vitalcare® of SOUTH DALLAS

Comparison of SCIG

P: 945.212.3707
F: 945.212.3708

	IG Medication Name								
MEDICATION DETAILS	**CUTAQUIG® 16.5%**	**CUVITRU™**	**GAMMAGARD LIQUID**	**GAMMAKED®**	**GAMUNEX-C®**	**HIZENTRA**	**HYQVIA**		**XEMBIFY® 20%**
							Recombinant Human Hyaluronidase	**Immune Globulin Infusion (Human) 10%**	
PHARMACEUTICAL MANUFACTURER	Octapharma	Takeda	Takeda	Kedrion BioPharma	Grifols	CSL Behring	Takeda		Grifols
INDICATIONS	Primary Humoral Immunodeficiency (PI) in adults. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congential agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.	Replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age and older. This includes, but is not limited to, common variable agammaglobulinemia, Wiskott-Aldrich syndrome, and sever combined immunodeficiencies 1 ,2.	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).	Intravenous (IV): CIDP, PI, ITP. Subcutaneous (SC): PI	Intravenous (IV): CIDP, PI, ITP Subcutaneous (SC): PI	Replacement therapy for PI in adults and pediatric patients 2 years of age and older. This includes, but is not limited to, Chronic inflammatory demyelinating polyneuropathy, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency, x-linked agammaglobulinemia, Wiskott-Aldrich Syndrome, and severe combined immunodeficiencies.	The treatment of adult patients (> 16yo) with primary immunodeficiency (PI) associated with defects in humoral immunity. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and sever combined immunodeficiencies.		Primary Humoral Immunodeficiency (PI) in patients 2 years of age or older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congential agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
CONTRAINDICATIONS	In patients with history of anaphylactic or severe systemic reaction to human immune globulin or other components of Cutaquig (Polysorbate 80) and in IgA deficient patients with antibodies against IgA and a history of hypersensitivity	Contraindicated in patients who have had an anaphylactic or severe systemic hypersensitivity reaction to the subcutaneous administration of human immune globulin. CUVITRU is contraindicated in IgA-deficient patients with antibodies against IgA and a history of hypersensitivity to human immune globulin treatment.	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.	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.	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 who have had an anaphylactic reaction or severe systemic reaction to human immune globulin or components of Hizentra, such as polysorbate 80, Individuals with Hyperprolinemia, and IgA-deficient patients with antibodies against IgA and a history of hypersensitivity.	History of anaphylactic or severe systemic hypersensitivity reactions to Immune Globulin (Human). IgA deficient patients with antibodies against IgA and a history of hypersensitivity. Known system hypersensitivity to hyaluronidase or Recombinant Human Hyaluronidase of HyQvia.		In patients with history of anaphylactic or severe systemic reaction to human immune globulin or inactive ingredients of Xembify (Polysorbate 80) and in IgA deficient patients with antibodies against IgA and a history of hypersensitivity
IGA CONTENT	≤ 0.6mg/mL	Average: 80mcg/mL in 20% solution	Average: 37 mcg/mL in a 10% solution	Average: 46 mcg/mL	Average: 46 mcg/mL	The average IgA concentration in a 20% solution is 50 mcg/mL (In a 10% solution, the IgA content would measure 25 mcg/mL)	0 µg/mL	Average 37 µg/mL	≤ 0.7mg/mL
OSMOLALITY	310 - 380 mOsmol/kg	280-292 mOsm/kg	240 - 300 mOsmol/kg	258 mOsmol/kg	258 mOsmol/kg	Hizentra is Isotonic, with an osmolality of 380mOsm/kg	290 - 350 mOsmol/kg	240-300 mOsmol/kg (physiologic range of 285-295)	280 – 404 mOsmol/kg
SUGAR CONTENT	Maltose	None	No sugar	No sugar	No sugar	No Sugar - Stabilized with L-proline.	No sugar		No sugar – stabilized with glycine and polysorbate 80
SODIUM CONTENT	Not more than 30mmol/L	None	No sodium	Trace amounts	Trace amounts	Trace amounts	8.5 mg/ml	No sodium	Trace amounts
PH OF MEDICATION	5.0 - 5.5	4.6 to 5.1	4.6 - 5.1	4.0 - 4.5	4.0 - 4.5	4.6 - 5.2	7.4	4.6 - 5.1	4.1 - 4.8
