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Dosage and Administration

Intravenous use only

- Recommended dose is 1.0 mL (50 mg/kg) given as a single intravenous infusion (2).
- Reconstitute in 2 mL Sterile Water for Injection USP and inject infusion within 2 hours of reconstitution (2).

- Administer BabyBIG through a separate intravenous line (2).

- Begin infusion slowly (0.5 mL/h); no more than 30 minutes to increase rate to 1.0 mL/h (2.2, 2.3).

- DO NOT EXCEED THE RECOMMENDED DOSE, CONCENTRATION, AND RATE OF INFUSION (2).

Dose Forms and Strengths

- Single-use vial of 10 mL (50 mg/kg lyophilized IgA) (2).
- Reconstitution as directed in a BabyBIG solution concentration of 50 mg/mL (2.1).

Warnings and Precautions

- Assess renal function prior to and following administration (5).
- Anaphylaxis and anaphylactoid reactions may occur (5).

- This risk should be considered when an IgA-deficient patient is to receive subsequent administration of blood products containing IgA after previous treatment with BabyBIG (4).

- Hypersensitivity, increased serum viscosity and hypoglycemia may occur in patients receiving immune globulin intravenous (human) (IGIV) therapy (5).

- Thrombotic events have occurred in patients receiving IGIV products. Monitor patients with known risk factors for thrombotic events; consider baseline assessment of blood viscosity for those at risk of hyperviscosity (5).

- Hemolytic anemia can develop subsequent to IGIV therapy due to enhanced RBC sequestration (5.6).

- IGIV recipients should be monitored for pulmonary adverse reactions, such as Transfusion-Related Acute Lung Injury (TRALI) (5.9).

- Anaphylactoid syndrome (AMS) has been reported with other IGIV treatment (5).

- Infusion reactions, including fever, chills, hypertension, pleural effusion, and malaise, have been observed (5).

- The product is made from human plasma and may contain infectious agents, e.g., viruses and, theoretically, the Creutzfeldt-Jakob disease agent (5).

Adverse Reactions

The most common adverse reactions occurring in at least 5% of the patients treated with BabyBIG in a controlled clinical study was mild and transient erythrocythema rash of the face or trunk (5).

To report SUSPECTED ADVERSE REACTIONS, contact the California Department of Public Health at 1-800-231-6600 and http://www.infantbig.org/ or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Drug Interactions

The presence of antihistamines may result in increased response to live viral vaccines (7).

Use in Specific Populations

- For use only in patients below one year of age (8.4).

- Renal impairment: Administer at minimum concentration and rate of infusion (2.3).

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Dosage and Administration

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Dose Forms and Strengths

- Single-use vial of 10 mL (50 mg/kg lyophilized IgA) (2).
- Reconstitution as directed in a BabyBIG solution concentration of 50 mg/mL (2.1).

Warnings and Precautions

- Assess renal function prior to and following administration (5.1, 5.2).
- Anaphylaxis and anaphylactoid reactions may occur (5.4).

- This risk should be considered when an IgA-deficient patient is to receive subsequent administration of blood products containing IgA after previous treatment with BabyBIG (4).

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Drug Interactions

The presence of antihistamines may result in increased response to live viral vaccines (7).

Use in Specific Populations

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- Renal impairment: Administer at minimum concentration and rate of infusion (2.3).

*Sections or subsections omitted from the full prescriptive information are not listed.

5.5 Aseptic Meningitis Syndrome

- Only administer BabyBIG as an intravenous infusion, since other routes of administration have not been evaluated. Do not use BabyBIG if the reconstituted solution is turbid (see DOSAGE AND ADMINISTRATION (2.1)).

5.1 Patient Monitoring for Administration

- Patients should be monitored at least one hour after the initiation of the BabyBIG infusion.

- Assess renal function, including the measurement of blood urea nitrogen (BUN) or serum creatinine (SCr), or both, and the infusion schedule and dose at the time of administration to the minimum rate of infusion practicable.

- Do NOT EXCEED THE RECOMMENDED INFUSION RATE of 1 mL/hour (50 mg/hp), and do not start the infusion schedule and dose closer than one day to two following other treatments with IV IGIV products.

- During administration, monitor the patient’s vital signs consistently and observe the infusion site carefully for any associated symptoms.

