

# Subcutaneous Immune Globulin

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Product Specifics	CUVITRU Shire	GAMMAGARD LIQUID Shire	Gammaked® Kedrion	Gamunex-C® Grifols	Hizentra® CSL Behring	HYQVIA® Shire	
	Recombinant Human Hyaluronidase						Immune Globulin Infusion (Human) 10%
<b>Indications</b>	CUVITRU 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.	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 Intravenous (IV) 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.	GAMUNEX-C is an immune globulin injection (human), 10% liquid indicated for Intravenous (IV) 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.	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.	HYQVIA is an immune globulin with a recombinant human hyaluronidase indicated for the treatment of Primary Immunodeficiency (PI) in adults	
<b>Contraindications</b>	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.	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.	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.	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.	Individuals who have had an anaphylactic or severe systemic reactions to human immune globulin or components of Hizentra®, such as polysorbate 80. Individuals with hyperproliferemia. 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.	
<b>IgA Content</b>	Contains trace amounts of IgA (average concentration of 80 mcg/mL).	The average immunoglobulin A (IgA) concentration is 37mcg/mL (in a 10% solution).	Average 46 mcg/mL	Average 46 mcg/mL	The IgA concentration in a 20% solution is < 50 mcg/mL	N/A	The average immunoglobulin A (IgA) concentration is 37 mcg/mL (in a 10% solution).
<b>Osmolality</b>	280-292 milli-osmoles per kilogram.	240 - 300 mOsmol/kg	258 mOsmol/kg	258 mOsmol/kg	380mOsm/kg	290 to 350 mOsm/kg	240-300 mOsmol/kg
<b>Sugar Content</b>	No added sugars	No sugar added	Gammaked does not contain sucrose	GAMUNEX-C does not contain sucrose	No added sugars	No added sugars	No added sugars
<b>Sodium Content</b>	No sodium added	No sodium added	Trace amounts	Trace amounts	Trace amounts	8.5 mg/mL	No sodium added
<b>pH of Product</b>	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
<b>Viral Safety Processes</b>	Solvent/detergent (S/D) treatment, 35 nm nanofiltration, and a low pH incubation at elevated temperature (30°C to 32°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).	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).	pH 4.0 incubation; 20nm virus filtration, depth filtration; TSE validation and removal	<ul style="list-style-type: none"> <li>Comprehensive virus testing at the Master Cell Bank, Working Cell Bank, and bulk harvest stage</li> <li>Effective virus reduction during the purification process</li> <li>Use of pharmaceutical grade human albumin</li> </ul>	<ul style="list-style-type: none"> <li>S/D treatment</li> <li>35 nm filtration</li> <li>Incubation at low pH</li> </ul>
<b>Formulation &amp; Concentration</b>	20% Liquid	10% Liquid	10% Liquid	10% Liquid	20% Liquid	10% Liquid	
<b>Storage Requirements</b>	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 CUVITRU 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	<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°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.	Stable when stored up at room temperature 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.	
<b>Shelf Life from Date of Manufacture</b>	Up to 36 months when refrigerated. Up to 12 months at room temperature.	24 months at room temperature, 36 months when refrigerated, 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	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.	
<b>How Supplied</b>	Single use vials 1 g (5mL), 2 g (10mL), 4 g (20mL), 8 g (40mL)	Vial 1.0 g, 2.5 g, 5 g, 10 g, 20 g, 30 g	Vial 1 g (10 mL), 2.5 g (25 mL), 5 g (50 mL), 10 g (100 mL), 20 g (200 mL)	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)	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)  25 mL (2.5 g), 50 mL (5.0 g), 100 mL (10.0 g), 200 mL (20.0 g), 300 mL (30 g)	

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