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

DESCRIPTION	EVOGAM	HIZENTRA	CUVITRU
Presentation	Solution; 0.8g (5mL), 3.2g (20mL) vials	Solution; 1g (5mL), 2g (10mL), 4g (20mL), 10g (50mL) vials	Solution; 1g (5mL), 2g (10mL), 4g (20mL), 8g (40mL) vials
Concentration	16%	20%	20%
Source Plasma	Australian volunteer non-renumerated donors	European and USA remunerated and non-remunerated donors	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 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-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-1 and parvovirus B19
Manufacturer	CSL Behring, Broadmeadows, Australia	CSL Behring AG, Wankdorfstrasse 10, CH–3000 Bern 22, Switzerland	Baxalta Belgium Manufacturing SA, Lessines, Belgium
Distributor	Australian Red Cross Lifeblood		
Manufacturing Process	Cold ethanol fractionation, adsorption/filtration, anion exchange chromatography	Cold ethanol fractionation, octanoic acid fractionation, depth filtration, anion exchange chromatography	Cold ethanol fractionation, weak cation exchange and anion exchange chromatography
Viral Safety	Two dedicated steps: • Pasteurisation (60ºC for 10 hours) • 20nm nanofiltration	Three steps to optimise pathogen safety. Two dedicated steps: • Incubation at pH 4 • Nanofiltration Third step contributes to virus reduction capacity: • Depth filtration	Three steps of viral inactivation incorporated into the downstream purification: • Solvent detergent treatment • Nanofiltration (35nm) • Incubation at a low pH and elevated temperature (30ºC to 32ºC, pasteurisation for 21 to 23 days)
Stabiliser [1]	Glycine	Proline (non-essential amino acid)	Glycine

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DESCRIPTION	EVOGAM	HIZENTRA	CUVITRU
Storage Conditions	Refrigerate at 2°C to 8ºC for up to 2 years. Do not freeze. Once removed from refrigeration, store below 25ºC and use within 2 weeks. Protect from light.	Store below 25ºC for up to 30 months. Do not freeze. Protect from light.	Store below 25°C for up to 24 months from date of manufacture. Do not freeze. Protect from light.
Need for Reconstitution	No	No	No
Dosage and Administration	For subcutaneous use only, see approved Product Information for rate of infusion		
Relative IgG subclass content	IgG1 47.8 - 58.1% IgG2 38.8 - 49.3% IgG3 0.9 - 1.4% IgG4 1.4 - 2.1%	IgG1 68% IgG2 27% IgG3 3% IgG4 2%	IgG1 ≥ 56.9% IgG2 ≥ 26.6% IgG3 ≥ 3.4% IgG4 ≥ 1.7%
IgA level [2]	< 0.025mg/mL	≤ 0.05mg/mL (normally below 0.005mg/mL).	0.08 mg/mL (average IgA concentration)
Precautions and Adverse Reactions	See approved Product Information. Note that different SCIg 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 and Takeda. Australian Red Cross Lifeblood makes no warranties in relation to the products EVOGAM, HIZENTRA or CUVITRU, 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 also advised during administration of any SCIg product.
2. For IgA deficient patients, product with the lowest IgA level should be selected.