GAMMAGARD LIQUID ERC
[Immune Globulin Infusion (Human)]
≤2 µg/mL IgA in a 10% Solution

For patients who may need a low-IgA IG therapy

GAMMAGARD LIQUID ERC® is an option for your patients with PI on IVIG or SCIG[1]

INDICATION

GAMMAGARD LIQUID ERC [Immune Globulin Infusion (Human)] ≤2 µg/mL IgA in a 10% solution is indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients ≥2 years.

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS, RENAL DYSFUNCTION, AND ACUTE RENAL FAILURE

- **Thrombosis may occur with immune globulin (IG) products, including GAMMAGARD LIQUID ERC. 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.**
- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients with immune globulin intravenous (IGIV) products. 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. GAMMAGARD LIQUID ERC does not contain sucrose.**
- **For patients at risk of thrombosis, administer GAMMAGARD LIQUID ERC 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 of hyperviscosity.**

Please see additional Important Safety Information throughout and click for Full Prescribing Information.

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What to know about another option for PI care from Takeda

No reconstitution

GAMMAGARD LIQUID ERC is the first low-IgA immunoglobulin in a ready-to-use solution that helps streamline preparation[1]

Administration setting options

Patients can infuse at home after appropriate training, or in a physician's office, hospital, or infusion center[1]

Multiple vial sizes

Available in 5 g/50 mL and 10 g/100 mL single-use vials[1] that enable you to meet patient dosing requirements with low product waste

State-of-the-art manufacturing

GAMMAGARD LIQUID with Enhanced Removal Capability (ERC) uses the same manufacturing process as other Takeda liquid IG products to deliver ≤2 µg/mL in a 10% solution[1]

IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

- History of anaphylactic or severe systemic hypersensitivity reactions to the administration of GAMMAGARD LIQUID ERC.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions: Severe hypersensitivity reactions may occur with immune globulin (IG) products, including GAMMAGARD LIQUID ERC, even in patients previously treated with IG products. Patients with known antibodies to IgA may have a greater risk of developing potentially severe hypersensitivity and anaphylactic reactions. In case of severe hypersensitivity, discontinue GAMMAGARD LIQUID ERC infusion immediately and manage with appropriate medications which may include epinephrine for immediate treatment.

Please see additional Important Safety Information throughout and click for Full Prescribing Information, including Boxed Warning regarding Thrombosis, Renal Dysfunction, and Acute Renal Failure.

Takeda Patient Support

Rely on the patient support you expect from Takeda

When your patient is enrolled, we're here to help them gain access to their prescribed Takeda medication

Our support specialists provide services including:

- **Benefits investigation** to help determine your patient's insurance benefits
- **Prior authorizations (PA)**, reauthorization, and appeals information in coordination with your patient's insurance company to determine any requirements
- **Financial assistance options**, including the Takeda Patient Support Co-Pay Assistance Program. The program may cover up to 100% of your patient's out-of-pocket co-pay costs, if they're eligible*†
- **Education and training** about their prescribed Takeda treatment or condition from nursing professionals. Our nurses cannot provide medical advice
- **Specialty pharmacy triage, coordination, and more**‡

Need assistance?

Our support specialists are never more than a tap or call away—

1-866-861-1750

Monday-Friday, 8 AM to 8 PM ET

Need to enroll your patient?

Visit our convenient online enrollment portal at TakedaPatientSupport.com/HCP

You can also enroll your patient by faxing the completed Start Form to:

1-866-861-1752

If English is not your patient's preferred language, we can assist them in a language of their choosing.

*Must meet eligibility requirements.

†**IMPORTANT NOTICE:** Takeda Patient Support Co-Pay Assistance Program (the Program) is not valid for prescriptions eligible to be reimbursed, in whole or in part, by Medicaid, Medicare (including Medicare Part D), Tricare, Medigap, VA, DoD, or other federal or state programs (including any medical or state prescription drug assistance programs). No claim for reimbursement of the out-of-pocket expense amount covered by the Program shall be submitted to any third party payer, whether public or private. The Program cannot be combined with any other rebate/coupon, free trial, or similar offer. Copayment assistance under the Program is not transferable. The Program only applies in the United States, including Puerto Rico and other U.S. territories, and does not apply where prohibited by law, taxed, or restricted. This does not constitute health insurance. Void where use is prohibited by your patient's insurance provider. If your patient's insurance situation changes, they must notify the Program immediately at 1-866-861-1750. Coverage of certain administration charges will not apply for patients residing in states where it is prohibited by law. Takeda reserves the right to rescind, revoke, or amend the Program at any time without notice.

