Comparison of Intravenous Immunoglobulin Products available under National Blood Supply Arrangements from 1 March 2021

DESCRIPTION	INTRAGAM 10	FLEBOGAMMA 5% DIF	FLEBOGAMMA 10% DIF	PRIVIGEN 10%	GAMUNEX 10%	OCTAGAM 10%
Presentation	Solution; 2.5g (25mL) 10g (100mL) 20g (200mL) vials	Solution; 0.5g (10mL) 2.5g (50mL) 5g (100mL) 10g (200mL) 20g (400mL) vials	Solution; 5g (50mL) 10g (100mL) 20g (200mL) vials	Solution; 5g (50mL) 10g (100mL) 20g (200mL) 40g (400mL) vials	Solution; 5g (50mL) 10g (100mL) 20g (200mL) vials	Solution; 2g (20mL) 5g (50mL) 10g (100mL) 20g (200mL) vials
Concentration	10%	5%	10%	10%	10%	10%
Source Plasma	Australian volunteer non- remunerated donors	USA and European remunerated and non-remunerated Qualified Only donors (QSEAL certified)	USA and European remunerated and non-remunerated Qualified Only donors (QSEAL certified)	European and USA remunerated and non-remunerated donors	USA and European remunerated and non-remunerated Qualified Only donors (QSEAL certified)	European and USA remunerated and non-remunerated donors
Plasma Testing	Hepatitis B surface antigen; antibodies to HIV 1/2 and hepatitis C; nucleic acid testing for hepatitis B, hepatitis C and HIV-1	Hepatitis B surface antigen; antibodies to HIV 1/2 and hepatitis C; nucleic acid testing for hepatitis A, hepatitis B, hepatitis C, HIV and parvovirus B19	Hepatitis B surface antigen; antibodies to HIV 1/2 and hepatitis C; nucleic acid testing for hepatitis A, hepatitis B, hepatitis C, HIV and parvovirus B19	Hepatitis B surface antigen; antibodies to HIV 1/2 and hepatitis C; nucleic acid testing for hepatitis A, hepatitis B, hepatitis C, HIV-1 and parvovirus B19	Hepatitis B surface antigen; antibodies to HIV 1/2 and hepatitis C; nucleic acid testing for hepatitis A, hepatitis B, hepatitis C, HIV and parvovirus B19	Hepatitis B surface antigen; antibodies to HIV 1/2 and hepatitis C; nucleic acid testing for hepatitis A, hepatitis B, hepatitis C, HIV-1 and parvovirus B19
Manufacturer	CSL Behring, Broadmeadows, Australia	Instituto Grifols, S.A. Can Guasch, 2 - Parets del Vallès 08150 Barcelona - Spain	Instituto Grifols, S.A. Can Guasch, 2 - Parets del Vallès 08150 Barcelona - Spain	CSL Behring, Broadmeadows, Australia CSL Behring AG, Wankdorfstrasse 10, CH–3000 Bern 22, Switzerland	Grifols Therapeutics LLC 8368 US Hwy 70 West Clayton, North Carolina 27520 USA	Octapharma AG, Seidenstrasse 2, CH-8853 Lachen, Switzerland
Distributor	Australian Red Cross Lifeblood					
Manufacturing Process	Chromatographic fractionation	Cold alcohol fractionation, polyethylene glycol precipitation, ion exchange chromatography and low pH treatment	Cold alcohol fractionation, polyethylene glycol precipitation, ion exchange chromatography and low pH treatment	Cold ethanol fractionation, octanoic acid fractionation, depth filtration, anion exchange chromatography	Cold ethanol fractionation, caprylate precipitation and depth filtration, and anion-exchange chromatography and low pH incubation	Cold ethanol fractionation

