

Subcutaneous Immunoglobulin (SQIG) Product Guide

AcariaHealth is a national comprehensive specialty pharmacy focused on improving care and outcomes for patients living with complex and chronic conditions. Through Specialty Therapeutic Care, our center of excellence for home infusion and hemophilia patients specializing in immunoglobulin, we work closely with physician offices to support patients on intravenous immunoglobulin (IVIG) and subcutaneous immunoglobulin (SQIG) therapy across various disease states. Our goal is to provide superior support to our providers and unrivaled care to our patients.

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SQIG

Product Name	Cutaquig®	HYQVIA®		Gamunex-C®	Xembify®	Gammagard Liquid	Hizentra®	Cuvitru®
		• Recombinant Human Hyaluronidase	• Human IG infusion (10%)			Adult and padiatria attinute Querry		
Indications	• PI	 Patients (≥ 16 years) with PI associated with defects in humoral immunity. This includes, but is not limited to, CVID, X-LA, congenital agammaglobulinemia, Wis-kott-Aldrich syndrome, severe combined immunodeficiencies, and with CIDP in adults 		 Intravenous (IV): CIDP, PI, ITP Subcutaneous (SC): PI 	 Subcutaneous (SC): primary humoral immunodeficiency disease (PIDD) in patients 2 years of age and older 	• Adult and pediatric patients 2 years and older with PI. Adult patients with Multifocal Motor Neuropathy (MMN)	• PID in pediatric patients 2 years of age and older. CIDP in adults	• PI in adults and children 2+ years old
Contra- inidcations	 Anaphylactic or severe systemic reactions to human IG or any other components of CUTAQUIG such as Polysorbate 80 IgA deficient patients with antibodies against IgA and history of hypersensitivity 	 Anaphylactic or severe systemic reactions to human IG IgA deficient patients with antibodies against IgA and history of hypersensitivity Systemic hypersensitivity to hyaluronidase or Recombinant Human Hyaluronidase of HYQVIA 		 Anaphylactic or severe systemic reactions to human IG IgA deficient patients with antibodies against IgA and history of hypersensitivity 	 Anaphylactic or severe systemic reactions to human IG or any other components of Xembify such as Polysorbate 80 IgA deficient patients with antibodies against IgA and history of hypersensitivity 	 Anaphylactic or severe systemic reactions to human IG IgA deficient patients with antibodies against IgA and history of hypersensitivity 	 Anaphylactic or severe systemic reactions to human IG or components of Hizentra such as polysorbate 80 IgA deficient patients with antibodies against IgA and history of hypersensitivity Hyperprolinemia 	Anaphylactic or severe systemic reactions to human IG. IgA deficien patients with antibodies against IgA and history of hypersentivity
IgA Content	• < 600 ug/ml	• 0 ug/ml	• Average 37 ug/ml	• Average 46 mcg/ml	• Average IgA: 68+19 μg/ml, average IgM: <4 μg/ml	• 37 mcg/ml	• ≤ 50 mcg/ml (20%)	• 80mcg/ml
Osmolality	• 310-380 mOsmol/kg	• 240-300 mOsmol/kg (physiologic range: 285-295)		• 258 mOsmol/kg	• 280-404 mOSm/kg	• 240-300 mOsm/kg	• 380 mOsm/kg	• 280-292mOsm/kg
ugar Content	• Maltose	• Glycine		• Glycine	• Glycine and Polysorbate 80	• Glycine	• L-proline	• Glycine
Sodium Content	• <30 mg/ml	• No sodium		• Trace amounts	• Trace amounts	• No sodium	• Trace amounts	• No sodium
H of Product	· 5-5.5	· 4.6-5.1		· 4.0-4.5	• 4.1-4.8	• 4.6-5.1	• 4.6-5.2	· 4.6-5.1
Half Life	• 49.3 days	• Mean: 59.3 days (SD: 36.1)		• Approximately 35 days	· N/A	• 35 days	• N/A	 105 (71-119) days dependent on disease state, immune system and patient age
Viral Safety Process	 Cold ethanol fractionation followed by ultrafiltration and chromatography Organic S/D mixture composed of tri-n-butyl phosphate (TNBP) and octoxynol Cold ethanol fractionation, S/D treatment and pH 4 treatment 	• S/D treatment, 35 nm filtration, low pH incubation		• Caprylate Incubation, Depth Filtration, Column Chromatography, Low pH Incubation	• Cold ethanol fractionation, caprylate precipitation and filtration, anion-exchange chromatography	• S/D treatment, 35 nm filtration, low pH incubation	 ph 4.0 incubation, 20nm virus filtration, depth filtration, TSE validation and removal 	• S/D treatment, nano-filtration, low PH incubation
Route of dministration	• Subcutaneous (SC)	• Subcutaneous (SC)		 Intravenous (IV): CIDP, PI, ITP Subcutaneous (SC): PI 	• Subcutaneous (SC)	 Intravenous (IV) Subcutaneous (SC): PI 	• Subcutaneous (SC)	• Subcutaneous (SC)
Formulation & Concentration	· 16.5%	• 10% Liquid		• 10% Liquid	• 20% Liquid	• 10% Liquid	• 20% Liquid	• 20% Liquid
Storage	• Refrigerator temperature 2°-8°C (36°-46°F)	• Refrigerator temperature 2°-8°C (36°-46°F). Do not freeze.		• Refrigerator temperature 2°-8°C (36°-46°F)	• Refrigerator temperature 2°-8°C (36°-46°F). Following refrigerated storage, use product immediately or discard.	• Refrigerator temperature 2°-8°C (36°- 46°F). Do not freeze.	• Refrigerator temperature 2°-8°C (36°- 46°F). Do not freeze. Protect from light.	• Refrigerator temperature 2°-8°C (36° 46°F) up to 36 months from the date of manufacture
Requirements	• 6 months at room temperature anytime during the 36-month shelf life	• 3 months at room temperature during the first 24 months from date of manufacture: 25°C (77°F)		• 6 months at room temperature anytime during the 36-month shelf life	• 6 months at room temperature anytime during the 36-month shelf life	• 24 months at room temperature anytime during the 36-month shelf life.		
helf Life from Date of Manufacture	• 36 months	• 36 months		• 36 months	• 36 months	• 36 months	• 30 months	• 36 months
How Supplied	• Vial	• Dual vial unit of two single use vials		• Vial	• Vial	• Vial	• Single use, tamper evident vial	• Vial
Available Sizes	• 1 gm, 1.65 gm, 2 gm, 3.3 gm, 4 gm, 8gm	• 1.25 ml, 2.5 ml, 5 ml, 10 ml, 15 ml 2.5 gm, 5 gm, 10 gm, 20 gm, 30 gm		• 1 gm, 2.5 gm, 5 gm, 10 gm, 20 gm, 40 gm	• 1 gm, 2 gm, 4 gm, 10 gm	• 1 gm, 2.5 gm, 5 gm, 10 gm, 20 gm, 30 gm	 1 gm, 2 gm, 4 gm, 10 gm vials 1 gm, 2 gm, 4 gm pre-filled syringes 	• 1gm, 2gm, 4gm, 8gm & 10gm

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