5.2 Renal Adverse Reactions

- If any adverse reaction is reported to be associated with renal dysfunction, acute renal failure, renal insufficiency, and in-patients judged to be at increased risk of developing renal insufficiency (including, but not limited to, those with diabetes mellitus, volume depletion, paraproteinemias, or whose renal function are impaired by nephrotic drugs) (see WARNINGS AND PRECAUTIONS (5)).

- To prevent the transmission of hepatic viruses or other infectious agents from one person to another, use sterile disposable syringes and needles. Never reuse syringes and needles.

5.3 Transfusion-Related Acute Lung Injury (TRALI)

- Do not pre-dilute BabyBIG before infusion.

- Begin infusion within 2 hours after reconstitution is complete and within 4 hours of reconstitution, unless infusion is temporarily interrupted for adverse reaction.

- Monitor vital signs continuously during infusion.

- Administer BabyBIG intravenously using only tube volume and a constant infusion pump (i.e., an IV pump or equivalent) through a separate intravenous line. If a separate line is not available, it may be “bypiped” into a pre-existing line if that line contains either Sodium Chloride Injection USP or one of the following dextrose solutions (with or without NaCl added): 2.5% dextrose in water, 5% dextrose in water, 10% dextrose in water or 20% dextrose in water. If a pre-existing line must be used, do not dilute BabyBIG more than 1:2 with any of the above-named solutions. Use an in-line or syringe-tip sterile, disposable filter (18) for the administration of BabyBIG.

- In the presence of prospective data allowing identification of the maximum safe dose, concentration, and rate of infusion in these patients, DO NOT EXCEED THE RECOMMENDED DOSE, CONCENTRATION, AND RATE OF INFUSION.
OVERDOSAGE

Although limited data are available, clinical experience with other immunoglobulin preparations suggests that the major manifestations would be those related to volume overload.

11 DESCRIPTION

BabyBIG, Botulism Immune Globulin Intravenous (Human) (BIG-IV), is a solution of purified human immunoglobulin derived from BPI-processed plasma of immunoglobulin G (IgG), stabilized with 5% sucrose and 1% albumin (human). It contains no preservatives. The purified immunoglobulin is derived from pooled adult plasma from persons who were unvaccinated against botulinum toxin, or 10 ml of single-dose human anti-toxin and selected for their high titer of neutralizing antibody against botulinum neurotoxin type A and B. Its dosage was tested and their sera found to be negative for antibodies against the human immunodeficiency virus and the hepatitis B and hepatitis C viruses.

The pooled plasma was fractionated by cold ethanol precipitation of the proteins according to the Cohn/Oxycryl method, modified to yield a product suitable for intravenous administration.6-10 Several steps in the manufacturing process have been validated for their ability to inactivate or remove viruses that may not have been detected in the Source Plasma analysis.

These include Cohn/Oxycryl fractionation (Fraction I through Supernate B filtrate); naphthalene precipitation through 25-35 cm filters; and solvent/detergent viral inactivation. These viral reduction steps have been validated in a series of in vitro experiments for their capacity to inactivate and/or remove Human Immunodeficiency Virus type 1 (HIV-1) and the following human viral model viruses: bovine viral diarrhea virus (BVDV) as a model for hepatitis C virus, mouse scrapieprion virus (MVM) as a model for hepatitis A virus, and porcine and/or vesicular exanthem swine virus (VESV) and Sindbis virus to cover a wide range of physiochemical properties in the model virus studies. Total mean log reductions range from 4.63 to greater than 16 log10, as shown in the following table.

Inactivated viruses have been shown to be non-infectious in vitro or in vivo.6-10 This is consistent with the observation that the activity of biological agents inactivated by deactivizing processes is not transmitted by the product. Therefore, all biological agents that are not transmitted by the product shall not be expected to be transmitted by this product.

7 DRUG INTERACTIONS

• Admixture of BabyBIG with other drugs has not been evaluated. It is recommended that any drugs administered concurrently with BabyBIG administration should be compatible with intravenous administration. The patient should be observed for any adverse reactions.

8 USE IN SPECIFIC POPULATIONS

8.4 Pediatric Use

BabyBIG has been studied for safety and efficacy only in patients below one year of age. There are no adequate and well-controlled studies in children. Therefore, use in children is not recommended.

BabyBIG administration should be carefully monitored in patients with impaired renal function.

10 Length of hospital stay was also analyzed by patient age in both the adequate and well-controlled study and in an open label study.

11 REFERENCES


