Grifols introduces new 40-g IVIG vial size for GAMUNEX-C

- The widest range of vial sizes expands convenience options for Ig therapy

RTP, NC (November 6, 2014).—Grifols, a leading provider of plasma-derived therapies, announced today that the 40-g (400 mL) vial size for GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified) became available on November 3.

With the addition of the new 40-g vial, GAMUNEX-C now comes in 6 different vial sizes, including 1 g (10 mL), 2.5 g (25 mL), 5 g (50 mL), 10 g (100 mL) and 20 g (200 mL)—the widest range of vial sizes currently available.

The wide range of vial sizes helps avoid unnecessary waste and provides an easier, more convenient way to dose according to prescription.

The addition of a 40-g vial is welcomed by both the nursing and patient communities. Jan E. Jones R.N., President of Immunoglobulin Nursing Society (IgNS) said, “The convenience of the new 40-g vial size for GAMUNEX-C will mean less time for preparation of IVIG.”

GAMUNEX-C offers versatility with proven efficacy in 3 FDA-approved indications: chronic inflammatory demyelinating polyneuropathy (CIDP), primary humoral immunodeficiency disease (PIDD), and idiopathic thrombocytopenic purpura (ITP).


Important Safety Information

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

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 noncardiogenic pulmonary edema (transfusion-related acute lung injury [TRALI]), hemolytic anemia, and aseptic meningitis 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, 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, fever, chills, hypertension, rash, nausea, and asthenia (in CIDP); headache, cough, injection-site reaction, nausea, pharyngitis, and urticaria with intravenous use (in PIDD) and infusion-site reactions, headache, fatigue, arthralgia and pyrexia with subcutaneous use (in PIDD); and headache, vomiting, fever, nausea, back pain, and rash (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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About Grifols
Grifols is a global healthcare company with a 70-year legacy of improving people's health and well being through the development of life-saving plasma medicines, diagnostics systems, and hospital pharmacy products.

The company is present in more than 100 countries worldwide and is headquartered in Barcelona, Spain. Grifols is a leader in plasma collection with a network of 150 plasma donor centers in the U.S., and a leading producer of plasma-derived biological medicines. The company also provides a comprehensive range of transfusion medicine, hemostasis, and immunoassay solutions for clinical laboratories, blood banks and transfusion centers, and is a recognized leader in transfusion medicine.

In 2013, sales exceeded 2,740 million euros with a headcount of 13,200 employees. Grifols demonstrates its commitment to advancing healthcare by allocating a significant portion of its annual income to R&D.

The company’s class A shares are listed on the Spanish Stock Exchange, where they are part of the Ibex-35 (MCE:GRF). Its non-voting class B shares are listed on the Mercado Continuo (MCE:GRF.P) and on the U.S. NASDAQ via ADRs (NASDAQ: GRFS). For more information visit www.grifols.com.