

## Immune Globulin Comparison Table

I. Formulation data					
Attributes	Gammagard S/D Baxter Corporation	Gamunex®/IGIVnex® Talecris Biotherapeutics	Gammagard Liquid Baxter Corporation	Privigen® CSL Behring	Vivaglobin® CSL Behring
Formulation	Lyophilized	Liquid	Liquid	Liquid	Liquid
Concentration	5% or 10% upon reconstitution	9-11%	9.0-11.0%	10%	16%
Administration set provided?	Yes	No	No	No	No
IgA content	≤ 2.2 µg/mL (In a 5% solution)	46 µg/mL (average)	≤ 140 µg/mL	5.6 mcg/mL (average)	Not indicated in Product Monograph
Osmolality (in mOsmol/kg) Physiological osmolality is approx. 285-295.	Not indicated in Product Monograph	258	240-300	320	Not indicated in Product Monograph
pH	6.4-7.2	4.0-4.3	4.6-5.1	4.8	6.4 - 7.2
Relevant non medical ingredients	In a 5% solution: 3 mg/mL Albumin (human) 22.5 mg/mL Glycine 20 mg/mL Dextrose 2 mg/mL PEG 1 µg/mL Tri(n-butyl) phosphate 1 µg/mL Octoxynol9 100 µg/mL Polysorbate 80	0.16-0.24 M Glycine (No preservative)	0.20-0.30 M Glycine as a stabilizing agent (No preservative)	250 mM L-Proline (No preservative)	22.5 mg/mL Glycine 0.3% Sodium chloride  (No preservative)

## Immune Globulin Comparison Table

I. Formulation data					
Attributes	Gammagard S/D Baxter Corporation	Gamunex®/IGIVnex® Talecris Biotherapeutics	Gammagard Liquid Baxter Corporation	Privigen® CSL Behring	Vivaglobin® CSL Behring
Shelf life	Not indicated in Product Monograph	36 months	36 months	Not indicated in Product Monograph	36 months
Sodium content	Approximately 8.5 mg/mL (In a 5% solution)	None listed	None listed	1 mEq/L or less	0.3 %
Storage requirements	Up to 25 °C Do not freeze	2-8 °C (36 months) Up to 25 °C (6 months) Do not freeze	2-8 °C (36 months) Up to 25 °C (for a single period of up to 12 months within the first 24 months from date of manufacture) Do not freeze	Can be stored at room temperature (up to 25 °C) Do not freeze Keep in its original carton to protect it from light	2-8 °C May be stored at room temperature (not to exceed 25 °C ) for up to 5 months within an overall storage period of 36 months at 2-8 °C Once the product is removed from refrigeration, it cannot be returned to the refrigerator. Do not freeze Keep vials in storage box until use
Sugar content	20 mg/mL (2%) Glucose (in 5% solution) No sucrose	None listed	None listed	Contains no carbohydrates stabilizers (e.g.: sucrose, maltose)	None listed

## Immune Globulin Comparison Table

II. Medical/Clinical information					
Attributes	Gammagard S/D Baxter Corporation	Gamunex®/IGIVnex™ Talecris Biotherapeutics	Gammagard Liquid Baxter Corporation	Privigen® CSL Behring	Vivaglobin® CSL Behring
Administration	Intravenous	Intravenous or Subcutaneous	Intravenous	Intravenous	Subcutaneous injection  Do not inject intravenously
Concentration	5% or 10% upon reconstitution	9-11%	9.0-11.0%	10%	16%
Infusion rate & Dosage	<p>5% Solution</p> <p>Recommended initial rate of 0.5 mL/kg/hr. If well tolerated, the rate may be gradually increased to a maximum rate of 4 mL/kg/hr.</p> <p>Patients who tolerate the 5% concentration at 4 mL/kg/hr can be infused with the 10% concentration starting at 0.5 mL/kg/hr. If no adverse effects occur, the rate can be increased gradually up to a maximum of 8 mL/kg/hr.</p>	<p><u>Intravenous</u></p> <p>Recommended initial infusion rate of 1 to 2 mg/kg/min for the first 30 minutes. If well tolerated, the rate may gradually be increased to a maximum of 14 mg/kg/min.</p> <p>Up to 1000 mg/kg/day for ITP</p> <p><u>Subcutaneous</u> (PID or SID)</p> <p>1.37 X weekly IV dose divided by number of weeks (previous IV interval)</p> <p>In clinical studies a mean volume of 34 mL (range: 17-69 mL) was administered, and most infusions were at a rate of 20 mL/hr/site</p>	<p>Initial rate of 0.5mL/kg BW/hr for 30 minutes. If well tolerated, the rate of administration may gradually be increased to a maximum of 8 mL/kg BW/hr BW=body weight</p> <p>The dose and dosage regimen are dependent on the indication. Refer to Table I-5 within PM for recommended dose and dosage administration.</p>	<p>Recommended initial infusion rate is 0.5 mg/kg/min. If well tolerated, the rate of administration may gradually be increased up to a maximum infusion rate of 12 mg/kg/min.</p> <p>Usual Dose for: <u>PID and SID</u> is 200-800 mg/kg body weight (bw) every 3-4 weeks</p> <p>Usual Dose for: <u>ITP</u> is 1 g/kg bw for 2 consecutive days, resulting in a total dosage of 2 g/kg bw</p>	<p>Recommended weekly dose 100 to 200 mg/kg body weight</p> <p>The initial weekly dose can be calculated by multiplying the previous IGIV dose by 1.37, then dividing this dose into weekly doses based on the patient's previous IGIV treatment interval.</p> <p>In clinical studies, a volume of 15 mL per injection site at a rate of 20 mL per hour per site was not exceeded.</p>

