Canadian Blood Services
Société canadienne du sang

IVIG Comparison Table

I. Formulation data				
Attributes	**Gammagard S/D Baxter Corporation**	**Gamunex® / IGIVnex™ Talecris Biotherapeutics, Inc.**	**Gammagard Liquid Baxter Corporation**	**Sandoglobulin® NF Liquid CSL Behring Canada**
Formulation	Lyophilized	Liquid	Liquid	Liquid
Concentration	5% or 10% upon reconstitution	9-11%	9.0-11.0%	12%
Administration set provided?	Yes	No	No	No
IgA content	≤ 2.2 µg/mL (In a 5% solution)	46 µg/mL (average)	≤ 140 µg/mL	Normally below 15 µg/mL
Osmolality (in mOsmol/kg) Physiological osmolality is approx. 285-295.	—	258	240-300	Approximately 360
pH	6.4-7.2	4.0-4.3	4.6-5.1	5.3
Relevant non medical ingredients	In a 5% solution: 3 mg/mL Albumin (human) 22.5 mg/mL glycine 20 mg/mL glucose 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)	100 mM L-isoleucine 120 mM L-Proline 80 mM Nicotinamide (No preservative)

This IVIG 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.

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Shelf life	Not indicated	36 months	36 months	32 months
Sodium content	Approximately 8.5 mg/mL (In a 5% solution)	Not indicated	Not indicated	≤ 10 mM
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 9 months within the first 24 months from date of manufacture), Do not freeze	2-8 °C (32 months), up to 25 °C (for a single period of 6 months maximum), Do not freeze, Protect from light
Sugar content	20 mg/mL (2%) Glucose (in 5% solution) No sucrose	Contains no sucrose	Contains no sucrose	Contains no carbohydrates like sucrose or maltose

IVIG Comparison Table

II. Medical/Clinical information				
Attributes	**Gammagard S/D Baxter Corporation**	**Gamunex® / IGIVnex™ Talecris Biotherapeutics, Inc.**	**Gammagard Liquid Baxter Corporation**	**Sandoglobulin® NF Liquid CSL Behring Canada**
Administration	Intravenous	Intravenous	Intravenous	Intravenous
Concentration	5% or 10% upon reconstitution	9-11%	9.0-11.0%	12%
Infusion rate & Dosage	For a 5% solution: 4 mL/kg/Hr maximum (3.3 mg/kg/min. maximum) For a 10% solution: 8 mL/kg/Hr maximum (*Calculated rate:* 13.3 mg/kg/min. maximum) Up to 1000 mg/kg/day for ITP	0.14 mL/kg/min. (14 mg/kg/min. maximum) Up to 1000 mg/kg/day for ITP	8 mL/kg/Hr maximum (*Calculated rate:* 13.3 mg/kg/min. maximum) Up to 1000 mg/kg/day for ITP	1 mL/kg/h maximum (2 mg/kg/min. maximum) Up to 1000 mg/kg/day
Diluent, if further dilution is required	Water for Injection (for reconstitution and dilution)	5% dextrose in water (D5W), Not saline.	5% dextrose in water, Not saline.	Not indicated
Half-life (in vivo)	37.7 ± 15 days	35.74 days	Approximately 30-35 days.	Median of 34 days in PID study.
Drug interaction	May interfere with patient responses to live vaccines.	May interfere with the response to live viral vaccines.	May interfere with patient responses to live vaccines.	May interact with the following drugs: • Phenytoin, • Primidone, • Carbamazepine. May impair the efficacy of certain live attenuated virus vaccines.

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Attributes	**Gammagard S/D Baxter Corporation**	**Gamunex® / IGIVnex™ Talecris Biotherapeutics, Inc.**	**Gammagard Liquid Baxter Corporation**	**Sandoglobulin® NF Liquid CSL Behring Canada**
Indications	1. Primary immunodeficiency diseases 2. B-cell chronic lymphocytic leukemia (CLL) 3. Idiopathic thrombocytopenic purpura (ITP)	1. Primary Humoral immunodeficiency 2. Idiopathic thrombocytopenic purpura (ITP) 3. Allogeneic bone marrow transplantation (for patients at least 20 years of age) 4. Pediatric HIV infection	1. Primary and secondary immuno deficiency syndromes (PID, SID). 2. Idiopathic thrombocytopenic purpura (ITP)	1. Primary and secondary immuno deficiency syndromes in adult and pediatric patients (PID, SID)

