its shelf-life, the product may be stored at ≤ +25°C (77°F) for up to 12 months. After storage at ≤ +25°C (77°F), either use immediately or discard. Do not freeze.	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	Stored until expiration date on vial packaging at 2°C to 8°C (36°F to 46°F)	Stored until expiration date on vial packaging at 2°C to 8°C (36°F to 46°F)	24 Months	24 Months	36 Months or until expiration date	24 Months	36 Months. Do not use after the labeled expiration date.	24 Months as indicated by expiration date printed on label.	36 months. Do NOT use beyond expiration date on the product label.	36 Months. Do not use after the labeled expiration date.	For 36 months at +2°C to + 8°C (36°F to 46°F) from the date of manufacture. Within the first 24 months of this shelf life, the product may be stored at ≤ +25°C (77°F). After storage at ≤ +25°C (77°F) the product must be used or discarded.	For 36 months at +2°C to + 8°C (36°F to 46°F) from the date of manufacture. Within this shelf-life, the product may be stored up to 9 months at +≤25°C (77°F). After storage at ≤ +25°C (77°F) the product must be used or discarded.	24 months refrigerated (2°C -8°C or 36°F - 46° F) from the date of manufacture.	36 Months
AVAILABLE SIZES	5gm (50mL)	5gm (50mL) 10 gm (100mL)	2.5 gm (50 mL) 5 gm (100 mL) 10 gm (200 mL) 20 gm (400 mL) 0.5gm (10ml)	5 gm (50 mL) 10 gm (100 mL) 20 gm (200 mL)	1.0 gm (10 mL) 2.5 gm (25 mL) 5 gm (50 mL) 10 gm (100 mL) 20 gm (200mL) 30 gm (300mL)	5 gm 10 gm	1.0 gm (10 mL) 2.5 gm (25 mL) 5 gm (50 mL) 10 gm (100 mL) 20 gm (200 mL)	5 gm (100 mL) 10 gm (200 mL) 20 gm (400mL)	5gm (50ml) 10gm (100ml) 20gm (200ml)	1 gm (10 mL) 2.5 gm (25 mL) 5 gm (50 mL) 10 gm (100 mL) 20 gm (200 mL) 40 gm (400mL)	1.0 gm (20 mL) 2.5 gm (50 mL) 5 gm (100 mL) 10 gm (200 mL) 25gm (500ml) single use bottle	2 gm (20 ml) 5 gm (50 ml) 10 gm (100 ml) 20 gm (200 ml) 30gm (300ml)	1gm (10ml) 2.5gm (25ml) 5gm (50ml) 10gm (100ml) 20gm (200ml) 30gm (300ml)	5 gm (50 mL) 10 gm (100 mL) 20 gm (200 mL) 40 gm (400 mL)