

Product Specifics	Hizentra® CSL Behring	HYQVIA® Shire		Cuvitru® Shire	Gamunex-C® Grifols	Gammaked® Kedrion	Gammagard Liquid Shire
Indications	Replacement therapy for primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older. This includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency, x-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.	Recombinant Human Hyaluronidase	Immune Globulin Infusion (Human) 10%	CUMTRU is an Immune Globulin Subcutaneous (Human), 20% solution indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age and older.	Intravenous (IV): CIDP, PI, ITP. Subcutaneous (SC): PI	Intravenous (IV): CIDP, PI, ITP. Subcutaneous (SC): PI	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].
Contraindications	Individuals who have had an anaphylactic or severe systemic reactions to human immune globulin or components of Hizentra®, such as polysorbate 80. Individuals with Hyperprolinemia. 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 systemic hypersensitivity to hyaluronidase or Recombinant Human Hyaluronidase of HYQVIA.		Anaphylactic or severe systemic hypersensitivity reactions to subcutaneous administration of Immune Globulin (Human). 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 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.	<ol style="list-style-type: none"> In patients who have had a history of anaphylactic or severe systemic hypersensitivity reaction to the administration of human immune globulin. 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.
IgA Content	The IgA concentration in a 20% solution is < 50 mcg/mL. (In a 10% solution, the IgA concentration would measure < 25 mcg/mL)	N/A	The average immunoglobulin A (IgA) concentration is 37 mcg/mL in a 10% solution).	Contains trace amounts of IgA (average concentration of 80 mcg/mL).	Average 46 mcg/mL	Average 46 mcg/mL	The average immunoglobulin A (IgA) concentration is 37mcg/mL (in a 10% solution).
Osmolality	Hizentra® is isotonic, with an osmolality of 380mOsm/kg	290 to 350 mOsm/kg	240-300 mOsmol/kg	280-292 milli-osmoles per kilogram.	258 mOsmol/kg	258 mOsmol/kg	240 - 300 mOsmol/kg
Sugar Content	No added sugars	No added sugars	No added sugars	No added sugars	No added sugars	No added sugars	No sugar added
Sodium Content	Trace amounts	8.5 mg/mL	No sodium added	No sodium added	Trace amounts	Trace amounts	No sodium added
pH of Product	4.6 - 5.2	7.4	4.6-5.1	4.6 to 5.1	4.0 - 4.5	4.0 - 4.5	4.6 - 5.1
Viral Safety Process	ph 4.0 incubation; 20nm virus filtration, depth filtration; virus filtration; TSE validation and removal	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> S/D treatment 35 nm filtration Incubation at low pH 	Solvent/detergent (S/D) treatment, 35 nm nanofiltration, and a low pH incubation at elevated temperature (30 C to 32 C).	Caprylate Precipitation/Depth Filtration, Caprylate Incubation, Depth Filtration, Column Chromatography, Nanofiltration, Low pH Incubation. Manufacturing process includes steps that provide significant removal (≥ 6.6 log10) of TSE infectivity.	Caprylate Precipitation/Depth Filtration, Caprylate Incubation, Depth Filtration, Column Chromatography, Low pH Incubation	Solvent Detergent, 35 nm filtration, incubation (elevated temp) at low pH
Formulation & Concentration	20% Liquid	10% Liquid		20% Liquid	10% Liquid	10% Liquid	10% Liquid
Storage Requirements	Stable when stored up to 25°C (77°F) for 30 months. Do not freeze. Protect from light.	Do not freeze. Keep the vials in the carton in order to protect from light. Refrigeration: 2° to 8°C [36° to 46°F] for up to 36 months. Room Temperature: up to 25°C [77°F] for up to 3 months during the first 24 months from the date of manufacturing (Mfg date) printed on the carton. HYQVIA must be used within 3 months after removal to room temperature but within the expiration date on the carton and vial label. Do not return HYQVIA to the refrigerator after it has been stored at room temperature.		Store at 2°C to 8°C [36° F to 46° F] for up to 36 months or Room temperature (not to exceed 25°C [77°F]) for up to 12 months. Do not return CUMTRU to the refrigerator if you take it out to room temperature. Do not freeze. Do not shake. Keep the vials in the carton in order to protect from light. Discard any unused product. Do not use past the expiration date	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°C (77°F) anytime during the 36-month shelf life.	<ul style="list-style-type: none"> Do not freeze. Store GAMMAGARD LIQUID in the refrigerator or at room temperature. Refrigeration: 2° to 8°C [36° to 46°F] for up to 36 months. Room Temperature: up to 25°C [77°F] for up to 24 months. Expiration dates for both storage conditions are printed on the outer carton and vial label. Do not use past the applicable expiration date.
Shelf Life from Date of Manufacture	30 months room temperature	Refrigeration: 2° to 8°C [36° to 46°F] for up to 36 months. Room Temperature: up to 25°C [77°F] for up to 3 months during the first 24 months from the date of manufacturing.		Up to 36 months when refrigerated. Up to 12 months at room temperature.	36 months. Do not use after the labeled expiration date.	36 months. Do not use after the labeled expiration date.	24 months at room temperature, 36 months when refrigerated, or until expiration date
How Supplied	Single use, tamper evident vial 1 g (5 mL), 2 g (10 mL), 4 g (20 mL) and 10 g (50 mL)	Dual vial unit of two single use vials 1.25 mL (200 units), 2.5 mL (400 units), 5.0 mL (800 units), 10.0 mL (1600 units), 15.0 mL (2400 units)		Single use vials 1g (5mL), 2g (10mL), 4g (20mL), 8g (40mL)	Vial 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)	Vial 1 g (10 mL), 2.5 g (25 mL), 5 g (50 mL), 10 g (100 mL), 20 g (200 mL)	Vial 1.0 g, 2.5 g, 5 g, 10 g, 20 g, 30 g