
Prior Authorization DRUG Guidelines

Gamunex®-C (Immune Globulin)

Effective Date: 1/31/12

Date Developed: 12/9/11 by Albert Reeves MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18

(Archived 1/22/19)

Gamumex ® –C is a Blood Product Derivative; Immune Globulin.

Other brand names of Immune Globulin: Carimune® NF; Flebogamma® DIF; GamaSTAN™SD; Gammagard S/D®; Gammagard®Liquid; Gammaplex®; Gamumex® [DSC]; Hizentra®; Octagam®; Privigen®; Vivaglobin®[DSC]

Pre-Authorization Criteria :immune thrombocytopenia; primary immuno-deficiency states; secondary immunodeficiency in chronic lymphocytic leukemia, pediatric HIV infection, Parvovirus B19 infection, and allogeneic bone marrow transplantation; Kawasaki syndrome; prevention of graft versus host disease and infection in adult hematopoietic cell transplantation; certain neuromuscular disorders, such as chronic inflammatory demyelinating polyneuropathy (CIDP), Guillain-Barre syndrome, myasthenia gravis and polymyositis/dermatomyositis

NOTE: VCHCP requires that Gamumex®-C be prescribed by a Hematologist- Oncologist, Neurologist, Infectious Disease or Immunologist.

Dosing: ADULTS:

Chronic inflammatory demyelinating polyneuropathy (CIDP) (Gamunex®, Gamunex®-C): I.V.: Loading dose: 2000 mg/kg (given in divided doses over 2-4 consecutive days); Maintenance: 1000 mg/kg every 3 weeks. Alternatively, administer 500 mg/kg/day for 2 consecutive days every 3 weeks.

Immune (idiopathic) thrombocytopenic purpura (ITP): Gamunex-C®: I.V.: 1000 mg/kg/day for 2 consecutive days (second dose may be withheld if

adequate platelet response in 24 hours) **or** 400 mg/kg once daily for 5 consecutive days

Measles: Gamunex-C®: I.V.: Prophylaxis in patients with primary humoral immunodeficiency (**ONLY** if routine dose is <400 mg/kg): ≥400 mg/kg immediately before expected exposure.

Treatment in patients with primary immunodeficiency: 400 mg/kg administered as soon as possible after exposure

Primary humoral immunodeficiency disorders: Gamunex-C®: I.V.: 300-600 mg/kg every 3-4 weeks; adjusted based on dosage and interval in conjunction with monitored serum IgG concentrations and clinical response. SubQ infusion: Begin 1 week after last I.V. dose.

Dosing: Pediatric

Refer to adult dosing.

Dosing: Geriatric

Refer to adult dosing.

Dosage Forms

Gamunex®-C: 10% [100 mg/mL] (10 mL, 25 mL, 50 mL, 100 mL, 200 mL)
[contains glycine]

Administration

Gamunex-C®:

Injection sites: ≤8 simultaneous injection sites

Recommended infusion rate: 20 mL/hour per injection site

WARNINGS / PRECAUTIONS

Concerns related to adverse effects:

Anaphylaxis/hypersensitivity reactions: Hypersensitivity and anaphylactic reactions can occur; a severe fall in blood pressure may rarely occur with anaphylactic reaction; immediate treatment (including epinephrine 1:1000) should be available.

Aseptic meningitis: Aseptic meningitis syndrome (AMS) has been reported with intravenous immune globulin administration (rare); may occur with high doses (≥ 1 -2 g/kg [product-dependent]) and/or rapid infusion. Syndrome usually appears within several hours to 2 days following treatment; usually resolves within several days after IVIG is discontinued. Patients with a migraine history may be at higher risk for AMS.

Hematoma: Increased risk of hematoma formation when administered subcutaneously for the treatment of ITP.

Hemolysis: Intravenous immune globulin has been associated with antiglobulin hemolysis; monitor for signs of hemolytic anemia.

Hyperproteinemia: Hyperproteinemia, increased serum viscosity, and hyponatremia may occur; distinguish hyponatremia from pseudohyponatremia to prevent volume depletion, a further increase in serum viscosity and a higher risk of thrombotic events.

Infusion reactions: Patients should be monitored for adverse events during and after the infusion. Stop administration with signs of infusion reaction (fever, chills, nausea, vomiting, and rarely shock). Risk may be increased with initial treatment, when switching brands of immune globulin, and with treatment interruptions of >8 weeks.

Pulmonary edema: Monitor for transfusion-related acute lung injury (TRALI); noncardiogenic pulmonary edema has been reported with intravenous immune globulin use. TRALI is characterized by severe respiratory distress, pulmonary

edema, hypoxemia, and fever in the presence of normal left ventricular function. Usually occurs within 1-6 hours after infusion.

Renal impairment: **[U.S. Boxed Warning]: I.V. formulation only: Acute renal dysfunction (increased serum creatinine, oliguria, acute renal failure, osmotic nephrosis) can rarely occur; usually within 7 days of use (more likely with products stabilized with sucrose). Use with caution in the elderly, patients with renal disease, diabetes mellitus, volume depletion, sepsis, paraproteinemia, and nephrotoxic medications due to risk of renal dysfunction.** In patients at risk of renal dysfunction, the rate of infusion and concentration of solution should be minimized. Discontinue if renal function deteriorates.

Thrombotic events: Thrombotic events have been reported with administration of intravenous immune globulin and subcutaneous immune globulin; use with caution in patients with a history of atherosclerosis or cardiovascular and/or thrombotic risk factors or patients with known/suspected hyperviscosity. Consider a baseline assessment of blood viscosity in patients at risk for hyperviscosity.

DRUG Interactions

Vaccines (Live): Immune Globulins may diminish the therapeutic effect of Vaccines (Live). Management: Live organism vaccination should be withheld for up to six months following immune globulin administration. Live vaccine given immediately prior to immune globulin administration may require repeat vaccination. **Exceptions:** Yellow Fever Vaccine. *Risk D: Consider therapy modification*

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