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Viral Safety	Three dedicated steps: • Pasteurisation (60°C for 10 hours) • Incubation at low pH • Nanofiltration (20nm)	Three dedicated steps: • Pasteurisation • Solvent detergent treatment • Two sequential nanofiltrations (35nm and 20nm)	Three dedicated steps: • Pasteurisation • Solvent detergent treatment • Two sequential nanofiltrations (35nm and 20nm)	Three steps to optimise pathogen safety. Two dedicated steps: • Incubation at pH 4 • 20nm nanofiltration Third step contributes to virus reduction capacity: • Depth filtration	The following process steps contribute to virus inactivation and/or removal: caprylate precipitation/depth filtration, caprylate incubation, column chromatography and final container low pH incubation.	Three stage viral inactivation/removal process: • Solvent/detergent treatment • Incubation at low pH • Cold ethanol fractionation (which also includes further filtration steps that contribute to viral safety)
Stabiliser [1]	Glycine (non-essential amino acid)	Sorbitol [2a]	Sorbitol [2b]	Proline (non-essential amino acid)	Glycine	Maltose[3]
Storage Conditions	Refrigerate at 2°C to 8°C for up to 2 years. Do not freeze. Once removed from refrigeration, store below 25°C and use within 3 months. Protect from light.	Store below 30°C for up to 2 years. Do not freeze. Protect from light.	Store below 30°C for up to 2 years. Do not freeze. Protect from light.	Store below 25°C for up to 3 years. Do not freeze. Protect from light.	Store at 2°C to 8°C for up to 36 months, AND may be stored at temperatures not to exceed 25ºC for up to 6 months anytime during the 36 month shelf life, after which the product must be used immediately or discarded. Do not freeze.	Store at 2°C to 8°C for up to 2 years. Refrigerate. Do not freeze. Protect from light. Once removed from refrigeration, the product may be stored below 25°C for a single period of 9 months.
Need for Reconstitution	No	No	No	No	No	No
Dosage and Administration	For intravenous use only, see approved Product Information for rate of infusion	For intravenous use only, see approved Product Information for rate of infusion	For intravenous use only, see approved Product Information for rate of infusion	For intravenous use only, see approved Product Information for rate of infusion	See approved Product Information for rate of infusion	For intravenous use only. See approved Product Information for rate of infusion

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DESCRIPTION	INTRAGAM 10	FLEBOGAMMA 5% DIF	FLEBOGAMMA 10% DIF	PRIVIGEN 10%	GAMUNEX 10%	OCTAGAM 10%
Relative IgG Subclass Content	IgG1 47.6-56.2% IgG2 41.5-49.5% IgG3 1.3-1.6% IgG4 0.9-1.3%	IgG1 66.6% IgG2 28.5% IgG3 2.7% IgG4 2.2%	IgG1 66.6% IgG2 27.9% IgG3 3.0% IgG4 2.5%	IgG1 67.8% IgG2 28.7% IgG3 2.3% IgG4 1.2%	The distribution of IgG subclasses is similar to that found in normal serum.	IgG1 60% IgG2 32% IgG3 7% IgG4 1%
IgA Level [4]	<0.025 mg/mL	<0.05 mg/mL	<0.1 mg/mL	≤ 0.025 mg/mL	≤ 0.084 mg/mL	≤ 0.4 mg/mL
Precautions and Adverse Reactions [5]	See approved Product Information. Note that different IVIg products have different infusion rates and some adverse reactions may be infusion rate dependent					

The information contained in the above table has been provided and approved by CSL Behring Australia, Grifols Australia and Octapharma Australia.

Australian Red Cross Lifeblood makes no warranties in relation to the products, INTRAGAM 10, PRIVIGEN 10%, FLEBOGAMMA 5% DIF, FLEBOGAMMA 10% DIF, GAMUNEX 10% and OCTAGAM 10%, nor the information provided about these products.

Notes:

1. Although the majority of renal adverse events have occurred with sucrose containing IVIg products, caution is advised during administration of any IVIg product.
2. a) Patients with rare hereditary problems of fructose intolerance should not take this medicine. Special precautions should be taken with babies and young children because this fructose intolerance may not yet be diagnosed and may be fatal. (Reference: FLEBOGAMMA 5% DIF Product Information)

   b) Patients with rare hereditary problems of fructose intolerance should not take this medicine. Babies and young children should not receive FLEBOGAMMA 10% DIF because this fructose intolerance may not yet be diagnosed and may be fatal. (Reference: FLEBOGAMMA 10% DIF Product Information).
3. Some older style glucose monitoring systems (test strips) that use the glucose dehydrogenase pyrroloquinoline quinone (GDH-PQQ) or glucose-dye-oxidoreductase method will report falsely elevated glucose readings in the presence of maltose. OCTAGAM 10% contains maltose.

   To.reduce the risk of inappropriate administration of insulin due to falsely elevated glucose readings, the following precautions should be taken when patients are receiving maltose containing products:

   - review the product insert of the glucose monitoring system, or contact the manufacturer to determine which glucose determination method is used.
   - only use systems that use glucose oxidase or hexokinase, or glucose dehydrogenase-NAD (GDH-NAD) for the method of glucose determination.
4. In IgA deficient patients, product with the lowest IgA level should be selected.
5. Infusion of IVIg may lead to a relative increase in blood viscosity. Patients should be adequately hydrated prior to commencement of the infusion. IVIg should NOT be infused rapidly to patients at increased risk of thromboembolic and renal adverse events, particularly when using higher concentration IVIg products.