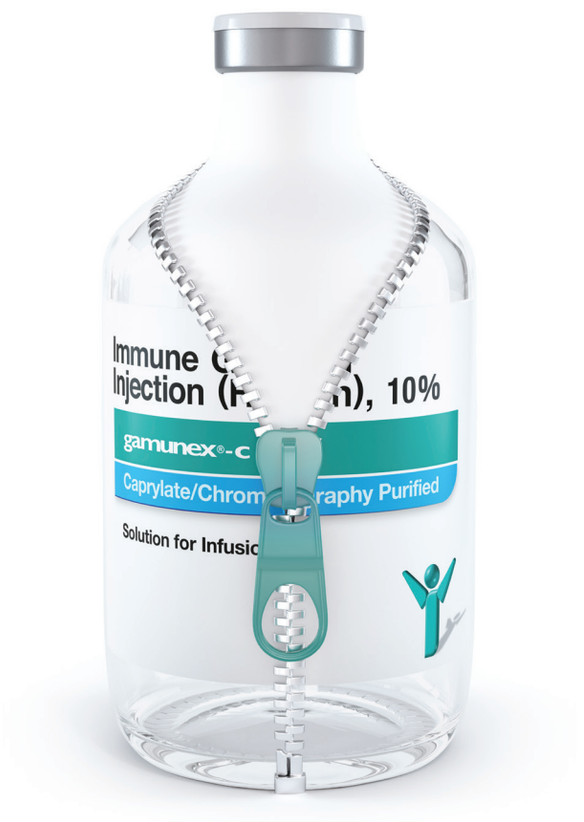
CIDP | PIDD | ITP

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

FOR THE TREATMENT OF CIDP, PIDD, AND ITP*

Uncover the Difference



A PROVEN FORMULATION FOR A WIDE RANGE OF PATIENT TYPES[1,2]

- Maximum purity of IgG with no sugar, trace amounts of sodium, and glycine stabilized[1-3]
- More than 87% of responders were relapse-free from symptoms related to CIDP at 48 weeks[4]
- ICE study first established the standard for IVIG dosing in CIDP[4]
- ~2X lower annual rate of validated infections with no validated cases of pneumonia in PIDD patients in a head-to-head trial[5†]
- Gamunex Connexions for patient support

*CIDP, chronic inflammatory demyelinating polyneuropathy; PIDD, primary immunodeficiency disease; ITP, idiopathic thrombocytopenic purpura.

†In the only US head-to-head IVIG trial in PIDD, GAMUNEX-C (caprylate/chromatography process) vs Gamimune N (solvent/detergent process).

In IV, it is recommended that the initial infusion rate be used for the first 30 minutes. If well tolerated, the rate may be gradually increased to a maximum of 0.08 mL/kg/min. Certain severe adverse drug reactions may be related to the rate of infusion. Slowing or stopping the infusion usually allows the symptoms to disappear promptly. Ensure that patients with preexisting renal insufficiency are not volume depleted; discontinue if renal function deteriorates. For patients at risk of renal dysfunction or thromboembolic events, administer at the minimum infusion rate practicable.

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.

GRIFOLS

Please see Important Safety Information on page 3, and refer to accompanying full Prescribing Information for GAMUNEX-C.

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Proven dosing regimen

IV DOSING REGIMEN ACROSS ALL 3 INDICATIONS[1]

INDICATION	DOSE	INITIAL INFUSION RATE	MAINTENANCE INFUSION RATE (if tolerated)
CIDP	Loading dose: 2 g/kg Maintenance dose: 1 g/kg	2 mg/kg/min (0.02 mL/kg/min)	8 mg/kg/min (0.08 mL/kg/min) every 3 weeks
PIDD	300-600 mg/kg	1 mg/kg/min (0.01 mL/kg/min)	8 mg/kg/min (0.08 mL/kg/min) every 3-4 weeks
ITP	2 g/kg	1 mg/kg/min (0.01 mL/kg/min)	8 mg/kg/min (0.08 mL/kg/min)

IV and sub Q administration and dosing options available in PIDD.[1]

Convenient formulation for your needs

A VERSATILE IG TREATMENT WITH 3 FDA-APPROVED INDICATIONS[1]

DOSING FORMS/VIAL SIZES[1,2]

IV and sub Q dosing administration in PIDD

Latex-free, ready-to-infuse 10% liquid

Vials available in 1 g, 2.5 g, 5 g, 10 g, 20 g, 40 g

SHELF LIFE/STORAGE[1,2]

36 months at refrigerated temperature 2°C-8°C (36°F-46°F). Do not freeze

6 months at temperatures not to exceed 25°C (77°F) anytime during the 36-month shelf life

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.