‡If your patients' medication is dispensed by specialty pharmacy.

Visit GAMMAGARD.com/HCP/PIDD/Dosing-Administration#ERC to learn more about GAMMAGARD LIQUID ERC

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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Renal Injury: Renal injury, including acute renal failure, acute tubular necrosis, proximal tubular nephropathy, and osmotic nephrosis may occur with use of IG products, including GAMMAGARD LIQUID ERC. Ensure patients are not volume depleted before administering GAMMAGARD LIQUID ERC. In patients who are at risk of renal injury because of pre-existing renal insufficiency or predisposition to acute renal failure (such as diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs), administer GAMMAGARD LIQUID ERC at the minimum rate of infusion practicable.

Hyperproteinemia, Hyperviscosity, and Hyponatremia: May occur in patients receiving IG products, including GAMMAGARD LIQUID ERC. Distinguish true hyponatremia from pseudohyponatremia that is temporally or causally related to hyperproteinemia with concomitant decreased calculated serum osmolality or elevated osmolar gap. Treatment aimed at decreasing serum free water in patients with pseudohyponatremia may lead to volume depletion and hyperviscosity and a predisposition to thromboembolic events.

Thrombosis: May occur following treatment with IG products, including GAMMAGARD LIQUID ERC. Risk factors 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. Ensure adequate hydration in patients before administration of GAMMAGARD LIQUID ERC. For patients at risk of thrombosis, administer GAMMAGARD LIQUID ERC at the minimum dose and infusion rate practicable. Monitor patients for signs and symptoms of thrombosis. Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity.

Aseptic Meningitis Syndrome (AMS): May occur with use of IG products, including GAMMAGARD LIQUID ERC. The risk of AMS may be higher with high doses (2g/kg) and/or rapid infusion. Conduct a thorough neurological exam on patients exhibiting signs and symptoms, to rule out other causes of meningitis. Discontinuing IG treatment has resulted in remission within several days without sequelae.

Hemolysis: May occur with IG products, including GAMMAGARD LIQUID ERC due to the presence of blood group antibodies, which may cause a positive direct antiglobulin reaction and hemolysis. Monitor patients for signs and symptoms of hemolysis and delayed hemolytic anemia and, if present, perform appropriate confirmatory lab testing.

Transfusion-Related Acute Lung Injury (TRALI): May occur following treatment with IG products, including GAMMAGARD LIQUID ERC. Symptoms typically occur within 1 to 6 hours after treatment. Monitor patients for signs and symptoms of TRALI. If suspected, perform appropriate tests for presence of anti-neutrophil and anti-HLA antibodies in both product and patient serum. Manage patients using oxygen therapy with ventilatory support as appropriate.

Transmission Infectious Agents: There is risk of transmission of infectious disease or agents including viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and the Creutzfeldt-Jakob disease agent with GAMMAGARD LIQUID ERC administration because it is manufactured using human blood.

Interference with Lab Tests: False positive serological test results and certain assay readings may occur as the result of passively transferred antibodies.

ADVERSE REACTIONS

No clinical studies have been conducted using GAMMAGARD LIQUID ERC. The safety of GAMMAGARD LIQUID ERC in patients with primary humoral immunodeficiency (PI) is supported by two clinical studies conducted on GAMMAGARD LIQUID.

IV Administration: The most common adverse reactions observed in ≥5% of patients in study 1 were headache, fatigue, pyrexia, chills, nausea, pain in extremity, diarrhea, migraine, vomiting, dizziness, urticaria, cough, asthma, oropharyngeal pain, infusion site extravasation, arthralgia, rash, myalgia, pruritus, and cardiac murmur.

Subcutaneous administration: The most common adverse reactions observed in ≥5% of patients in study 2 were infusion site (local) event, headache, pyrexia, fatigue, heart rate increased, abdominal pain upper, vomiting, arthralgia, nausea, asthma, blood pressure systolic increased, diarrhea, ear pain, aphthous ulcer, migraine, oropharyngeal pain, and pain in extremity.

DRUG INTERACTIONS

Passive transfer of antibodies may transiently interfere with immune responses to live attenuated virus vaccines (e.g., measles, mumps, rubella, and varicella).

Please see additional Important Safety Information throughout and click for Full Prescribing Information, including Boxed Warning regarding Thrombosis, Renal Dysfunction, and Acute Renal Failure.

Reference: 1. GAMMAGARD LIQUID ERC. Prescribing Information. Takeda Pharmaceuticals U.S.A., Inc.; 2025.