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| **Other Names** | • Gammagard Liquid, Gammagard S/D, Gamunex, IGIVnex, Octagam, Panzyga, Privigen |
| **Description** | Human immune globulin protein derived from human plasma for intravenous administration. |
| **Special Approvals/Authorizations** | • An independent 2 person check is required nurses* and student nurses* may administer on the written approval of the attending physician.<br>The physician's order must include the number of doses required.<br>The physician must be readily available for the 1st dose of each course of therapy.<br>• Supplied by Canadian Blood Services (CBS)<br>• Contact your facility blood bank/transfusion service regarding stock availability on site<br>• IVIG Physician Request Form is required for first time requests and every 6 months<br>• This is not a pharmacy item |
| **Classification** | Plasma protein product |
| **Indications** | • Primary and secondary immune deficiency, hypogammaglobulimenia<br>• Idiopathic thrombocytopenia purpura<br>• Chronic inflammatory demyelinating polyneuropathy, central/peripheral nervous system disorders<br>• B-cell chronic lymphocytic leukemia (CLL)<br>• Kawasaki syndrome |
| **Contraindications** | • Known anaphylactic or severe systemic response to immune globulin (human)<br>**Caution:**<br>• Individuals with severe, selective IGA deficiencies (serum IGA < 0.05 g/L) who have known antibody against IgA<br>• Depending upon dosage, defer administration of live viral vaccines (e.g. measles, mumps, rubella) for 3-11 months<br>• Persons with diabetes – at high dosages, the glucose content of some products has produced hyperglycemia<br>• Persons with previous neurologic reaction – slow infusion, push fluids, consider using prednisone<br>• Pre-existing renal impairment – slow infusion, decrease maximum infusion rate to no more than 2 mL/kg/hour<br>• Human plasma derivative; risk of transmitting infectious agent<br>• DO NOT MIX DIFFERENT IVIG PRODUCTS. |
| **Supplied** | • Canadian Blood Services<br>○ The intended recipient must be properly identified before the infusion is started.<br>○ Refer to Manitoba Transfusion Best Practice Resource Manual section 2.6 Monitoring of Patients Receiving Transfusion |
| **Dosage** | • **Maximum concentration:** 100ml/ml (10%)<br>• **Maximum rate:** Refer to chart below under administration, method<br>• 100-2000mg/kg/dose in 1-4 divided doses administered once daily (usual max: 1000mg/kg/24hr)<br>• **Kawasaki Disease:** 2 g/kg/dose as a single dose or 400mg/kg/day for 4 consecutive days<br>• **Hypogammaglobulinemia:** 400-500mg/kg/dose q1-4weeks<br>• **Central/peripheral nervous system disorders:** 1gm/kg/dose once daily x 2 days, or 400mg/kg/day for 5 consecutive days<br>• **Renal Impairment:** Reduce concentration or rate of administration, especially with glucose containing products<br>• **Hepatic Impairment:** No dosage adjustment required<br>• **Obesity:** No data<br>Round dose to closest vial sizes to minimize wastage. |
| **Stability** | • DO NOT SHAKE PRODUCTS<br>• Solutions must be at room temperature and clear in appearance prior to start of infusion. |

**Reconstitution**

NOTE: Gamunex is typically provided as default product for pediatric patients unless otherwise specified on physician orders.

Six IVIG products are available from the Canada Blood Services (CBS). Refer to ADDITIONAL NOTES for information on differences between and selection of product.

