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

VOLUNTARY WITHDRAWAL

August 2025

At Grifols, we are committed to the highest level of quality and tolerability of our medicines for the patients who rely upon them. In addition to our quality and safety testing throughout the manufacturing process, we closely monitor adverse events for all our medicines in the market.

Out of an abundance of caution, since the beginning of the year we have issued a voluntary withdrawal in the US for specific lots of GAMUNEX-C as a precautionary measure due to allergic/hypersensitivity type reactions reported to Grifols Pharmacovigilance. Hypersensitivity reactions are a known risk with immunoglobulin products, as noted in the prescribing information.

These withdrawals are being conducted with the knowledge of the US Food and Drug Administration, Center for Biologics Evaluation and Research.

The GAMUNEX-C 10% lots affected by this withdrawal are:

Lot Number	Material Number	Expiration Date	Market Release	NDC Number	Withdrawal Date
B23K001433	730807	12/18/2027	01/28/2025	13533-800-40	March 21, 2025
B01J112733	730807	11/08/2027	12/13/2024	13533-800-40	February 19, 2025
B01J093362	729688	12/02/2027	02/14/2025	13533-800-24	August 8, 2025
B01J094362	729688	12/02/2027	02/13/2025	13533-800-24	August 8, 2025

If you have product from the withdrawn lots, cease use immediately and return it to the authorized distributor of record.

Distributors, in turn, should return product to Grifols Therapeutics, 8368 Clayton Blvd, Clayton, NC, 27520. For questions concerning return of the product, contact US Customer Service at (800) 243-4153.

For questions or more information, please contact Grifols Medical Information directly at 1-800-520-2807.

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Please see Important Safety Information on page 2 and refer to accompanying full Prescribing Information for GAMUNEX-C.

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.

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