INDICATIONS AND USAGE

GAMMAKED™ [Immune Globulin Injection (Human) 10% Caprylate/Chromatography Purified] is an immune globulin injection that is indicated to treat primary humoral immunodeficiency (PI) in patients 2 years of age and older, idiopathic thrombocytopenic purpura (ITP) in adults and children, and chronic inflammatory demyelinating polyneuropathy (CIDP) in adults.

IMPORTANT SAFETY INFORMATION

Boxed Warning: Thrombosis, Renal Dysfunction and Acute Renal Failure

- **Thrombosis may occur with immune globulin products, including GAMMAKED. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.**
- **For patients at risk of thrombosis, administer GAMMAKED 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 (IGIV) products in predisposed patients. 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. GAMMAKED does not contain sucrose.**
- **For patients at risk of renal dysfunction or failure, administer GAMMAKED at the minimum concentration available and the minimum infusion rate practicable.**

Please see additional Important Safety Information throughout and the accompanying Full Prescribing Information, located in the back pocket, for complete prescribing details including Boxed Warning, contraindications and dosing and administration information.

KEDRION BIOPHARMA

GAMMAKED is approved as first-line therapy for CIDP and is designed to meet the needs of patients and clinicians[1]

GAMMAKED has been a trusted treatment option for patients with CIDP since 2011[1]

GAMMAKED is indicated for the treatment of CIDP in adults to improve neuromuscular disability and impairment and for maintenance therapy to prevent relapse[1]

- Sucrose free
- Only trace amounts of sodium
- Ready-to-infuse liquid solution with built-in vial hanger for infusion convenience
- Trace amounts of IgA
- Glycine stabilized and near physiologic osmolality
- pH 4.0-4.5

Kedrion is here to support you and your patients

Customer Service Phone Number
(855) 353-7466

Customer Service Email
US_CustomerService@kedrion.com

Customer Service Hours
Monday-Friday, 8:00am-6:00pm CT

Customer Service Fax Number
(855) 751-7951

Medical Information Email
US_Medicalinfo@kedrion.com

CIDP, chronic inflammatory demyelinating polyneuropathy; FDA, U.S. Food & Drug Administration; IgA, immunoglobulin A; IVIG, intravenous immune globulin.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATONS

GAMMAKED is contraindicated in patients who have had an anaphylactic or severe systemic reaction to human immunoglobulin. It is also contraindicated in IgA deficient patients with antibodies against IgA and history of hypersensitivity. Have epinephrine available immediately to treat any acute severe hypersensitivity reactions.

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GAMMAKED offers optimized dosing and administration for the treatment of CIDP

GAMMAKED Dosing and Administration, Vial Sizes, and Storage and Handling

Administration Route	Dose	Initial Infusion Rate	Maintenance Infusion Rate (if tolerated)
Intravenously (IV)	**Loading dose:** **2 g/kg** (20 mL/kg) given in divided doses over 2 to 4 consecutive days	2 mg/kg/min (0.02 mL/kg/min)	8 mg/kg/min (0.08 mL/kg/min) Every 3 weeks
	Maintenance dose: **1 g/kg** (10 mL/kg) over 1 day or divided into 2 doses of 0.5 g/kg given on 2 consecutive days, **every 3 weeks**		

Do NOT administer GAMMAKED subcutaneously (SC) for CIDP

GAMMAKED Vials		
NDC Number	**Size**	**Grams Protein**
76125-900-50	50 mL	5 g
76125-900-10	100 mL	10 g
76125-900-20	200 mL	20 g

Storage and handling

- Available in 3 color-coded package sizes with barcoding
- 3-year refrigerated shelf life, and up to 6-month room temperature storage within the 3-year refrigerated shelf life
- Peel-off labels to help simplify record-keeping

For a current list of specialty pharmacies that carry GAMMAKED, SCAN THE CODE

gammaked™
immune globulin injection (human), 10%
caprylate/chromatography purified

