Reset Form

Flebogamma® 5% DIF
Immune Globulin Intravenous (Human)

Flebogamma DIF Patient Assistance Program – Application

PATIENT INFORMATION

First Name: _____ Middle Initial: _____ Last Name: _____

Date of Birth: _____ Parent/Guardian: _____

Street Address: _____ Apartment Number: _____

City: _____ State: _____ Zip Code: _____

Patient Certification

I agree I have no insurance coverage for Flebogamma DIF at this time and insufficient financial resources to pay for the prescribed medication. I hereby permit my healthcare providers, physicians, or third-party service providers to disclose, share and use the information on these forms and other information pertaining to me, to the minimum extent necessary, for adjudication of the application, as requested by the Flebogamma DIF Patient Assistance Program. I verify that the information provided in this application is complete and accurate to the best of my knowledge. I understand that if my health insurance coverage or employment status changes, I will notify the Flebogamma DIF Patient Assistance Program promptly of such change. I understand that this may affect my eligibility to participate in the program before my eligibility period ends. I also understand that any and all information that I provide may be shared with my treating physician. I understand that this authorization will remain in effect throughout my participation in the program. I understand that I must re-affirm my status as requested and re-apply at the end of the calendar year, and that my eligibility will be reassessed at these times. I understand that my access to Flebogamma DIF within this program may be delayed depending on the number of participants and the availability of drug product for the program. The Flebogamma DIF Patient Assistance Program may be discontinued or modified at any time, without notice. I understand that I am under no obligation to use or purchase any product or service as a condition of receipt of free product from Grifols, the manufacturer of Flebogamma DIF. I shall not seek reimbursement from any sources for the free product that I receive, and acknowledge that neither I nor any provider is entitled to reimbursement for free product. Free product is non-transferable.

In order to apply for the Flebogamma DIF Patient Assistance Program, please return the completed form along with: a letter of medical necessity explaining how the product will be used, utility bill, proof of lapse of insurance, and a driver's license or other state or federal identification. Failure to provide proper documentation will result in ineligibility for the Flebogamma DIF Patient Assistance Program.

Patient Signature (Parent/Guardian if applicable) _____ Date: _____

PHYSICIAN

Prescribing Physician: _____ Physician Phone: _____

Provider Name: _____ Provider Phone: _____

Grifols Product: _____ Medical Record Number: _____

Start of Therapy Date: _____ Grams per Month: _____

Annual Household Income: _____ Number of Persons in Household: _____

Diagnoses: _____

Physician Certification

I attest that the information provided is correct and complete and that the patient for whom the product is intended has been diagnosed with a primary immune deficiency. In the event that there are any changes to this information, I agree to notify the Flebogamma DIF Patient Assistance Program. I understand that no third party or patient may be charged for product received through this program and that no product received through this program can be sold, traded, distributed for resale, or used by another individual. I understand that Grifols reserves the right at any time and without notice to modify this application; modify or discontinue any or all of the program and related eligibility criteria; or terminate assistance provided by the program. I understand and hereby certify that the Patient is not actively participating in any state or federal insurance programs or financial assistance programs.

Physician Signature _____ Date: _____

Please return the completed form to confidential **FAX (866) 539-0319** and mail hard copy to:
Grifols Flebogamma, PO Box 5428, Williamsburg, VA 23188

Please see Important Safety Information about Flebogamma 5% DIF on the following pages and refer to accompanying full Prescribing Information for complete prescribing details.

GRIFOLS

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.

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