Last update : Dicembre 2007	Baxter	Baxter	Baxter	Biotest	CSL Behring	CSL Behring	KEDRION	GRIFOLS
Company	**Baxter**	**Baxter**	**Baxter**	**Biotest Pharma GmbH**	**CSL-Behring**	**CSL-Behring**	**Kedrion**	**Grifols**
Name of product	**Gammagard S/D**	**Endobulin S/D**	**SUBCUVIA**	**Intraglobin® F**	**Sandoglobulin (lyo)**	**Vivaglobin**	**IG VENA**	**Flebogamma**
Available for Hospital therapy	Yes	Yes	Yes	Yes	Registered	Registered	Yes	Yes
Available for Home therapy	May vary in different countries due to different licensing situations.	May vary in different countries due to different licensing situations.	Yes	not available for home therapy	-	Yes	None	
IVIG, SCIG or IMIG	IVIG	IVIG	SCIG	IVIG	IVIG	SCIG	IVIG	IVIG
Patient´s age	All ages	All ages	Adults and juveniles at the age of ≥ 12 years	unlimited	Adults and children	Adults and children	Adults & Children	
Présentation	Lyophilised Powder	Lyophilised Powder	Liquid	ready-to-use solution	Lyophilisat	Liquid	Liquid	Liquid
Concentration %	5% or 10%	5%	16%	5% solution	3%, 6%, 9%, 12%	16%	5%	5%
Content of IgG	≥ 90%	95% immunogloblin	≥ 90%	≥ 95%	≥ 96%	IgG monomers & dimers 97-97% • IgG polymers 3-5%	95%	≥ 99%
IgG1	63%	50-80%	45-75%	62%	60.7%	61%	24,3 - 37,2 mg	70.3%
IgG2	21,80%	20-50%	20-45%	34%	31.9%	28%	12,4 - 22,1 mg	24.7%
IgG3	5,40%	< 0.5%	3-10%	0.5%	3.8%	5%	0,9 - 1,5 mg	3.1%
IgG4	0,20%	1-3%	2-8%	3.5%	3.6%	6%	0,1 - 0,5 mg	2%
Content of IgA	≤ 3 µg/ml	≤ 0.05 mg/ml	≤ 4.8 mg/ml	≤ 2.5 mg/ml	1.2g/L (typical value)	max. 1.7 g/L	< 0,05 mg/ml	<0,05 mg/ml
Glucose, Maltose,…	Glucose	ENDOBULIN S/D contains 1 gram of glucose per gram of immunoglobulin G.	Glycine	glucose 25 mg	Sucrose	Glycine	Maltose	
Average dosage for PID	The dosage regimen should achieve a trough level of 4-6 g/l. The dose and dosage regimen may need to be individualised depending on pharmacokinetic and clinical response (Also see European core SPC).	The dosage regimen should achieve a trough level of 4-6 g/l. • The dose and dosage regimen may need to be individualised depending on pharmacokinetic and clinical response (Also see European core SPC).	The dosage should be adjusted to maintain an approximate level of at least 4-6 g/l of circulating IgG. • The dose and dosage regimen may need to be individualised depending on pharmacokinetic and clinical response	initial 0.4 - 0.8 g/kg, followed by 0.2 -0.8 g/ kg	0.2-0.8g/kg bodyweight	0.2-0.8g/kg bodyweight	0,4 - 0,8 g/kg	
Max. Speed of infusion	Gammagard S/D should be infused at an initial rate of 0.5 ml/kg BW/hour. If well tolerated, the rate of administration may gradually be increased to a maximum of 4 ml/ kg BW/hour. Patients who tolerate Gammagard S/D 5% solutions at 4 ml/kg BW/hour can be infused with the 10% concentration starting at 0.5 ml/kg BW/hour. If no adverse events occur, the rate can be increased gradually up to a maximum rate of 8 ml/kg BW/hour.	During the first 30 minutes, Endobulin S/ D is administered at an initial rate of 0.5 ml/kg BW/hour. If well tolerated, the rate of administration may gradually be increased to a maximum of approx. 8 ml/kg BW/ hour for the remainder of the infusion. In adults, if well tolerated, the rates of subsequent infusions may be increased to a maximum of 15 ml/kg BW/hour.	It is recommended to use an initial administration speed of 10 ml/h/pump. The infusion speed can be enhanced for 1 ml/h/ pump every subsequent infusion. The recommended maximum speed is 20 ml/h/pump. More than 1 pump can be used simultaneously.	2.2 mg/ml per hour	About 2.5ml/min	About 22ml/hour	40 drops/minute	
Intervals of infusion for PID	See European core SPC	See European core SPC	After the loading dose, maintenance doses at repeated intervals to reach a cumulative monthly dose of 0.4-0.8 g/kg	dependent on the individual serum IgG level between 2 and 4 weeks	Usually every 2-4 weeks	usually weekly	21-28 days	
Preserving	• Do not store above 25°C. • Do not freeze, the solvent vial might break. • Keep vial in the outer carton to protect from light.	• Store in a refrigerator (2°C - 8°C) • Do not freeze, the solvent vial might break • Keep vial in the outer carton in order to protect from light	• Store in a refrigerator (2°C - 8°C) • The packaged product may be kept at room temperature (up to 25°C) for up to 6 weeks. In this case, the product expires at the end of the 6 weeks period. • Do not freeze • Keep the vial in the carton to protect from light.	storage in refrigerator (+2 to +8 ^{0}C) - shelf-life: 2 years	3 years ≤25°C	3 years	+2C°< T <+8C°	Between +2ºC and +25ºC. Do not freeze. Discard after expiration date.
Time for reconstitution	General information not available.	General information not available.	N/A		A few minutes	none	Ready for use	none
Packaging*	Pack sizes of 0.5g, 2.5g, 5g, and 10g of lyophilized Gammagard S/D per vial, with appropriate volume of water for injections. Each pack also contains devices for reconstitution and administration.	Pack sizes of 0.5g, 1g, 2.5g, 5g and 10g of lyophilized Endobulin S/D per vial with appropriate volume of water for injections. • Each pack also contains devices for reconstitution and administration.	Pack sizes of 1 x 5 ml, 20 x 5 ml, 1 x 10 ml, and 20 x 10 ml.	containers with 20, 50, 100 or 200 ml	1g, 3g, 6g, 12g	10ml, 20ml	1g/ 20 ml ; 2,5 g/ 50 ml ; 5 g/ 100 ml ; 10 g/ 200 ml	

* May be different from country to country