

Subcutaneous Immune Globulins



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PRODUCT SPECIFICS	Hizentra®	Gamunex-C®	Gammaked®	Gammagard Liquid
INDICATIONS	PID	CIDP, PI, ITP	Intravenous (IV): CIDP, PI, ITP. Subcutaneous (SC): PI	Replacement therapy for PI in adult and pediatric patients two years of age or older
CONTRAINDICATIONS	Individuals who have had an anaphylactic or severe systemic reactions to human immune globulin or components of Hizentra®. Individuals with Hyperprolinemia. 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.	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.	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
IG A CONTENT	≤50 mcg/mL	Average 46 mcg/mL	Average 46 mcg/mL	The average immunoglobulin A (IgA) concentration is 37mcg/mL (in a 10% solution)
OSMOLALITY	380 mOsm/kg	258 mOsmol/kg	258 mOsmol/kg	240 to 300 mOsmol/kg,
SUGAR CONTENT	None. Hizentra® is stabilized with L-proline.	No sugar	No sugar	No sugar added
SODIUM CONTENT	≤10 mmol/L	Trace amounts	Trace amounts	No sodium added
pH OF LIQUID PRODUCT	4.6-5.2	4.0-4.5	4.0-4.5	4.6-5.1
PRODUCT HALF LIFE	NA	Approximately 35 days	Approximately 35 days	35 days Median value
ROUTE OF ADMINISTRATION	SQ administration only; check prescription information for dosing; initial infusion rate: 15 mL/h; may be increased to 25 mL/h as tolerated; 50 mL/h total for all sites combined	Intravenous (IV): CIDP, PI, ITP. Check prescribing information for initial 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.	Intravenous (IV): CIDP, PI, ITP. Subcutaneous (SC): PI.	IV or SC
VIRAL SAFETY PROCESS	pH 4.0 incubation; depth filtration; virus filtration; TSE reduction	Caprylate Precipitation/Depth Filtration, Caprylate Incubation, Depth Filtration, Column Chromatography, Low pH Incubation	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	10% Liquid	10% Liquid
STORAGE REQUIREMENTS	Stable when stored up to 25°C (77°F) for 30 months. Do not freeze.	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.	36 months refrigerated 2°-8°C (36°-46°F), 12 months room temperature 25°C (77°F) within the first 24 months of the date of manufacture; Do not freeze
SHELF LIFE FROM DATE OF MANUFACTURE	30 months room temperature	36 months. Do not use after the labeled expiration date	36 months. Do not use after the labeled expiration date	36 months or until expiration date
HOW SUPPLIED	Single use, tamper evident vial	Vial	Vial	Vial
AVAILABLE SIZES	5, 10, 20 mL	1g (10 mL), 2.5g (25 mL), 5g (50 mL), 10g (100 mL), 20g (200 mL)	1g (10 mL), 2.5g (25 mL), 5g (50 mL), 10g (100 mL), 20g (200 mL)	1.0, 2.5, 5.0, 10.0, 20.0, 30.0 grams

IMPORTANT NOTICE - The information provided herein is a summary of available information only. This summary is to be used as a general educational tool and is not intended for use as a guideline for clinical evaluations. Such evaluations (including but not limited to initial and/or subsequent dosing, conversions from specific product brands, etc.) should utilize a thorough review of appropriate clinical data. For a copy of a product insert or to request any additional information at our disposal, please contact us at 1-800-948-9834. The possibility of error (typographical or otherwise) exists in this summary. No liability is assumed by the distributor for improper use of this literature. ©2011. BDI Pharma, Inc. All rights reserved.