## Immune Globulin Comparison Table

II. Medical/Clinical information					
Attributes	Gammagard S/D Baxter Corporation	Gamunex®/IGIVnex™ Talecris Biotherapeutics	Gammagard Liquid Baxter Corporation	Privigen® CSL Behring	Vivaglobin® CSL Behring
Diluent, if further dilution is required	Water for Injection (for reconstitution and dilution)	5% dextrose in water (D5W) - Not saline.	5% dextrose in water (D5W) - Not saline.	5% dextrose in water (D5W)	None listed
Half-life (in vivo)	37.7 ± 15 days	35.74 days	Approximately 30-35 days.	Median of 36.6 days in PID study	Not indicated in Product Monograph
Drug interaction	May interfere with patient responses to live attenuated vaccines.	May interfere with the response to live viral vaccines.	May interfere with patient responses to live vaccines.	May transiently impair the efficacy of live attenuated virus vaccines.	May transiently impair the efficacy of live attenuated virus vaccines.
Indications	<ol style="list-style-type: none"> <li>1. Primary immunodeficiency diseases</li> <li>2. B-cell chronic lymphocytic leukemia (CLL)</li> <li>3. Idiopathic thrombocytopenic purpura (ITP)</li> </ol>	<p>Including Intravenous and Subcutaneous Administration</p> <p>Primary and secondary immune deficiency syndromes (PID, SID)</p> <p>Intravenous Administration only</p> <ol style="list-style-type: none"> <li>1. Idiopathic thrombocytopenic purpura (ITP)</li> <li>2. Chronic inflammatory demyelinating polyneuropathy (CIDP) in adults, 18 years of age or older</li> </ol>	<ol style="list-style-type: none"> <li>1. Primary and secondary immunodeficiency syndromes (PID, SID)</li> <li>2. Idiopathic thrombocytopenic purpura (ITP)</li> </ol>	<ol style="list-style-type: none"> <li>1. Primary and secondary immunodeficiency syndromes (PID, SID)</li> <li>2. Immune thrombocytopenic purpura (ITP)</li> </ol>	<ol style="list-style-type: none"> <li>1. Primary immune deficiency (PID) in adult and pediatric patients</li> </ol>

## Immune Globulin Comparison Table

II. Medical/Clinical information					
Attributes	Gammagard S/D Baxter Corporation	Gamunex®/IGIVnex™ Talecris Biotherapeutics	Gammagard Liquid Baxter Corporation	Privigen® CSL Behring	Vivaglobin® CSL Behring
Contraindications	<p>History of severe systemic or anaphylactic reactions to IVIG.</p> <p>In patients with selective IgA deficiency where it is the only abnormality of concern.</p>	<p>Known hypersensitivity to formulation ingredients or components of container.</p> <p>Known anaphylactic or severe systemic response to human immune globulin.</p> <p>Individuals with severe, selective IgA deficiencies who have known antibody against IgA (anti-IgA antibody) should only receive Gamunex® / IGIVnex® with utmost cautionary measures.</p>	<p>Hypersensitivity to the active substance or to the excipient.</p> <p>Hypersensitivity to homologous immunoglobulins, especially in very rare cases of IgA deficiency when the patient has antibodies against IgA.</p>	<p>Previous anaphylactic or severe systemic reaction to human immune globulin.</p> <p>In patients with hyperprolinemia due to the presence of L-proline as stabilizer.</p> <p>IgA deficiency.</p>	<p>History of anaphylactic or severe systemic response to immune globulin preparations.</p> <p>In persons with IgA deficiency who have known antibody against IgA</p> <p>Patients hypersensitive to this drug or to any ingredient in the formulation or component of the container.</p>

