CIDP | PIDD | ITP

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

Expand your treatment possibilities

VERSATILE IG: MULTIPLE VIAL SIZES AND CONVENIENT STORAGE[1]

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Primary Humoral Immunodeficiency Disease (PIDD)

Idiopathic Thrombocytopenic Purpura (ITP)

IG, immune globulin.

Not actual size.

GAMUNEX-C is indicated for the treatment of PIDD in patients 2 years of age and older, for the treatment of adults and children with ITP to raise platelet counts to prevent bleeding or to allow a patient with ITP to undergo surgery, and for the treatment of CIDP in adults to improve neuromuscular disability and impairment and for maintenance therapy to prevent relapse.[1]

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.[1]

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.[1]

GRIFOLS

Please see Important Safety Information for GAMUNEX-C on page 6 and full Prescribing Information.

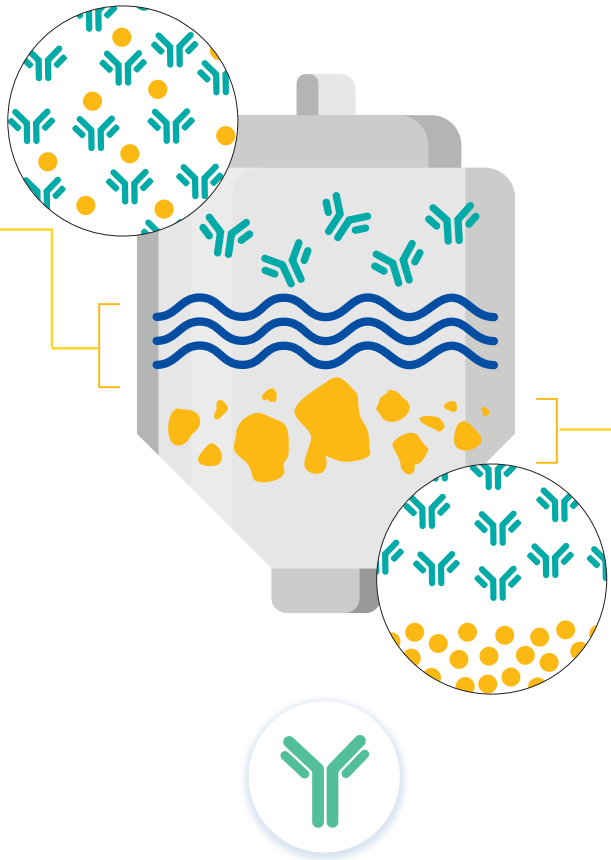
The process is the product

GAMUNEX-C USES A UNIQUE CAPRYLATE CHROMATOGRAPHY MANUFACTURING PROCESS THAT YIELDS ≥ 98% IgG[1-5]

- 100% monomers and dimers means no aggregates, which are known to increase inflammation and the risk of adverse events.[3-5]
- The manufacturing process is 70% shorter than a solvent process with 50% greater yield of IgG.[2]

CAPRYLATE PRECIPITATION AND INCUBATION

- Caprylate is added to a fractionated plasma solution.
- Viruses and impurities are removed while protecting the structure and function of IgG.
- **IgG is maintained in liquid phase to minimize denaturing of the protein.**



ANION-EXCHANGE CHROMATOGRAPHY

- Removes non-IgG proteins
- Removes caprylate
- **Yields maximum percentage (≥ 98%) of IgG and maximum monomeric levels**

MAXIMUM PURITY

The caprylate/chromatography process delivers ≥ 98% IgG.[1-5]

PRODUCT CHARACTERISTICS TO MEET A WIDE RANGE OF PATIENT NEEDS[1,6,7]

- **Sugar-free**
- **Trace amounts of sodium**
- **Stabilized with glycine**

IgG, immunoglobulin G.

