

**Comparison of INTRAGAM® P, Flebogamma 5% DIF, and OCTAGAM® 5%  
from 24 October 2011 to 31 December 2011**

DESCRIPTION	INTRAGAM® P	Flebogamma 5% DIF	OCTAGAM® 5%
Presentation	Solution; 3g (50mL) or 12g (200mL) vials	Solution; 2.5g (50mL), 5g (100mL), 10g (200mL) vials	Solution; 2.5g (50mL), 5g (100mL), 10g (200mL) vials
Concentration	6%	5%	5%
Source Plasma	Australian volunteer non-remunerated donors	United States remunerated Qualified Only donors (FDA approved plasmapheresis centres)	European and USA remunerated and non-remunerated donors
Plasma Testing	Hepatitis B surface antigen; antibodies to HIV 1/2, hepatitis C and HTLV-I/II; 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 B, hepatitis C and HIV-1
Manufacturer	CSL Limited, Biotherapies Division, Broadmeadows, Australia	Instituto Grifols, S.A., Barcelona, Spain	Octapharma Produktionsges.m.b.H., Vienna, Austria Octapharma Lingolsheim, France
Distributor	Australian Red Cross Blood Service	Lateral Grifols Pty Ltd, Australian Red Cross Blood Service	Octapharma Australia Pty Ltd, Australian Red Cross Blood Service
Manufacturing Process	Chromatographic fractionation	Cold alcohol fractionation, polyethylene glycol precipitation, ion exchange chromatography and low pH treatment	Cold ethanol fractionation
Viral Safety	Two dedicated steps: <ul style="list-style-type: none"> <li>• Pasteurisation (60°C for 10 hours)</li> <li>• Incubation at low pH</li> </ul>	Three dedicated steps: <ul style="list-style-type: none"> <li>• Pasteurisation (60°C for 10 hours)</li> <li>• Solvent/Detergent (S/D) treatment</li> <li>• Two sequential nanofiltrations (35nm and 20nm)</li> </ul>	Two dedicated steps: <ul style="list-style-type: none"> <li>• Solvent/Detergent (S/D) treatment</li> <li>• Incubation at low pH (pH4)</li> </ul>
Stabiliser <sup>1</sup>	Maltose <sup>2</sup>	Sorbitol <sup>3</sup>	Maltose <sup>2</sup>
Storage Conditions	Refrigerate at 2-8°C for up to 2 years. Once removed from refrigeration, store below 25°C and use within 3 months	Store below 30°C for up to 2 years	Store below 25°C for up to 2 years
Need for Reconstitution	No	No	No
Dosage and Administration	For intravenous use only, see approved Product Information for rate of infusion		
Relative IgG subclass content	IgG1 61% IgG2 36% IgG3 3% IgG4 1%	IgG1 66.6% IgG2 28.5% IgG3 2.7% IgG4 2.2%	IgG1 ca. 65% IgG2 ca. 29% IgG3 ca. 4% IgG4 ca. 2%
IgA level <sup>4</sup>	< 0.025mg/mL	< 0.05mg/mL	< or equal to 0.2mg/mL
Precautions and Adverse Reactions	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 Biotherapies, Lateral Grifols Pty Ltd and Octapharma.  
The Australian Red Cross Blood Service makes no warranties in relation to the products, Flebogamma 5% DIF and OCTAGAM® 5%, 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. The maltose present in INTRAGAM P and OCTAGAM® 5% may interfere with some blood glucose measurements, resulting in the overestimation of blood glucose results. If this glucose measurement is used to guide treatment, hypoglycaemia may occur. (Reference: INTRAGAM P and OCTAGAM® 5% Product Information).
3. 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)
4. In IgA deficient patients, product with the lowest IgA level should be selected.