Important Safety Information

Flebogamma® 5% DIF is an immune globulin intravenous (human) solution indicated in adults and pediatric patients 2 years of age and older for the treatment of primary immunodeficiency (PIDD), including the humoral immune defects in common variable immunodeficiency, x-linked agammaglobulinemia, severe combined immunodeficiency, and Wiskott-Aldrich syndrome.

Thrombosis may occur with immune globulin products, including Flebogamma 5% DIF. 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 Flebogamma 5% DIF 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 have been related to intravenous immune globulin (IVIG) products. Patients predisposed to acute renal failure include patients with any degree of preexisting renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Administer Flebogamma 5% DIF at the minimum rate of infusion practicable in patients at risk for renal dysfunction or failure. Reports of renal dysfunction and acute renal failure occur more commonly in patients receiving IVIG products containing sucrose as a stabilizer. They account for a disproportionate share of the total number of reported cases of renal dysfunction and acute renal failure. Flebogamma 5% DIF does not contain sucrose.

Flebogamma 5% DIF is contraindicated in patients who have had a history of anaphylactic or severe systemic hypersensitivity reactions to the administration of human immune globulin and in IgA-deficient patients with antibodies to IgA and a history of hypersensitivity.

Severe hypersensitivity reactions may occur with IVIG products, including Flebogamma 5% DIF. In case of hypersensitivity, discontinue Flebogamma 5% DIF 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 Flebogamma 5% DIF therapy.

Aseptic meningitis syndrome (AMS) has been reported to occur following IVIG treatment. AMS may occur more frequently following high dose (eg, > 1.0 g/kg body weight) and/or rapid infusion of IVIG.

Hemolysis, either intravascular or due to enhanced red blood cell sequestration, can develop subsequent to Flebogamma 5% DIF treatments. Risk factors include high doses and non-O blood group. Monitor patients for hemolysis and hemolytic anemia.

Noncardiogenic pulmonary edema (transfusion-related acute lung injury [TRALI]) has been reported in patients following IVIG treatment. If TRALI is suspected, perform appropriate tests for the presence of antineutrophil antibodies and anti-HLA antibodies in both the product and patient serum.

Individuals receiving Flebogamma 5% DIF for the first time or being restarted on the product after a treatment hiatus of more than 8 weeks may be at a higher risk for the development of fever, chills, nausea, and vomiting. Careful monitoring of recipients and adherence to recommendations regarding dosage and administration may reduce the risk of these types of events.

Because Flebogamma 5% DIF is made from human plasma, 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. This also applies to unknown or emerging viruses and other pathogens. No cases of transmission of viral diseases or CJD have been associated with the use of Flebogamma 5% DIF.

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 Flebogamma 5% DIF 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.

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.

Flebogamma 5% DIF contains sorbitol. The presence of sorbitol presents a risk to those with hereditary fructose intolerance (HFI). Flebogamma 5% DIF must not be administered to subjects with HFI.

The most common adverse reactions (reported in at least 5% of clinical trial adult subjects) were headache, pyrexia/fever, pain, infusion site reactions, diarrhea, rigors or chills, urticaria, and infusion site inflammation.

The most common adverse reactions (reported in at least 5% of clinical trial pediatric subjects) were headache, pyrexia, hypotension, tachycardia, diastolic hypotension, nausea, abdominal pain, diarrhea, pain, and vomiting.

Please see accompanying full Prescribing Information for Flebogamma 5% DIF.

Important Safety Information

Flebogamma® 10% DIF is an immune globulin intravenous (human) 10% preparation that is indicated for the treatment of primary immunodeficiency disease (PIDD), including the humoral immune defect in common variable immunodeficiency, x-linked agammaglobulinemia, severe combined immunodeficiency, and Wiskott-Aldrich syndrome. Flebogamma 10% DIF is also indicated for the treatment of chronic primary immune thrombocytopenia (ITP) in patients 2 years of age and older.

Thrombosis may occur with immune globulin products, including Flebogamma 10% DIF. 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 Flebogamma 10% DIF 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 have been related to intravenous immune globulin (IVIG) products. Patients predisposed to acute renal failure include patients with any degree of preexisting renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Administer Flebogamma 10% DIF at the minimum rate of infusion practicable in patients at risk for renal dysfunction or failure. Reports of renal dysfunction and acute renal failure occur more commonly in patients receiving IVIG products containing sucrose as a stabilizer. They account for a disproportionate share of the total number of reported cases of renal dysfunction and acute renal failure. Flebogamma 10% DIF does not contain sucrose.

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Severe hypersensitivity reactions may occur with IVIG products, including Flebogamma 10% DIF. In case of hypersensitivity, discontinue Flebogamma 10% DIF 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 Flebogamma 10% DIF therapy.

Aseptic meningitis syndrome (AMS) has been reported to occur following IVIG treatment. AMS may occur more frequently following high doses (2 g/kg) and/or rapid infusion of IVIG.

Hemolytic anemia can develop subsequent to IVIG therapy, including Flebogamma 10% DIF. Flebogamma 10% DIF may contain blood group antibodies that may act as hemolysins and induce in vivo coating of red blood cells (RBCs) with immunoglobulin, causing a positive direct antiglobulin test and hemolysis. If signs and/or symptoms of hemolysis are present after an infusion of Flebogamma 10% DIF, perform appropriate laboratory testing for confirmation.

Noncardiogenic pulmonary edema (transfusion-related acute lung injury [TRALI]) has been reported in patients following IVIG treatment. If TRALI is suspected, perform appropriate tests for the presence of antineutrophil antibodies and anti-HLA antibodies in both the product and patient serum. TRALI may be managed using oxygen therapy with adequate ventilatory support.

Individuals receiving Flebogamma 10% DIF for the first time or being restarted on the product after a treatment hiatus of more than 8 weeks may be at a higher risk for the development of fever, chills, nausea, and vomiting. Careful monitoring of recipients and adherence to recommendations regarding dosage and administration may reduce the risk of these types of events.

Because Flebogamma 10% DIF is made from human plasma, 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. This also applies to unknown or emerging viruses and other pathogens. No cases of transmission of viral diseases or CJD have been associated with the use of Flebogamma 10% DIF.

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 Flebogamma 10% DIF 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 potential for increased risk of thrombosis.

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.

Flebogamma 10% DIF contains sorbitol. The presence of sorbitol presents a risk to those with hereditary fructose intolerance (HFI). HFI is typically suspected based on dietary history, especially in young children who become symptomatic after breast-feeding. Flebogamma 10% DIF must not be administered to subjects with HFI.

In clinical studies, the most common adverse reactions observed with Flebogamma 10% DIF were headache, fever/pyrexia, shaking, tachycardia, hypotension, back pain, myalgia, hypertension, chest pain, pain, nausea, infusion-site reactions, and pain in extremities (in PIDD) and headache, pyrexia, nausea, chills, vomiting, body temperature increase, dizziness, back pain, hypotension, hypertension, heart rate increase, and diarrhea (in ITP).

The most serious adverse reactions observed with Flebogamma 10% DIF were back pain, chest pain, headache, and chills/tachycardia (2 patients) and bacterial pneumonia, subcutaneous abscess, and cellulitis (1 patient) (in PIDD) and soft tissue inflammation (1 patient) unrelated to the study drug and headache (2 patients) possibly related to the study drug (in ITP).

Please see accompanying full Prescribing Information for Flebogamma 10% DIF.