

Section S: Blood Product Overview -

Gamunex[®] Intravenous Immune Globulin (IVIG) – 10% CBS IGIV-nex[®]

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DESCRIPTION of PRODUCT

- Made from large pools of human plasma by a combination of cold ethanol fractionation and caprylate precipitation and filtration and anion-exchange chromatography.
- Viral inactivation and/or removal processes include: caprylate incubation, column chromatography and final container low pH incubation.
- Contains 9-11% protein (98% of which is gamma globulin) in 0.16-0.24 M glycine.
- pH is 4.0 - 4.5
- Contains no preservative.
- Majority of gamma globulin is IgG, but contains trace amounts of IgA (avg 0.046mg/mL) and IgM (below measurable limit of 0.002g/L).
- **Baxter Gammagard S/D[®] contains the least amount of IgA of all the IVIG products manufactured, and should be the product that is used, with caution, if a patient that has an anti-IgA requires IVIG. This product is not routinely stocked, and will be ordered only if a patient has a documented anti-IgA.**

NOTE: CBS IGIV-nex[®] is made from plasma supplied to Talecris from the Canadian Blood Services (CBS). It is made by the same process as Gamunex[®] and therefore can be used interchangeably. The Blood Transfusion Lab will supply either of these products based on what is available at the time.

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AVAILABILITY of PRODUCT

- The CBS provides 3 different IVIG products from 3 different manufacturers, and requires all hospitals to use Talecris Gamunex (or CBS IGIV-nex), Baxter [Gammagard](#) Liquid and CSL Behring [Privigen](#) at a predetermined percentage.
- All LHSC/SJHC sites stock IVIG. Contact the BTL to see which specific product(s) is stocked at your site.
- Patient should NOT receive IVIG products from different manufacturers in the same dose.
- All attempts will be made to maintain a patient on the same product throughout their course of treatment, but in some circumstances it may be necessary to substitute.

STORAGE of PRODUCT

- Talecris Gamunex (and CBS IGIV-nex) is stored at 2-8°C.
- Do NOT freeze.
- Expiry date is on each vial. Once entered the vial should be infused within 4 hours.

CLINICAL INDICATIONS (see package insert for contraindications)

- Primary humoral immune deficiency;
- Kawasaki's disease;
- Pediatric post-liver or -BMT transplant;
- Pediatric sepsis;
- Hemolytic Disease of the Newborn;
- Prophylaxis of alloimmune neonatal thrombocytopenia;
- Idiopathic Thrombocytopenia Purpura;
- Necrotizing fasciitis ("flesh eating" disease);
- Prophylaxis of allogenic bone marrow transplant recipients;
- Prophylaxis of infection in BMT;
- Autoimmune neutropenia with severe bacterial infections;
- Neurological disorders (Guillain-Barre, myasthenia gravis);
- Renal transplant rejection.

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REQUESTS for GAMUNEX (IVIG)

- “IVIG Request Form” must be completed when IVIG is initially requested for patient.
- Any request for use other than above indications requires pre-authorization by a Hematologist. If product is in short supply, each request is assessed on a case-by case basis, and IVIG is issued based on diagnosis and product availability.
- Maximum volume issued for a patient at any given time: 24 hour dose.

ADMINISTRATION of PRODUCT

- Should be inspected visually for particulate matter and discolouration prior to administration. Infuse only if solution is colourless, free of particulate matter and not turbid.
- IVIG should only be administered intravenously.
- IVIG is issued from the BTL in a glass bottle and requires a vented administration set. Vented administration sets for use with Infusion Pumps can be obtained from HMMS (#38680). Do NOT use a needle as a vent. *NOTE:* Gamunex[®] does not need to be filtered.
- Dosage is determined by the clinical indication. See product insert.
- Infusions should be started slowly (possible anaphylactic reactions).
- Rates should be specified by ordering physician. Guidelines include an initial rate of 0.01-0.02mL/ kg/minute with a gradual increase to 0.06mL/kg/minute if tolerated well.
- Maximum approved rate for Gamunex[®] is 0.14mL/kg/min.
- Vital signs should be taken and documented pre-infusion, at each rate increase and at least hourly until infusion is complete.
- IVIG is only compatible with 5% dextrose in water. Do not administer together with 0.9% NaCl.
- If dilution is required, contact the BTL.

ADDITIONAL COMMENTS

- Comparison chart of the different IVIGs available in Canada is provided by the [Canadian Blood Services](#) (Plasma Protein Products Information, Product Comparison Tables, Immune Globulin Comparison Table).
- A Subcutaneous Immune Globulin (SCIg) has been approved for the treatment of Primary Immune Deficiency (PID) and is available as an alternate to IVIG. See CSL Behring [Vivaglobin[®]](#) for additional information.

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LINK to WEBSITE for PRESCRIBING INFORMATION

Product monograph available at <http://www.talecris-pi.info/inserts/Gamunex.pdf>

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