**Supplied as:**

| Product | Concentration | Form | Storage |
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| Gammagard® S/D (Baxter) | 50 or 100 mg/mL (5 or 10%)* | Lyophilized powder* 5g | Room temperature, (not to exceed +25°C) |
| Gammagard Liquid® (Baxter) | 100 mg/mL (10%) | Liquid 2.5, 5, 10, 20, 30g | Refrigerate +2°C to +8°C, within the first 24 months of the date of manufacture; product may be stored for a single period of up to 12 months at room temperature (below +25°C). Do not freeze |
| Gamunex™ (Talecris) | 100 mg/mL (10%) | Liquid 2.5, 5, 10, 20g | Refrigerate +2°C to +8°C, product may be stored at temperatures not to exceed +25°C for up to 6 months anytime during the 36 month shelf life Do not freeze |
| IGIVnex™ (Talecris) | 100 mg/mL (10%) | Liquid 10, 20g | |
| Panzyga (Octapharma) | 100 mg/mL (10%) | Liquid 2.5, 5, 10, 20, 30g | Refrigerate +2°C to +8°C for 24 months from date of manufacture, may be stored for up to 6 months at +8°C to +25°C, protect from light Do not freeze |
| Octagam® (Octapharma) | 100 mg/mL (10%) | Liquid 5, 10, 20g | Refrigerate +2°C to +8°C for 23 months from date of manufacture, may be stored for up to 3 months at +8°C to +25°C, Protect from light Do not freeze |
| Privigen® (CSL Behring) | 100 mg/mL (10%) | Liquid 2.5, 5, 10, 20, 40g | Refrigerator or at room temperature +2°C to +25°C Do not freeze |

* Refer to package insert for reconstitution directions.

**Compatibilities/ Incompatibilities**

**Compatible Solutions:**

- Gamunex, Immune Globulin IV (CBS), IVIGnex, Privigen: Compatible with D5W, **INCOMPATIBLE** with normal saline
- Gammagard S/D: compatible with normal saline (NS) or D5W

Administer separately; do not mix or "piggyback" with other medications or parenteral fluids.
Do **not** mix different brands of IVIG in same bag or syringe. **Exception:** Gamunex and IVIGnex

**Administration, Identification**

Refer to **Manitoba Transfusion Best Practice Resource**

- Section 2.2 Standards - Identification and Administration
- Section 2.1 Informed Consent
- Anaphylaxis Precautions: have epinephrine 1:1000 ampule, hydrocortisone vial and diphenhydramine (Benadryl) 50mg ampule/vial available in the patient care area
- Record of Transfusion (ROT) to be returned to Blood Bank upon initiation of last bottle

**Additional Notes**

Central Venous Access Devise: No special considerations.

**Administration, Method**

**Administration Set:**

- Administer through the Baxter solution set 1W5000s with15 micron disc filter

| | Gammagard Liquid® | Gamunex® & IGIVnex® | Privigen | Gammagard® S/D | Octagam® |
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| **Preparation [Do not mix different brands of IVIG in same bag or syringe.]** | Use 16 gauge needle to withdraw solution or hang 100 or 200 mL vial. May pool several vials into a 50 mL syringe or sterile empty bag.<br><br>**To make IVIG 5%:** dilute 25 mL of IVIG 10% with 25 mL D5W ONLY | | | 5%: use transfer needle<br><br>10%: use transfer set<br><br>Refer to package insert for reconstitution directions | |
| **Administration** | Administer undiluted or dilute to 5% in D5W | | | Use 5% concentration for first dose | |
| **Initial Rate** | 0.5 mL/kg/h<br>x 30 min | first dose:<br>0.6 mL/kg/h<br>x 15 min<br><br>other doses:<br>1.2 mL/kg/h | 0.3 mL/kg/h<br>x 30 min | 0.5 mL/kg/h<br>x 30 min | |
| **Titration (refer to max. rate below)** | 1 mL/kg/h<br>x 15 min<br><br>2 mL/kg/h<br>x 15 min<br><br>4 mL/kg/h<br>x 15 min<br><br>8 mL/kg/h | 1.2 mL/kg/h<br>x 15 min<br><br>3.6 mL/kg/h<br>x 15 min<br><br>8.4 mL/kg/h | 0.6 mL/kg/h<br>x 30 min<br>then (refer to max. rate)<br>2.4 mL/kg/h<br>or<br>7.2 mL/kg/h | 1 mL/kg/h<br>x 15 min<br><br>2 mL/kg/h<br>x 15 min<br><br>4 mL/kg/h<br>x 15 min<br><br>8 mL/kg/h | |
| **Maximum Rate** | 1st dose in last 12 months:<br>5 mL/kg/h<br><br>Subsequent doses*:<br>max 8 mL/kg/h | 1st dose in last 12 months:<br>4.8 mL/kg/h<br><br>Subsequent doses*:<br>max 8.4 mL/kg/h | 7.2 mL/kg/h<br>except max<br>2.4 mL/kg/h<br>for indications below ** | 1st dose in last 12 months:<br>4 mL/kg/h<br><br>Subsequent doses*:<br>max 8 mL/kg/h | |
| **Filter** | Optional | Optional | No | Yes (included) | |
| **Stability** | | 24 hours at room temp<br><br>8 hours at room temp if pooled | 24 hours at room temp | 24 hours refrigerated<br><br>12 hours at room temp | |
| **Compatibility** | D5W | D5W | D5W | D5W, Normal Saline | |

