BIVIGAM® INFORMATION

BioCareSD™ is the authorized distributor of BIVIGAM

To order BIVIGAM:

CALL
1-800-304-3064

VISIT
www.BioCareSD.com

EMAIL
order@biocaresd.com

OR

contact your **BioCareSD representative** directly.

Order 24/7/365

24 HOURS

There is a live BioCareSD team member available 24 hours a day, 7 days a week, 365 days a year

Product delivery

Standard next-day delivery

Information about BIVIGAM for healthcare professionals, patients with primary immune deficiency disease, and their healthcare partners can be found at: **www.bivigam.com**. Through the BIVIGAM website, physicians can access the prescription request form and request a meeting with a sales professional. Any medical or scientific questions regarding BIVIGAM, or any other products produced by ADMA Biologics, should be directed to our Medical Affairs Department at **medicalaffairs@admabio.com** or **1-800-458-4244**, prompt 2.

Please see the Indication and Detailed Important Risk Information on back, and the accompanying full Prescribing Information, including Boxed Warning.

BIVIGAM®
IMMUNE GLOBULIN INTRAVENOUS (HUMAN), 10% LIQUID

BY YOUR SIDE

Indication

BIVIGAM® is an Immune Globulin Intravenous (Human), 10% Liquid, indicated for the treatment of patients with primary humoral immunodeficiency (PI). This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency (CVID), X linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies (SCID).

Important Safety Information for BIVIGAM®

WARNING: THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE

See full prescribing information for complete boxed warning.

Thrombosis may occur with immune globulin (IGIV) products, including BIVIGAM®. 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.

Use of immune globulin intravenous (IGIV) products, particularly those containing sucrose, has been reported to be associated with renal dysfunction, acute renal failure, osmotic nephrosis, and death. Patients at risk of acute renal failure include those with any degree of pre-existing renal insufficiency, diabetes mellitus, advanced age (above 65 years of age), volume depletion, sepsis, paraproteinemia, or receiving known nephrotoxic drugs.

Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. BIVIGAM does not contain sucrose.

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

For additional safety information about BIVIGAM, please see full prescribing information.

Contraindications

BIVIGAM® is contraindicated in:

- Patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin.
- IgA deficiency patients with antibodies to IgA and a history of hypersensitivity.

Warnings and Precautions

Thrombosis may occur following treatment with immune globulin (IGIV) products, including BIVIGAM. Thrombosis may occur in the absence of known risk factors. Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity and ensure adequate hydration before administration. For patients at risk of thrombosis, administer BIVIGAM at the minimum dose and infusion rate practicable. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Severe hypersensitivity reactions may occur with IGIV products, including BIVIGAM. In case of hypersensitivity, discontinue BIVIGAM infusion immediately and institute appropriate treatment. Medications such as epinephrine should be available for treatment of acute hypersensitivity reactions. Patients with known antibodies to IgA may have a greater risk of developing potentially severe hypersensitivity and anaphylactic reactions.

Acute renal dysfunction/failure, osmotic nephrosis, and death may occur upon use of human IGIV products. Ensure that patients are not volume depleted before administering BIVIGAM. 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 blood urea nitrogen (BUN) and serum creatinine, before the initial infusion of BIVIGAM and at appropriate intervals thereafter. If renal function deteriorates, consider discontinuing BIVIGAM. In at risk patients, administer BIVIGAM at the minimum infusion rate practicable.

Hyperproteinemia, increased serum viscosity, and hyponatremia may occur in patients receiving IGIV treatment, including BIVIGAM. It is critical to clinically distinguish true hyponatremia from a pseudohyponatremia that is associated with or causally related to hyperproteinemia. 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 thrombotic events.

Aseptic meningitis syndrome (AMS) may occur with IGIV treatments, including BIVIGAM. AMS usually begins within several hours to 2 days following IGIV treatment. AMS may occur more frequently in association with high doses (2 g/kg) and/or rapid infusion of IGIV. Conduct a thorough neurological examination on patients exhibiting signs and symptoms of AMS, including cerebrospinal fluid (CSF) studies, to rule out other causes of meningitis.

IGIV products, including BIVIGAM, may contain blood group antibodies that can act as hemolysins and induce in vivo coating of red blood cells (RBCs) with immunoglobulin, causing a positive direct antiglobulin reaction and, rarely, hemolysis. Monitor patients for clinical signs and symptoms of hemolysis, including appropriate confirmatory laboratory testing.

Noncardiogenic pulmonary edema may occur in patients following IGIV treatment, including BIVIGAM. Transfusion-Related Acute Lung Injury (TRALI) is characterized by severe respiratory distress, pulmonary edema, hypoxemia, normal left ventricular function, and fever. Symptoms typically appear within 1 to 6 hours following treatment. Monitor patients for pulmonary adverse reactions. If TRALI is suspected, perform appropriate tests for the presence of anti-neutrophil antibodies in both the product and the patient's serum. TRALI may be managed using oxygen therapy with adequate ventilatory support.

Because BIVIGAM is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent. All infections suspected by a physician to possibly have been transmitted by this product should be reported to ADMA Biologics at 1-800-458-4244.

After infusion of immunoglobulin, 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. Passive transmission of antibodies to erythrocyte antigens (e.g., A, B, and D) may cause a positive direct or indirect antiglobulin (Coombs') test.

Adverse Reactions

Serious adverse reactions observed in clinical trial subjects receiving BIVIGAM were vomiting and dehydration in one subject.

The most common adverse reactions to BIVIGAM (≥5% of clinical study subjects) were headache, fatigue, infusion site reaction, nausea, sinusitis, increased blood pressure, diarrhea, dizziness, and lethargy.

You are encouraged to report side effects of prescription drugs to ADMA Biologics @ 1-800-458-4244 or the FDA. Visit www.fda.gov/MedWatch or call 1-800-FDA-1088.

Please see accompanying full Prescribing Information enclosed in this kit, including Boxed Warning.

ADMA BIOLOGICS

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