MEDICATION HALF LIFE	~ 39 days	Not Available	35 Days	Approximately 35 days	Approximately 35 days	NA	Mean: 59.3 days (SD: 36.1)		Can't be determined by the manufacturer
VIRAL SAFETY PROCESS	Cohn-Oncley cold ethanol fractionation, solvent/detergent treatment, ultrafiltration, chromatography, low pH incubation	35nm viral filtration, Low pH incubation at elevated temperature, S/D treatment, Ethanol fractionation	Solvent detergent, 35 nm filtration, Incubation (elevated temp)at low pH	Caprylate preclpitation/ depth filtration, caprylate incubation, depth filtration, column chromatography, low pH incubation.	Caprylate preclpitation/depth filtration, caprylate incubation, depth filtration, column chromatography, low pH incubation.	pH 4.0 incubation; 20nm virus filtration; depth filtration; virus filtration; TSE validation and removal.	Comprehensive virus testing at the Master Cell Bank, Working Cell Bank, and bulk harvest stage; Effective virus reduction during the purification process; use of pharmaceutical grade human albumin.	S/D treatment; 35nm filtration; incubation at low pH.	Cold ethanol fractionation, caprylate precipitation and filtration, and anion-exchange chromatography, nanofiltration, low pH final container incubation
ROUTE OF ADMINISTRATION	Subcutaneous ONLY	Subcutaneous ONLY	Intravenous (IV) or Subcutaneous (SC)	Intravenous (IV): CIDP, PI, ITP. Subcutaneous (SC): PI	Intravenous (IV): CIDP, PI, ITP check prescribing information for intital 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.	SC administration ONLY; Hizentra is approved for dosing once weekly or biweekly.	Subcutaneous (SC)		Subcutaneous only
FORMULATION & CONCENTRATION	16.5% Liquid	20% Liquid	10% Liquid	10 % Liquid	10% Liquid	20% Liquid	10% Liquid		20% Liquid
STORAGE REQUIREMENTS	+2°C to +8° C (36°F to 46°F) for up to 24 months from the date of manufacture. Do not freeze. Protect from light	36 months refrigerated at 2 to 8°C (36 to 46°F); 12 months room temperature not exceeding 25°C(77°F) ; Do NOT freeze Protect from light; Do NOT use after expiration date ; Do NOT return to refrigerator if room temperature is reached	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.	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.	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.	Stable when stored up to 25C (77F) for 30 months. Do not freeze. Protect from light.	36 months at refrigerated temperature from the date of manufacture: 2 to 8°C (36 to 46°F). Protect from light.		+2°C to +8°C (36°F to 46°F) Do not freeze
SHELF LIFE FROM DATE OF MANUFACTURE	+2°C to +8° C (36°F to 46°F) for up to 24 months from the date of manufacture. Within its self-life, the product may be stored at room temperature up to +25°C (77°F) for up to 6 months without being refrigerated again during this period, and must be discarded if not used after this	36 Months at 2-8°C (36-46°F); 12 months room temperature not greater than 25°C (77°F)	36 Months or until expiration date	36 Months. Do not use after the labeled expiration date.	36 Months. Do not use after the labeled expiration date.	30 months room temperature.	3 months at room temperature during the first 24 months from date of manufacture: 25°C (77°F); HyQvia must be used within 3 months after removal to room temperature but within the expiration date.		May be stored at temperatures not to exceed 25°C (77°F) for up to 6 months any time prior to the expiration date.
AVAILABLE SIZES	1 gm (6mL) 1.65 gm (10mL) 2 gm (12mL) 3.3 gm (20mL) 4 gm (24mL) 8 gm (48mL)	1 gm (5mL) 2 gm (10mL) 4 gm (20mL) 8 gm (40mL) 10 gm (50ml)	1.0 gm (10 mL) 2.5 gm (25 mL) 5 gm (50 mL) 10 gm (100 mL) 20 gm (200mL) 30 gm (300mL)	1.0 gm (10 mL) 2.5 gm (25 mL) 5 gm (50 mL) 10 gm (100 mL) 20 gm (200 mL)	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 gm (5mL) 2 gm (10mL) 4 gm (20mL) 10 gm (50mL)	1.25 mL (200 units) 2.5 mL (400 units) 5 mL (800 units) 10 mL (1600 units) 15 mL (2400 units) Dual vial unit of two single use vials	25 mL (2.5g) 50 mL (5g) 100 mL (10g) 200 mL (20g) 300 mL (30g) Dual vial unit of two single use vials	1 gm (5mL) 2 gm (10mL) 4 gm (20mL) 10gm (50mL)