## Immune Globulin Comparison Table

II. Medical/Clinical information					
Attributes	Gammagard S/D Baxter Corporation	Gamunex <sup>®</sup> /IGIVnex <sup>™</sup> Talecris Biotherapeutics	Gammagard Liquid Baxter Corporation	Privigen <sup>®</sup> CSL Behring	Vivaglobin <sup>®</sup> CSL Behring
<p><b>Serious Warnings &amp; Precautions</b> (Please refer to the Product Monographs for a detailed listing of Warnings &amp; Precautions and Adverse Reactions)</p>	<p>May cause: Renal dysfunction Acute renal failure Osmotic nephrosis Death</p> <p>Patients predisposed to acute renal failure include patients with any degree of pre-existing renal insufficiency, diabetes mellitus, hypertension, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs.</p> <p>May contain infectious agents.</p>	<p>May cause: Renal dysfunction Acute renal failure Osmotic nephrosis Death Hemolysis/ haemolytic anemia</p> <p>May contain infectious agents.</p>	<p>May cause: Renal dysfunction Acute renal failure Osmotic nephrosis Death</p> <p>Patients predisposed to acute renal failure include patients with any degree of pre-existing renal insufficiency, diabetes mellitus, hypertension, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs.</p> <p>May contain infectious agents.</p>	<p>May cause: Renal dysfunction Acute renal failure Osmotic nephrosis Death</p> <p>Patients predisposed to acute renal failure include patients with any degree of pre-existing renal insufficiency, diabetes mellitus, hypertension, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs.</p> <p>May contain infectious agents.</p>	<p>May cause: Aseptic meningitis syndrome Thromboembolism Renal impairment Hemolysis/ haemolytic anemia TRALI</p> <p>May contain infectious agents.</p>

## Immune Globulin Comparison Table

III. Manufacturing & Safety data					
Attributes	Gammagard S/D Baxter Corporation	Gamunex®/IGIVnex™ Talecris Biotherapeutics	Gammagard Liquid Baxter Corporation	Privigen® CSL Behring	Vivaglobin® CSL Behring
Manufacturing process	Cohn-Oncley fractionation, ultrafiltration, ion exchange chromatography and solvent / detergent treatment	Combination of cold ethanol fractionation, caprylate precipitation and filtration and anion-exchange chromatography	Modified Cohn-Oncley cold alcohol fractionation procedure, ion exchange chromatographies, solvent detergent treatment, nanofiltration and low pH and elevated temperature incubation	Combination of cold ethanol fractionation, octanoic acid fractionation, and anion exchange chromatography	Cold alcohol fractionation
Viral reduction steps  (Please refer to the Product Monographs for further details)	<ol style="list-style-type: none"> <li>1. Cold ethanol fractionation steps</li> <li>2. Solvent / detergent treatment</li> </ol>	<ol style="list-style-type: none"> <li>1. Caprylate precipitation and depth filtration</li> <li>2. Caprylate incubation</li> <li>3. Column chromatography</li> <li>4. Final container low pH incubation</li> </ol>	<ol style="list-style-type: none"> <li>1. Solvent / detergent treatment</li> <li>2. Nanofiltration (35 nm)</li> <li>3. Incubation at low pH and elevated temperature of the final filled product.</li> </ol>	<ol style="list-style-type: none"> <li>1. Octanoic acid fractionation</li> <li>2. pH 4 incubation</li> <li>3. Depth filtration</li> <li>4. Virus filtration (20 nm)</li> </ol>	<ol style="list-style-type: none"> <li>1. Partitioning (precipitation)</li> <li>2. Pasteurization in aqueous solution at 60°C for 10 hours</li> </ol>

### Reference Monographs Approval/Revision Dates:

Gammagard S/D    October 6, 2010  
Gammagard Liquid    August 27, 2010

Gamunex®    May 13, 2010  
IGIVnex®    August 9, 2010

Privigen®    October 15, 2010  
Vivaglobin®    April 7, 2010

2010-11-01

This Immune Globulin Comparison Table contains information specified in the product monographs, and is for reference purposes only. Please consult the product monograph or product insert for more detailed information.