

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

BRAND NAME	Gammagard S/D		Gammagard Liquid	Gammaplex	Carimune NF	Hizentra	Privigen	³Vivaglobin	Flebogamma DIF		Gammaked	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		Kedrion	Octapharma	Talecris	
METHOD OF PRODUCTION (Including Viral Inactivation)	Cohn-Onclay fractionation, ultra-filtration, ion-exchange chromatography, solvent detergent treatment		Cohn-Onclay fractionation, ion-exchange chromatography solvent/detergent treatment, 35nm nanofiltration, low pH/elevated temperature incubation	Kistler & Nitschmann fractionation, DEAE-Sephadex chromatography, Solvent/detergent, CM-Sepharose 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-Onclay fractionation, caprylate/ chromatography purification, cloth and depth filtration, final container low pH incubation	Cohn-Onclay cold ethanol fractionation, ultra-filtration, chromatography, solvent detergent treatment	Cohn-Onclay fractionation, caprylate/ chromatography purification, cloth and depth filtration, final container low pH incubation	
FORM	Lyophilized		Liquid	Liquid	Lyophilized	Liquid	Liquid	Liquid	Liquid		Liquid	Liquid	Liquid	
SHELF-LIFE/STORAGE REQUIREMENT	24 Months (room temperature storage)		36 Months (refrigerated) 12 Months (room temperature storage)	24 Months (room temperature storage)	24 Months	30 Months (room temperature storage)	36 Months (room temperature storage)	24 Months	24 Months (room temperature storage)		36 Months	24 Months	36 Months	
RECONSTITUTION TIME	N/A		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)	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%	10%	5%	10%	
MAXIMUM RECOMMENDED INFUSION RATE	4 mL/kg/hour	8 mL/kg/hour	5 mL/kg/hour (IV)	< 40 kg: 20mL/hr/site ≥ 40 kg: 30mL/hr/site with a maximum of 8 sites (SC)	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	4.8 mL/kg/hour (IV) 20 mL per hour (SC)	<4.2 mL/kg/hour	4.8 mL/kg/hour (IV) 20 mL per hour (SC)
¹TIME TO INFUSE 35 gms	Time will vary based on concentration and tolerability		Time will vary based on tolerability and route of administration	125 minutes or 2:05 hours	<3.3 hours (6% Solution)	Time will vary depending upon volume & tolerability	63 minutes	²Time will vary depending upon volume & tolerability	1.6 hours	1 hour	Time will vary depending on route of administration	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		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		Trace Amounts	≤30 mmol/L	Trace Amounts	
OSMOLARITY/ OSMOLALITY	636 mOsm/kg	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		258 mOsm/kg	310 - 380 mOsm/kg	258 mOsm/kg	
PH	6.8 ± 0.4		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		4.0 – 4.5	5.1 – 6.0	4.0 – 4.5	
IgA CONTENT	< 1 µg/mL < 2.2 µg/mL		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)	46 µg/mL	<100 µg/mL	46 µg/mL	
APPROVED METHOD OF ADMINISTRATION	Intravenous		Intravenous Subcutaneous	Intravenous	Intravenous	Subcutaneous	Intravenous	Subcutaneous	Intravenous		Intravenous Subcutaneous	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.

³No longer sold in the U.S.

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.