gamunex® connexions

gamunex®-C
immune globulin injection (human), 10% caprylate/chromatography purified

CIDP PRESCRIPTION REFERRAL FORM

Please fax completed form to **1-855-710-7035**

PATIENT INFORMATION:

Name: Date of birth: / / ☐ Male ☐ Female

Address: Height: (ft/in) Weight: lb kg

City: State: ZIP: Diagnosis: ICD-10 ☐ CIDP G61.81 ☐ Other:

Phone: Email: Current therapy:

Parent/guardian name (if patient is under 18):

PATIENT INSURANCE INFORMATION: **Please provide a copy of the front and back of insurance card**

COORDINATION OF CARE:

Preferred site of care: ☐ Outpatient infusion center ☐ Physician office ☐ Home ☐ Other:

Facility name: Contact name: Title: Phone:

PRESCRIBING INFORMATION: For patients with CIDP, clinical response was determined using IGIV-C efficacy (ICE) study dosing protocol with a loading dose of 2 g/kg IV over 1 to 2 days and a maintenance dose of 1 g/kg IV over 1 day every 3 weeks.[1,2]

LOADING DOSE: g/kg IV divided over: day(s)

MAINTENANCE DOSE: g/kg IV divided over: day(s) every: week(s)

ROUTE: ☐ Peripheral IV ☐ Central line **REFILLS:** times

PREMEDICATE: ☐ Yes ☐ No ☐ Acetaminophen (oral) 650 mg ☐ Diphenhydramine (oral)

Other medications (specify): Drug allergies:

☐ Nursing services:

☐ Anaphylaxis kit:

☐ Provide any medical/ancillary supplies as necessary to safely administer prescribed medication

☐ Other order(s):

PRESCRIBER INFORMATION AND SIGNATURE: Required to process

Physician name (print): Office contact:

City: State: ZIP:

Phone: Email: Fax:

Facility or prescriber tax ID#: NPI#: DEA#:

I verify that the patient and prescriber information contained in this enrollment form is complete and accurate to the best of my knowledge and that I have prescribed GAMUNEX-C based on my professional judgment and medical necessity. I also attest that I have obtained the patient's affirmative authorization to release the above information and such other personal information as may be necessary to Gamunex Connexions and/or their agents. I authorize Grifols and its affiliated companies, agents and representatives, and contracted third parties to forward this prescription electronically, by facsimile, or by mail to the dispensing pharmacy selected above (if applicable). If patient is younger than 18 years I attest that I have obtained permission from the patient's legal guardian.

PHYSICIAN SIGNATURE: Date:

☐ **DISPENSE AS WRITTEN:** Exact terminology may be based on state regulations. Please provide state-specific prescription language here:

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If you have questions, please call Gamunex Connexions toll free at 1-888-MYGAMUNEX (694-2686), Monday to Friday from 8 AM to 8 PM EST.

Please see Important Safety Information on the next page and refer to accompanying full Prescribing Information for GAMUNEX-C.

CIDP=chronic inflammatory demyelinating polyneuropathy.

Important Safety Information

GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified) is indicated for the treatment of primary humoral immunodeficiency disease (PIDD) in patients 2 years of age and older, idiopathic thrombocytopenic purpura (ITP) in adults and children, and chronic inflammatory demyelinating polyneuropathy (CIDP) in adults.

Thrombosis may occur with immune globulin products, including GAMUNEX-C. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors. For patients at risk of thrombosis, administer GAMUNEX-C 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 in patients at risk for hyperviscosity.

Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IVIG) products in predisposed patients. Patients predisposed to renal dysfunction include those with any degree of preexisting renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IVIG products containing sucrose. GAMUNEX-C does not contain sucrose. For patients at risk of renal dysfunction or failure, administer GAMUNEX-C at the minimum concentration available and the minimum infusion rate practicable.

GAMUNEX-C is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin. It is contraindicated in IgA-deficient patients with antibodies against IgA and history of hypersensitivity.

Severe hypersensitivity reactions may occur with IVIG products, including GAMUNEX-C. In case of hypersensitivity, discontinue GAMUNEX-C infusion immediately and institute appropriate treatment.

Monitor renal function, including blood urea nitrogen (BUN), serum creatinine, and urine output in patients at risk of developing acute renal failure.

Hyperproteinemia, increased serum viscosity, and hyponatremia may occur in patients receiving IVIG treatment, including GAMUNEX-C.

There have been reports of aseptic meningitis, hemolytic anemia, and noncardiogenic pulmonary edema (transfusion-related acute lung injury [TRALI]) in patients administered with IVIG, including GAMUNEX-C.

The high-dose regimen (1g/kg x 1-2 days) is not recommended for individuals with expanded fluid volumes or where fluid volume may be a concern.

Because GAMUNEX-C is made from human blood, it may carry a risk of transmitting infectious agents, eg, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Do not administer GAMUNEX-C subcutaneously in patients with ITP because of the risk of hematoma formation.

Periodic monitoring of renal function and urine output is particularly important in patients judged to be at increased risk of developing acute renal failure. Assess renal function, including measurement of BUN and serum creatinine, before the initial infusion of GAMUNEX-C and at appropriate intervals thereafter.

Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides), or monoclonal gammopathies, because of the potentially increased risk of thrombosis.

If signs and/or symptoms of hemolysis are present after an infusion of GAMUNEX-C, perform appropriate laboratory testing for confirmation.

If TRALI is suspected, perform appropriate tests for the presence of antineutrophil antibodies and anti-HLA antibodies in both the product and patient's serum.

After infusion of IgG, the transitory rise of the various passively transferred antibodies in the patient's blood may yield positive serological testing results, with the potential for misleading interpretation.

In clinical studies, the most common adverse reactions with GAMUNEX-C were headache, pyrexia, hypertension, chills, rash, nausea, arthralgia, and asthenia (in CIDP); cough, rhinitis, pharyngitis, headache, asthma, nausea, fever, diarrhea, and sinusitis with intravenous use (in PIDD) and local infusion-site reactions, fatigue, headache, upper respiratory tract infection, arthralgia, diarrhea, nausea, sinusitis, bronchitis, depression, allergic dermatitis, migraine, myalgia, viral infection, and pyrexia with subcutaneous use (in PIDD); and headache, ecchymosis, vomiting, fever, nausea, rash, abdominal pain, back pain, and dyspepsia (in ITP).

The most serious adverse reactions in clinical studies were pulmonary embolism (PE) in 1 subject with a history of PE (in CIDP), an exacerbation of autoimmune pure red cell aplasia in 1 subject (in PIDD), and myocarditis in 1 subject that occurred 50 days post-study drug infusion and was not considered drug related (in ITP).

Please see accompanying full Prescribing Information for GAMUNEX-C.

References: 1. GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified) Prescribing Information. Grifols.
2. Hughes RAC, Donofrio P, Bril V, et al. Intravenous immune globulin (10% caprylate chromatography purified) for the treatment of chronic inflammatory demyelinating polyradiculoneuropathy (ICE study): a randomised placebo-controlled trial. *Lancet Neurol*. 2008;7(2):136-144.

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