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Attributes	**Gammagard S/D Baxter Corporation**	**Gamunex® / IGIVnex™ Talecris Biotherapeutics, Inc.**	**Gammagard Liquid Baxter Corporation**	**Sandoglobulin® NF Liquid CSL Behring Canada**
Contraindications	History of severe systemic or anaphylactic reactions to IVIG. In patients with selective IgA deficiency where it is the only abnormality of concern.	Known hypersensitivity to formulation ingredients or components of container. Known anaphylactic or severe systemic response to human immuno globulins. Individuals with severe, selective IgA deficiencies who have known antibody against IgA (anti-IgA antibody) should only receive Gamunex® / IGIVnex™ with utmost cautionary measures.	Hypersensitivity to the active substance or to the excipient. Hypersensitivity to homologous immunoglobulins, especially in very rare cases of IgA deficiency when the patient has antibodies against IgA.	Hypersensitivity to immunoglobulin or to formulation ingredients or components of container. Hypersensitivity to homologous immunoglobulins, especially in very rare cases of IgA deficiency when the patient has antibodies against IgA. In patients with maple syrup urine disease (MSUD) and hyperprolinemia.

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Warnings, Precautions & Adverse reactions (Please refer to the Product Monograph for a detailed listing)	May cause: · Renal dysfunction · Acute renal failure · Osmotic nephrosis · Death · Immediate anaphylactic and hypersensitivity reactions · Thrombotic events · Aseptic meningitis syndrome (AMS) · Impaired efficacy of live attenuated virus vaccines · Risk of renal dysfunction · Minor reactions such as: mild to moderate hypotension, headache, fatigue, chills, backache, fever, nausea, etc. May contain infectious agents.	May cause: · Aseptic meningitis syndrome (AMS) · Thrombo-embolic events · Renal impairment · Death · Hemolysis/ haemolytic anemia · Transfusion related acute lung injury (TRALI) May contain infectious agents.	May cause: · Renal dysfunction · Acute renal failure · Osmotic nephrosis · Death · Hemolysis · Impaired renal functions · Transfusion related acute lung injury (TRALI) · Thrombotic events · Aseptic meningitis syndrome (AMS) · Chills, fever headache, back pain, dizziness, immediate anaphylactic and hypersensitivity reactions, etc. May contain infectious agents.	May cause: · Chills, fever headache, allergic reaction, low back pain, dizziness, etc · Sudden fall in blood pressure · anaphylactic shock · Reversible aseptic meningitis · Reversible haemolytic anemia/hemolysis · Thrombotic events · Acute renal failure and/or increase serum creatinine level May contain infectious agents.

IVIG Comparison Table

III. Manufacturing & Safety data				
Attributes	**Gammagard S/D Baxter Corporation**	**Gamunex® / IGIVnex™ Talecris Biotherapeutics, Inc.**	**Gammagard Liquid Baxter Corporation**	**Sandoglobulin® NF Liquid CSL Behring Canada**
Manufacturing process	Cohn-Oncley cold ethanol 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.	Not indicated
Viral reduction / inactivation steps (only significant steps are listed i.e. steps removing 4 Log or greater – enveloped viruses, unless otherwise indicated)	1. Solvent / detergent treatment	1. Caprylate incubation 2. Column chromatography 3. Final container low pH incubation	1. Solvent / detergent treatment 2. Nanofiltration (35 nm) 3. Incubation at low pH and elevated temperature of the final filled product.	1. Nanofiltration 2. pH 4 / pepsin treatment 3. DEAE-Sephadex batch adsorption chromatography and 2nd clarifying filtration 4. Aluminum hydroxide batch adsorption and 3rd clarifying filtration. *Note: The individual efficacies of these process steps are not provided but a total log_{10} viral reduction / inactivation of at least > 18 is reported.*

Reference Monographs Approval/Revision Dates:

Gammagard S/D	January 15, 2004.
Gammagard Liquid	April 12, 2006.
Gamunex®	June 1, 2006
IGIVnex™	May 4, 2006
Sandoglobulin® NF Liquid	March 30, 2007