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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.** Gelfand EW. Differences between IGIV products: impact on clinical outcome. *Int Immunopharmacol*. 2006;6(4):592-599. **3.** Alonso W, Vandeberg P, Lang J, et al. Immune globulin subcutaneous, human 20% solution. *Biologicals*. 2020;64:34-40. **4.** Hughes RAC, Donofrio P, Bril V, et al; on behalf of the ICE Study Group. 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. **5.** Roifman CM, Schroeder H, Berger M, et al. Comparison of the efficacy of IGIV-C, 10% (caprylate/chromatography) and IGIV-SD, 10% as replacement therapy in primary immune deficiency: a randomized double-blind trial. *Int Immunopharmacol*. 2003:3(9):1325-1333. **6.** Wasserman RL, Irani A-M, Tracy J, et al. Pharmacokinetics and safety of subcutaneous immune globulin (human), 10% caprylate/chromatography purified in patients with primary immunodeficiency disease. *Clin Exp Immunol*. 2010;161(3):518-526.

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UNCOVER THE DIFFERENCE

GAMUNEX-C offers a proven formulation for a wide range of patient types

A BALANCE OF IG CHARACTERISTICS[1-3]

- Maximum purity of IgG
- Sugar-free
- Trace amounts of sodium
- Glycine stabilized
- Osmolality close to physiologic

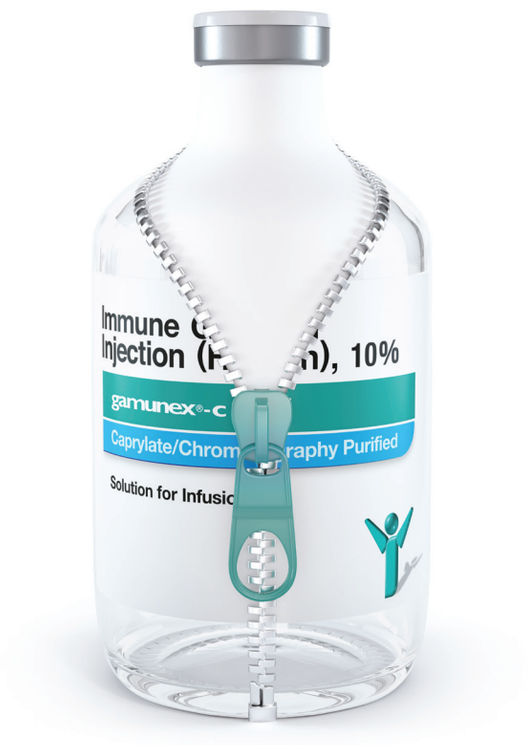
PROVEN DOSING

- More than 87% of responders were relapse-free from symptoms related to CIDP at 48 weeks[4]
- ICE study first established the standard for IVIG dosing in CIDP[4]
- ~2X lower annual rate of validated infections with no validated cases of pneumonia in PIDD patients in a head-to-head trial[5]
- SCIG demonstrated to be noninferior to IVIG in a PIDD pharmacokinetic study[6]

GAMUNEX CONNEXIONS OFFERS SUPPORT

- Copay Assistance Program to help eligible patients with costs of deductibles, copayment, and coinsurance*
- HCP assistance helps your office with billing and reimbursement support

*Terms and conditions apply. For more information, visit GAMUNEX-C.com.



$ ZERO COPAY FOR GAMUNEX-C

1-888-MYGAMUNEX
1-888-694-2686

GAMUNEX-C.com

Eligible patients may pay as little as $0 copay for GAMUNEX-C.

ADVERSE REACTIONS ACROSS ALL INDICATIONS

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).

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