BIVIGAM [Immune Globulin Intravenous (Human), 10% Liquid] is indicated for the treatment of primary humoral immunodeficiency (PI).

**Step 1**
Be sure to use aseptic technique when preparing and infusing BIVIGAM.

**Step 2**
Remove the BIVIGAM vial(s) needed for the infusion from the refrigerator and allow them to reach room temperature.

**Step 3**
Set up a clean work area and gather all supplies necessary for the intravenous infusion, including vial(s) of BIVIGAM, the infusion set, and ancillary supply.

**Step 4**
Remove the infusion set with a standard spike from the sterile plastic foil.

**Step 5**
Take the vial(s) out of the package and remove the protective cap to expose the center of the vial.

**Step 6**
Wipe the stopper with an alcohol pad and allow it to dry.

**Step 7**
It is necessary to precisely enter the stopper in the middle of the bull’s-eye. Outside of the bull’s-eye, the rubber is thicker, which makes it more difficult to enter the vial.

**Step 8**
Position the infusion set with the standard spike at a 90° angle to the rubber stopper and push directly into the bull’s-eye at the top of the stopper while holding and securing the vial.

**Step 9**
Apply low-to-moderate pressure to the spike to enter the rubber stopper, followed by steady pressure to ensure complete full entry through the bull’s-eye area.

**Step 10**
Repeat each of these steps for every vial.

Customer support is available by calling medical affairs at 1-800-458-4244, prompt 2.

Please see BIVIGAM Important Safety Information on back and full Prescribing Information in pocket, including black box safety warnings, contraindications, and dosing.
Important Safety Information

BIVIGAM® [Immune Globulin Intravenous (Human), 10% Liquid] is indicated for the treatment of 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.

Warning: Thrombosis may occur with immune globulin intravenous (IGIV) products, including BIVIGAM. Risk factors may include advanced age, prolonged immobilization, hypercoagulable conditions, a history of venous or arterial thrombosis, the use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors. Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with the administration of Immune Globulin Intravenous (Human) (IGIV) products in predisposed patients. 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 recommended and infusion rate practicable. Ensure adequate hydration in patients before administrations. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for viscosity.

See full Prescribing Information for complete boxed warning.

BIVIGAM is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin and in IgA-deficient patients with antibodies to IgA and a history of hypersensitivity.

Hyperproteinemia, increased serum viscosity, and hyponatremia or pseudohyponatremia can occur in patients receiving IGIV therapy.

Aseptic meningitis syndrome (AMS) has been reported with IGIV treatments; AMS may occur more frequently in association with high doses (2 g/kg) and/or rapid infusion of IGIV.

As hemolysis can develop subsequent to treatment with IGIV products, monitor patients for hemolysis and hemolytic anemia.

Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]). If TRALI is suspected, test the product and patient for antineutrophil antibodies.

Because BIVIGAM is made from human blood, it may carry a risk of transmitting infectious agents, eg, viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Serious adverse reactions observed in clinical trial subjects receiving BIVIGAM were vomiting and dehydration in one subject. The most common adverse reactions to BIVIGAM (reported in ≥5% of clinical study subjects) were headache, fatigue, infusion site reaction, nausea, sinusitis, blood pressure increase, diarrhea, dizziness, and lethargy.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. For more information about BIVIGAM, please see full Prescribing Information in pocket.