Live Life Fully

Gammaplex®
Immune Globulin Intravenous (Human), 5% Liquid

The Gammaplex Copay Program

The Gammaplex Copay Program is designed for patients who are having difficulty paying their out-of-pocket costs for their IVIG prescription.

Patient eligibility:

- Patients must express a need for financial assistance or difficulty paying copay
- Patients must have coverage under a private US insurance plan. Not valid for prescriptions eligible for reimbursement by any federal or state healthcare program, such as Medicare, Medicare advantage plans, Medicaid, PCIP, Champus, TriCare, Veterans Administration (VA), or any other state or federal program
- Patients whose insurance policy prohibits copay assistance are not eligible. Prior to enrolling, participants are responsible for checking with their insurance carrier to confirm that their participation is not inconsistent with their plan's requirements

Benefit:

- Patients can receive up to $2000 in assistance per calendar year
- Up to $1000 is available at first fill and $250 for subsequent fills up to annual maximum

For more information and complete program rules please visit **gammaplex.medmonk.com** or call **1-866-234-3732**

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Please see Important Safety Information on back and full prescribing information in pocket.

Important Safety Information

Gammaplex® (immune globulin intravenous [human], 5% liquid) is indicated for replacement therapy in primary humoral immunodeficiency (PI) in adults and pediatric patients two years of age and older. This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency, X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Gammaplex is also indicated for the treatment of chronic immune thrombocytopenic purpura (ITP).

Thrombosis may occur with immune globulin products, including Gammaplex. 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.

Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients who receive immune globulin intravenous (IGIV) products, including Gammaplex.

Patients predisposed to renal dysfunction include those with any degree of pre-existing 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 IGIV products containing sucrose. Gammaplex does not contain sucrose.

For patients at risk of thrombosis, renal dysfunction or acute renal failure, administer Gammaplex 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.

Gammaplex is contraindicated in patients who have had a history of anaphylactic or severe systemic reactions to human immune globulin; a hereditary intolerance to fructose and in infants and neonates for whom sucrose or fructose tolerance has not been established; and IgA deficient patients with antibodies to IgA and a history of hypersensitivity.

In patients at risk of developing acute renal failure, monitor renal function, including blood urea nitrogen (BUN), serum creatinine and urine output. Hyperproteinemia, increased serum viscosity, and hyponatremia may occur in patients receiving IGIV therapy.

Aseptic meningitis syndrome (AMS) may occur infrequently with IGIV treatment. AMS usually begins within several hours to 2 days following IGIV treatment. Discontinuation of IGIV treatment has resulted in remission of AMS within several days without sequelae. AMS may occur more frequently in association with high doses (2 g/kg) and/or rapid infusion of IGIV.

Hemolysis and hemolytic anemia can develop subsequent to IGIV treatments. Patient risk factors that may be associated with development of hemolysis include high dose (>2 g/kg), non-O blood group, and underlying inflammatory state. Noncardiogenic pulmonary edema may occur in patients following IGIV treatment (i.e. transfusion-related acute lung injury [TRALI]). Monitor patients for pulmonary adverse reactions. If TRALI is suspected, test product and patient's serum for anti-neutrophil antibodies.

Gammaplex is made from human plasma and may contain infectious agents, e.g. viruses and, theoretically, the Creutzfeldt-Jakob disease agent. No cases of transmission of viral diseases or CJD have been associated with the use of Gammaplex.

In clinical studies, the most common adverse reactions with Gammaplex were headache, pyrexia, vomiting, fatigue, nausea, sinusitis, and nasal congestion. Serious adverse reactions observed in clinical trial subjects with primary immunodeficiencies were thrombosis and chest pain. Serious adverse reactions observed in clinical trial subjects with Immune Thrombocytopenic Purpura were headache, vomiting and dehydration.

Please see accompanying Full Prescribing Information for complete prescribing details.

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Individual HCPCS code for Gammaplex **J1557**
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