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

- **Hypersensitivity:** Severe hypersensitivity reactions may occur with IGIV products, including GAMMAKED. In case of hypersensitivity, discontinue GAMMAKED infusion immediately and institute appropriate treatment. GAMMAKED contains trace amounts of IgA (average 46 micrograms/mL). Patients with known antibodies to IgA may have a greater risk of developing potentially severe hypersensitivity and anaphylactic reactions. It is contraindicated in IgA deficient patients with antibodies against IgA and history of hypersensitivity reaction.
- **Renal Failure:** Acute renal dysfunction/failure, acute tubular necrosis, proximal tubular nephropathy, osmotic nephrosis and death may occur upon use of IGIV products, especially those containing sucrose. GAMMAKED does not contain sucrose. Ensure that patients are not volume depleted prior to the initiation of the infusion of GAMMAKED. Periodic monitoring of renal function and urine output is particularly important in patients judged to have a potential increased risk for developing acute renal failure. Assess renal function, including measurement of blood urea nitrogen (BUN)/serum creatinine, prior to the initial infusion of GAMMAKED and again at appropriate intervals thereafter. If renal function deteriorates, consider discontinuation of GAMMAKED. For patients judged to be at risk for developing renal dysfunction, including patients with any degree of pre-existing renal insufficiency or risk factors for renal insufficiency, administer GAMMAKED at the minimum infusion rate practicable [less than 8 mg/kg/min (0.08 mL/kg/min)].
- **Hyperproteinemia, Increased Serum Viscosity, and Hyponatremia:** Hyperproteinemia, increased serum viscosity, and hyponatremia may occur in patients receiving IGIV therapy, including GAMMAKED. It is clinically critical to distinguish true hyponatremia from a pseudohyponatremia that is associated with concomitant decreased calculated serum osmolality or elevated osmolar gap, because treatment aimed at decreasing serum free water in patients with pseudohyponatremia may lead to volume depletion, a further increase in serum viscosity and a possible predisposition to thrombosis.
- **Aseptic Meningitis Syndrome (AMS):** Aseptic Meningitis Syndrome (AMS) may occur infrequently, especially with high doses or rapid infusion.
- **Hemolysis:** Hemolysis, either intravascular or due to enhanced red blood cell (RBC) sequestration, can develop subsequent to GAMMAKED treatment. Risk factors include high doses and non-O blood group. Closely monitor patients for hemolysis and hemolytic anemia, especially in patients with pre-existing anemia and/or cardiovascular or pulmonary compromise.
- **Transfusion-related Acute Lung Injury (TRALI):** Noncardiogenic pulmonary edema may occur in patients following treatment with IGIV products, including GAMMAKED. Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).
- **Volume Overload:** 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.
- **Transmission of Infectious Agents:** GAMMAKED is made from human plasma. Because this product is made from human plasma, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.
- **Hematoma Formation:** GAMMAKED is not approved for subcutaneous use in patients with ITP. Due to the potential risk of hematoma formation, GAMMAKED should not be administered subcutaneously in patients with ITP.
- **Interference with Laboratory Tests:** 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.

ADVERSE REACTIONS

In clinical studies, the most common adverse reactions with GAMMAKED (≥5% of subjects) were: **(in PI intravenous)** cough increased, rhinitis, pharyngitis, headache, asthma, nausea, fever, diarrhea, and sinusitis; **(in PI subcutaneous)** local infusion site reactions, fatigue, headache, upper respiratory tract infection, arthralgia, diarrhea, nausea, sinusitis, bronchitis, depression, allergic dermatitis, erythema, migraine, myalgia, viral infection, and pyrexia; **(in ITP)** headache, ecchymosis, vomiting, fever, nausea, rash, abdominal pain, back pain, and dyspepsia; **(in CIDP)** headache, pyrexia, hypertension, chills, rash, nausea, arthralgia, and asthenia.

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