Hemolytic anemia can develop subsequent to IGIV therapy due to enhanced RBC face or trunk (6.1).

Revised: [10/2011]

• Single-use vial of 100 mg ± 20 mg lyophilized immunoglobulin (3)

• (2)

Intravenous use only

• Anaphylaxis and hypersensitivity 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. (4.2)

• BabyBIG is made from human plasma and, like other plasma products, carries the possibility for transmission of blood-borne viral agents and, theoretically, the possibility for transmission of other agents. Despite these measures, some as yet unrecognized blood-borne infectious agents may not be inactivated by the manufacturing process. Therefore, BabyBIG, like any other blood product, should be given only if it is expected to be safe (see PATIENT COUNSELING INFORMATION (17)).

• As with other immunoglobulin preparations, BabyBIG should not be used in individuals with a prior history of severe reaction to other human immunoglobulin preparations. (5.4)

• Due to the risk of developing antibodies to immunoglobulin A and could have anaphylactic reactions to the subsequent administration of products that contain immunoglobulin A.

5.5 Aseptic Meningitis Syndrome

Aseptic Meningitis Syndrome has been reported to occur infrequently in patients who received IGIV therapy due to the high frequency of treatment-associated fever. (6.1)

• As adverse reactions experienced by patients treated with immune globulin intravenous (IgIV) products have been related to the infusion rate, if the patient develops a minor side effect (i.e., flushing), slow the rate of infusion or temporarily interrupt the infusion. If anaphylaxis or a significant drop in blood pressure occurs, discontinue the infusion and administer epinephrine.

3 DOSAGE FORMS AND STRENGTHS

• 100 mg ± 20 mg lyophilized immunoglobulin per single-dose vial

4 CONTRAINDICATIONS

• 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)).

1 Patient Monitoring for Administration

• Patients should be observed for 2 hours after the initiation of the BabyBIG infusion.

• Assess renal function prior to the initial administration of the BabyBIG infusion.

• In clinical trials, the following adverse reactions were observed in at least 5% of the patients treated with BabyBIG in a controlled clinical study was mild and transient erythrocytosis rash of the face or trunk (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact the California Department of Public Health at 1-800-233-4000 or by visiting their website (http://www.fda.gov/medwatch) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

2 DRUG INTERACTIONS

• The passive transfer of antibodies may interfere with the response to live viral vaccines (7.3).

3 USE IN SPECIFIC POPULATIONS

• For use only in patients below 18 years of age.

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

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4 ADVERSE REACTIONS

5 WARNINGS AND PRECAUTIONS

6 Adverse Reactions

7 Drug Interactions

8 Use In Specific Populations

9 Dosage And Administration For Intravenous Use Only

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8 USE IN SPECIFIC POPULATIONS

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6.1 Postmarketing Experience

Because postmarketing reporting of adverse reactions is voluntary and from a population of uncertain size, it is not always possible to reliably estimate the frequency of these reactions or establish a causal relationship to product exposure.

Experience with BabyBIG. No adverse reactions have been identified or reported that are the result of the use of BabyBIG during postapproval. Retrospective publications have shown safety-related information consistent with the safety-related information in the approved product labeling, and no new safety-related information has been presented for BabyBIG.15,16

Experience with Other IGIV Products. Some classes of adverse reactions that have not been reported in any of the other IGIV products or postmarketing experience have been observed in the overall post-approval use of other IGIV products, as shown in the following table.