* Within last 12 months

** Initial three doses of this product, first dose of this product in past 8 weeks, or all doses in patients with pre-existing renal

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| **Monitoring** | **Vital signs (VS):**<br>Patient should be under direct observation during transfusion. Nurse should remain with patient for first 15 minutes. Vital signs (HR, BP, RR) are to be monitored 15 minutes after start of infusion, after each rate change, every hour during and at the end of the transfusion and as clinically indicated. VS should be recorded one hour after the completion of the infusion for inpatient. Post infusion monitoring should be at the discretion of the person administering the infusion. |
| **Adverse Events** | Refer to **Manitoba Transfusion Best Practice Resource Manual s**ection 2.7 for Transfusion Reactions.<br>**POTENTIAL HAZARDS**<br>**NOTE:** Adverse effects may occur up to 72 hours post-infusion, especially with dosages > 500 mg/kg<br><br>Hypersensitivity: generalized flushing, urticaria, palpitations, respiratory distress, hypotension<br>CV: hypotension, palpitations, arrhythmias (rare)<br>GI: nausea, vomiting<br>HEMAT: hemolysis, thrombotic events<br>HEPATIC: hepatitis (rare)<br>METAB: hyperglycemia (especially in persons with diabetes and with glucose containing products)<br>NEURO: headache (very common), malaise, dizziness, fever, fatigue, aseptic meningitis<br>RENAL: acute renal failure (infusion related; especially in patients with pre-existing renal impairment)<br>RESP: noncardiogenic pulmonary edema with respiratory distress, hypoxemia and fever within 1-6 hours<br>LOCAL: phlebitis (especially with Gammagard® S/D 10%; use large peripheral or central vein)<br>OTHER: infusion rate related: flushing, myalgia, respiratory distress, chest tightness, chills, fever<br><br>**CAUTION:**<br>Individuals with severe, selective IGA deficiencies (serum IGA < 0.05 g/L) who have known antibody against IgA<br>Depending upon dosage, defer administration of live viral vaccines (e.g. measles, mumps, rubella) for 3-11 months<br>Persons with diabetes – at high dosages, the glucose content of some products has produced hyperglycemia<br>Persons with previous neurologic reaction – slow infusion, push fluids, consider using prednisone<br>Pre-existing renal impairment – slow infusion, decrease maximum infusion rate to no more than 2 mL/kg/hour<br>Human plasma derivative; risk of transmitting infectious agent |
| **Resources:** | • Manitoba Transfusion Best Practice Resource Manual<br>• http://www.transfusionmedicine.ca/resources/clinical-guide-transfusion<br>• Canadian Blood Services Guide to Transfusion (www.blood.ca )<br>• AABB Transfusion Therapy Clinical Principles and Practice (reference)<br>• Bloody Easy 3<br>• CBS IVIG Products<br>• Gammagard Liquid Product Monograph – Date of Approval: September 4, 2014<br>• Gammagard S/D Liquid Product Monograph – Date of Approval: August 27, 2014<br>• Gamunex Product Monograph – Date of Approval: January 26, 2016<br>• IGIVnex Product Monograph – Date of Approval: January 26, 2016<br>• Octagam Product Monograph – Date of Approval: February 24, 2015<br>• Privigen Product Monograph – Date of Approval: July 8, 2015<br>• Panzyga Product Monograph – Date of Approval: June 24, 2016 |
| **Review By** | |