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IV dosing across all 3 indications[1]

	DOSE	INITIAL INFUSION RATE	MAXIMUM INFUSION RATE
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 SC administration and dosing options available in PIDD.[1]
†Infusions for ITP are given at 1 g/kg for 2 consecutive days or 5 doses of 0.4 g/kg for 5 consecutive days.[1]

Versatile IG treatment with 3 FDA-approved indications[1]

DOSING FORMS	SHELF LIFE/STORAGE
IV and SC dosing administration in PIDD	36 months at a refrigerated temperature of 2 °C to 8 °C (36 °F to 46 °F). **Do not freeze.**
Ready-to-infuse 10% liquid; not made with natural rubber latex	Room temperature storage (not to exceed 25 °C or 77 °F) for up to 6 months at anytime during 36-month shelf life
Vials available in 1 g, 2.5 g, 5 g, 10 g, 20 g, 40 g	Keep the vial in the carton to protect from light

CIDP, chronic inflammatory demyelinating polyneuropathy; IG, immune globulin; IgA, immunoglobulin A; ITP, idiopathic thrombocytopenic purpura; PIDD, primary immunodeficiency disease; IV, intravenous; SC, subcutaneous.

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.[1]

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Multiple vial sizes to help reduce waste[1]

Not actual sizes.

VIAL SIZE	OUTER PACKAGE NDC 11	INNER PACKAGE NDC 11
1 g	13533-0800-12	13533-0800-13
2.5 g	13533-0800-15	13533-0800-16
5 g	13533-0800-20	13533-0800-21
10 g	13533-0800-71	13533-0800-72
20 g	13533-0800-24	13533-0800-25
40 g	13533-0800-40	13533-0800-41

For billing purposes, use the outer package 11-digit NDC code.

NDC, National Drug Code.

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CIDP | PIDD | ITP

GAMUNEX-C delivers maximum purity (≥ 98% IgG) with flexible dosing options across CIDP, PIDD, and ITP[1-3]

THE PROCESS IS THE PRODUCT

≥ 98% IgG

MAXIMUM PURITY[1-3]

Unique caprylate/chromatography fractionation and purification process

CONVENIENT FORMULATION[3]

RANGE OF DOSING OPTIONS[1]

IV and SC* options available with dosing flexibility

*SC option only for PIDD.[1]

Get customized support through Gamunex Connexions® for patients with PIDD and CIDP

$ ZERO COPAY FOR GAMUNEX-C

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

The Copay Assistance Program helps eligible patients with costs of deductibles, copayment, and coinsurance.†

HCP assistance helps your office with billing and reimbursement support.

1-888-MYGAMUNEX | 1-888-694-2686 | Gamunex Connexions®

CIDP, chronic inflammatory demyelinating polyneuropathy; HCP, healthcare professional; IgG, immunoglobulin G; ITP, idiopathic thrombocytopenic purpura; IV, intravenous; PIDD, primary immunodeficiency disease; SC, subcutaneous.

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

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).[1]

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).[1]

Please see Important Safety Information for GAMUNEX-C on page 6 and full Prescribing Information.

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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 full Prescribing Information for GAMUNEX-C.

References: 1. GAMUNEX-C Prescribing Information, Grifols. January 2020. **2.** Lebing W, Remington KM, Schreiner C, Paul HI. Properties of a new intravenous immunoglobulin (IGIV-C, 10%) produced by virus inactivation with caprylate and column chromatography. *Vox Sang*. 2003;84(3):193-201. **3.** Alonso W, Vandeberg P, Lang J, et al. Immune globulin subcutaneous, human 20% solution. *Biologicals*. 2020;64:34-40. **4.** Schwab I, Nimmerjahn F. Intravenous immunoglobulin therapy: how does IgG modulate the immune system? *Nat Rev Immunol*. 2013;13(3):176-189. **5.** Bertolini J. The purification of plasma proteins for therapeutic use. In: Simon TL, ed. *Rossi's Principles of Transfusion Medicine*. 5th ed. John Wiley & Sons; 2016:302-320. **6.** Gelfand EW. Differences between IGIV products: impact on clinical outcome. *Int Immunopharmacol*. 2006;6(4):592-599. **7.** Siegel J. IVIG medication safety: a stepwise guide to product selection and use. *Pharm Pract News*. December 2010.

GRIFOLS

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