GAMMAGARD LIQUID
[Immune Globulin Infusion (Human)] 10%
[Immunoglobulines (humaines) pour injection intraveineuse) à 10 %

Fact Sheet

TRADE NAME

GAMMAGARD® LIQUID
Immune Globulin Intravenous (Human) [IVIG] 100 mg/mL (10%) Solution for infusion

LIS ORDERING

Mnemonic: <facility specific>

PRODUCT COMPOSITION

GAMMAGARD LIQUID is a purified IgG liquid biologic product at 10% w/v proteinconcentration. This preparation is an isotonic solution containing a concentration of approximately 100 mg of protein per mL, of which at least 98% is gamma globulin, and has a pH of 4.6 to 5.1. The stabilizing agent is glycine and is present in the amount of 0.25M (0.20 to 0.30M). The product contains no preservatives. None of the nonmedicinal Ingredients are clinically relevant.

ALTERNATIVES

Panzyga – 2.5g/5g/10g/20g/30g (Aug-Sept 2018 phase-out)
Commercial Privigen – 2.5g/5g/40g (July 2018 phase-out)
Privigen – 10g/20g
IGIVnex – 20g

DOSAGE

For intravenous administration only. Other routes of administration have not been evaluated.

- Refer to GAMMAGARD LIQUID product monograph (pages 16-17/56 and Table I-3, page 17/58 for specific dosage guidelines for each clinical indication.
- The dose and dosage regimen are dependent on the indication.
- In replacement therapy the dosage may need to be individualized for each patient depending on the pharmacokinetic and clinical response. The dosage regimens in Table I-3 are given as a guideline.
- In general, it is recommended that patients beginning therapy or switching from one intravenous immunoglobulin brand to another be started at the lowest rate and then advanced to the maximal rate if they have tolerated several infusions at intermediate rates of infusion.
- GAMMAGARD LIQUID is intended for intravenous administration. Dosage will vary depending on condition and bodyweight. The doses outlined in Table I-3 are in agreement with currently suggested dosing schedules.
- In patients at risk for acute renal failure or thromboembolic adverse reactions, GAMMAGARD LIQUID should be administered at the lowest rate of infusion. Patients should be adequately hydrated before administration.

ADMINSTRATION

Human normal immunoglobulin should be infused intravenously at an initial rate of 0.5 mL/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. In patients at risk for acute renal failure or thromboembolic adverse reactions, GAMMAGARD LIQUID should not be administered at the maximum allowable rate of infusion.

For treatment of Multifocal Motor Neuropathy (MMN), Human normal immunoglobulin should be infused intravenously at an initial rate of 0.5 mL/kg BW/hr. If well tolerated, the rate of administration may gradually be increased to a maximum rate of 5.4 mL/kg BW/hr.

GAMMAGARD LIQUID is recommended for infusion at a concentration of 10%. Do not use normal saline as a diluent. If it must be diluted, 5% dextrose in water should be used as a diluent. The infusion line may be flushed with normal saline.

CLINICAL/ DIAGNOSTIC MONITORING

- Vital sign monitoring as per hospital policy for any blood, blood component and other related product. <facility specific>
- In the event of an immediate or suspected transfusion reaction, refer to hospital policy and procedures. <facility specific>

CLINICAL/ DIAGNOSTIC MONITORING continued...

- *Monitoring and Laboratory Tests*
  - If signs and/or symptoms of haemolysis are present after IGIV infusion, appropriate confirmatory laboratory testing should be done [see WARNINGS AND PRECAUTIONS section in PM].
  - If TRALI is suspected, appropriate tests should be performed for the presence of anti-neutrophil antibodies in both the product and patient serum [see WARNINGS AND PRECAUTIONS section in PM].
  - Because of the potentially increased risk of thrombosis, baseline assessment of blood viscosity should be considered in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides), or monoclonal gammopathies [see WARNINGS AND PRECAUTIONS].
- Monitor patients who are at an increased risk for developing renal failure or thrombotic events. Do not exceed the recommended dose, and infuse at the minimum infusion rate practicable.
- For patients at risk of thrombosis, administer GAMMAGARD LIQUID at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity for those at risk for hyperviscosity.

CLINICAL INDICATIONS

Primary Immunodeficiency

Replacement therapy in primary immunodeficiency syndromes (PID) such as:

- Congenital agammaglobulinaemia and hypogammaglobulinaemia
- Common variable immunodeficiency
- Severe combined immunodeficiency
- Wiskott Aldrich syndrome

Secondary Immunodeficiency

Replacement therapy in secondary immunodeficiency syndromes (SID) such as:

- B-cell chronic lymphocytic leukemia
- Pediatric HIV infection
- Allogeneic bone marrow transplantation

Idiopathic Thrombocytopenic Purpura (ITP)

Multifocal Motor Neuropathy (MMN) - Maintenance therapy to improve muscle strength and disability in adult patients with MMN.

SPECIAL CONSIDERATIONS

- Administer with caution to pregnant women and breast-feeding mothers and only if clearly indicated.

CONTRAINDICATIONS

- Patients with severe systemic hypersensitivity responses to Immune Globulin (Human)
- Patients with severe IgA deficiency may develop anti-IgA antibodies that can result in a severe anaphylactic reaction
- Patients who are sensitive to this drug or any ingredient in the formulation or component of the container

STORAGE CONDITIONS

- Refrigeration storage: Store in a refrigerator (2°C – 8°C) for up to 36 months. Do not freeze.
- Room temperature storage: Within the first 24 months from the date of manufacture, GAMMAGARD LIQUID may be stored for a single period of up to 12 months at room temperature (below 25° C). After this period, unused product must be discarded. See detailed storage information in Figure I, page 21/56 of Product Monogragh.
- The product should be brought to room or body temperature before use.
- Refer to Special Handling Instructions – page 22/56 of product monograph

REFERENCES

GAMMAGARD LIQUID Product Monograph, Baxalta Canada Corporation, Submission control #183472, June 30, 2017.

Canadian Product Monograph may be obtained by calling Shire Pharma Canada ULC at 1-800-268-2772 or online at https://www.shirecanada.com/-/media/shire/shireglobal/shirecanada/pdffiles/product%20information/gammagard liquid-pm-en.pdf

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