

Characteristics of Available Immune Globulin Products Licensed for Use in the United States

BRAND NAME	Gammagard S/D		Gammagard Liquid	Gammaplex	Carimune NF	Hizentra	Privigen	Vivaglobin	Flebogamma DIF		Octagam	Gamunex - C
	5%	10%							5%	10%		
MANUFACTURER	Baxter Corporation/ BioScience Division		Baxter Corporation/ BioScience Division	Bio Products Laboratory	CSL Behring	CSL Behring	CSL Behring	CSL Behring	Grifols		Octapharma	Talecris
METHOD OF PRODUCTION (Including Viral Inactivation)	Cohn-Oncley fractionation, ultra-filtration, ion-exchange chromatography, solvent detergent treatment		Cohn-Oncley fractionation, solvent/detergent treatment, ANX chromatography, 35nm nanofiltration, low pH/elevated temperature incubation	Kistler & Nitschmann fractionation, DEAE-Sephadex chromatography, Solvent/detergent, CM-Sephadex chromatography, Virus Filtration (20 nm) Terminal low pH incubation (30°C, 2 weeks)	Kistler Nitschmann fractionation, pH 4.0, trace pepsin, nanofiltration	Cold alcohol fractionation, octanoic acid fractionation, anion exchange chromatography; pH 4 incubation, depth filtration, nanofiltration; TSE reduction steps include octanoic acid fractionation, depth filtration, and virus filtration	Octanoic Acid Fractionation, CH9 Filtration, pH 4.0 incubation, Depth filtration, Chromatography, Nanofiltration	Cold alcohol fractionation, ethanol-fatty alcohol/pH precipitation, pasteurization, diafiltered and ultrafiltered	Cold alcohol fractionation, polyethylene glycol precipitation, ion exchange chromatography, pH 4 treatment (4 hours at 37° C), pasteurization (60° C for 10 hours), solvent detergent treatment, and double sequential nanofiltration through 35 and 20 nm filters		Cohn-Oncley cold ethanol fractionation, ultra-filtration, chromatography, solvent detergent treatment	Cohn-Oncley fractionation, caprylate/ chromatography purification, cloth and depth filtration, final container low pH incubation
FORM	Lyophilized		Liquid	Liquid	Lyophilized	Liquid	Liquid	Liquid	Liquid		Liquid	Liquid
SHELF-LIFE	24 Months		36 Months	24 Months (room temperature storage)	24 Months	30 Months (room temperature storage)	36 Months (room temperature storage)	24 Months	24 Months (room temperature storage)		24 Months	36 Months
RECONSTITUTION TIME	<5 minutes at room temperature >20 minutes if cold		None (Liquid Solution)	None (Liquid Solution)	Several Minutes	None (ready-to-use Liquid Solution)	None (Liquid Solution)	None (Liquid Solution)	None (Liquid Solution)		None (Liquid Solution)	None (Liquid Solution)
AVAILABLE CONCENTRATIONS	5%	10%	10%	5%	3 to 12%	20% (200 mg/mL)	10%	16% (160 mg protein/ per ml)	5%	10%	5%	10%
MAXIMUM RECOMMENDED INFUSION RATE	4 mL/kg/hour	8 mL/kg/hour	5 mL/kg/hour	4.8 mL/kg/hour	>2.5 mL/kg/hour	Up to 25 mL/hr/injection site (50 mL/hr for all sites combined)	4.8mL/kg/hour	20 mL per hour	6.0 mL/kg/hour	4.8 mL/kg/hour	<4.2 mL/kg/hour	4.8 mL/kg/hour (IV) 20 mL per hour (SC)
TIME TO INFUSE 35 gms	2.5 hours	0.6 hours	1 hour	125 minutes or 2:05 hours	<3.3 hours (6% Solution)	Time will vary depending upon volume & tolerability	63 minutes	² Time will vary depending upon volume & tolerability	1.6 hours	1 hour	2.5 hours	Time will vary depending on route of administration
SUGAR CONTENT	20 mg/ml glucose	40 mg/ml glucose	No added sugars	5% D-sorbitol (polyol)	1.67 gm sucrose per gram of protein	None	None	None	None		100 mg/ml. maltose	None
SODIUM CONTENT	8.5 mg/mL sodium chloride	17 mg/mL sodium chloride	No added sodium	30 - 50 mmol/L	<20 mg sodium chloride per gram of protein	Trace Amounts (≤10 mmol/L)	Trace Amounts	3 mg/mL	Trace Amounts		≤30 mmol/L	Trace Amounts
OSMOLARITY/ OSMOLALITY	636 mOsm/L	1250 mOsm/L	240 - 300 mOsm/kg	460 - 500 mOsm/kg	192 - 1074 mOsm/kg	380 mOsmol/kg	isotonic (320 mOsmol/kg)	445 mOsm/kg	240-370 mOsm/kg		310 - 380 mOsm/kg	258 mOsm/kg
PH	6.4 – 7.2		4.6 – 5.1	4.6 – 5.1	6.4 – 6.8	4.6 – 5.2	4.8	6.4 – 7.2	5.0 – 6.0		5.1 – 6.0	4.0 – 4.5
IgA CONTENT	< 2.2 µg/mL in a 5% solution		37 µg/mL	Average: <4 mcg/mL (Specification value: <10 mcg/mL)	720 µg/mL	≤50 mcg/ml	< or = 25mcg/mL	<1700 µg/mL	Average: < 3 mcg/mL (Specification value: < 50 mcg/mL)	Average: < 6 mcg/mL (Specification value: < 100 mcg/mL)	<100 µg/mL	46 µg/mL
APPROVED METHOD OF ADMINISTRATION	Intravenous		Intravenous	Intravenous	Intravenous	Subcutaneous	Intravenous	Subcutaneous	Intravenous		Intravenous	Intravenous Subcutaneous

10.5 gm/kg for a 70 kg adult = 35 gms; 5% Concentrations: 1g = 20 mL; 10% Concentrations: 1g = 10 mL.

²Time will vary depending upon volume and tolerability. Using 35 grams as monthly dose, calculate weekly dose=8.75 grams=55 mL. infused into 4 sites @ rate up to 20cc/hr/site, which can range from 45 mins. To 3 hrs.

The time to infuse is based on the maximal infusion rate. Check product label for storage temperatures, which vary among Immunoglobulin brands. Check package insert for detailed prescribing information. Information for each of the products listed above has been provided directly to IDF by the manufacturer of that product.

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