

## Characteristics of Available Immune Globulin Products Licensed for Use in the UNITED STATES

BRAND NAME	Gammagard S/D		Gammagard Liquid	Carimune NF	Vivaglobin	Privigen	Flebogamma 5%	Flebogamma 5% DIF	Octagam	Gamunex
	5%	10%								
MANUFACTURER	Baxter Corporation/BioScience Division		Baxter Corporation/BioScience Division	CSL Behring	CSL Behring	CSL Behring	Grifols	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, pH 4.0, trace pepsin, nanofiltration	Cold alcohol fractionation, ethanol-fatty alcohol/pH precipitation, pasteurization, diafiltered and ultrafiltered	Octanoic Acid Fractionation, CH9 Filtration, pH 4.0 incubation, Depth filtration, Chromatography, Nanofiltration	Cold alcohol fractionation, polyethylene glycol precipitation, ion exchange chromatography, pasteurization (60° C for 10 hours) and 8% PEG precipitation	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	Lyophilized	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid
SHELF-LIFE	24 Months		36 Months	24 Months	24 Months	24 Months (room temperature storage)	24 Months (room temperature storage)	24 Months (room temperature storage)	24 Months	36 Months
RECONSTITUTION TIME	<5 minutes at room temperature >20 minutes if cold		None (Liquid Solution)	Several Minutes	None (Liquid Solution)	None (Liquid Solution)	None (Liquid Solution)	None (Liquid Solution)	None (Liquid Solution)	None (Liquid Solution)
AVAILABLE CONCENTRATIONS	5%	10%	10%	3 to 12%	16% (160 mg protein/ per ml)	10%	5%	5%	5%	10%
MAXIMUM RECOMMENDED INFUSION RATE	4 mL/ kg/hour	8 mL/ kg/hour	5 mL/kg/hour	>2.5 mL/kg/hour	20 mL per hour	4.8mL/kg/hour	6.0 mL/kg/hour	6.0 mL/kg/hour	<4.2 mL/kg/hour	4.8 mL/kg/hour
<sup>1</sup> TIME TO INFUSE 35 gms	2.5 hours	0.6 hours	1 hour	<3.3 hours (6% Solution)	<sup>2</sup> Time will vary depending upon volume & tolerability	63 minutes	1.6 hours	1.6 hours	2.5 hours	1.0 hours
SUGAR CONTENT	20 mg/ml. glucose	40 mg/ml. glucose	No added sugars	1.67 gm sucrose per gram of protein	None	None	5% D-sorbitol (polyol)	5% D-sorbitol (polyol)	100 mg/ml. maltose	None
SODIUM CONTENT	8.5 mg/mL sodium chloride	17 mg/mL sodium chloride	No added sodium	<20 mg sodium chloride per gram of protein	3 mg/mL	Trace Amounts	<3.2 mmol/L	< 3.2 mmol/L	≤30 mMol/L	Trace Amounts
OSMOLARITY/ OSMOLALITY	636 mOsm/L	1250 mOsm/L	240 - 300 mOsm/kg	192 - 1074 mOsm/kg	445 mOsm/kg	isotonic (320 mOsmol/kg)	240-350 mOsm/kg	240-370 mOsm/kg	310 - 380 mOsm/kg	258 mOsm/kg
PH	6.4 – 7.2		4.6 – 5.1	6.4 – 6.8	6.4 – 7.2	4.8	5.0 – 6.0	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	720 µg/mL	<1700 µg/mL	< or = 25mcg/mL	< 50 µg/mL	Average: < 3 mcg/mL (Specification value: < 50 mcg/mL)	<100 µg/mL	46 µg/mL
APPROVED METHOD OF ADMINISTRATION	Intravenous		Intravenous	Intravenous	Subcutaneous	Intravenous	Intravenous	Intravenous	Intravenous	Intravenous

<sup>1</sup>0.5 gm/kg for a 70 kg adult = 35 gms; 5% Concentrations: 1g = 20 mL; 10% Concentrations: 1g = 10 mL.

<sup>2</sup>Time 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.