## Botulism Immune Globulin Intravenous (Human) – Baby BIG®

### Biological Product Information

<table>
<thead>
<tr>
<th>Standard #</th>
<th>07.201</th>
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<tbody>
<tr>
<td>Created by</td>
<td>Province-wide Immunization Program Standards and Quality</td>
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<tr>
<td>Approved by</td>
<td>Province-wide Immunization Program Standards and Quality</td>
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<tr>
<td>Approval Date</td>
<td>July 18, 2014</td>
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<tr>
<td>Revised</td>
<td>February 1, 2016</td>
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### Biological Page

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Cangene Corporation</th>
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<td>Biological Classification</td>
<td>Immune Globulin</td>
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### Indications for Provincially Funded Vaccine

**Treatment of botulism caused by toxin types A or B in infants under 1 year of age** – administer as soon as clinical diagnosis of infant botulism is made.
- Eligibility will be determined though discussion amongst the treating physician, the zone Medical Officer of Health (MOH) and Alberta Health Chief Medical Officer of Health as per the [Process for the Approval and Release of Botulism Immune Globulin Intravenous (Human) - BabyBIG®](#).

For further information about the disease and reporting requirements refer to the [Alberta Health Public Health Notifiable Disease Management Guidelines – Botulism](#).

### Serology

Blood should be collected to identify the specific toxin before antitoxin is administered; however the administration of the antitoxin should not be withheld pending the test results (refer to the [Alberta Health Public Health Notifiable Disease Management Guidelines – Botulism](#)).

### Schedule

**Treatment:**
Initiate infusion within two hours of reconstitution through a separate IV line. Begin infusion slowly (0.5mL/kg/h); if no untoward reaction within 15 minutes, increase rate to 1.0 mL/kg/h

**Note:**
- Refer to product monograph for patient monitoring for administration.

### Preferred Use

N/A

### Dose

1.5 mL/kg

Refer to schedule section above and product prescribing information for rate of infusion.

**Note:**
- Botulism antitoxin is supplied in single use dose vial containing 100 mg lyophilized immunoglobulin with a 2 mL vial of sterile water for reconstitution
- This is a treatment product administered under the direction of a physician in an acute care setting.

### Route

- Intravenous infusion
  - Refer to product prescribing information

### Contraindications/Precautions

**Contraindications:**
- None as this is a vital indication due to life-threatening condition.
### Botulism Immune Globulin Intravenous (Human) – Baby BIg

**Precautions:**
- Administer with caution to individuals with a history of prior systemic allergic reactions following the administration of human immune globulin preparations.
- Individuals with IgA deficiency have increased potential for developing antibodies to IgA and could have anaphylactic reactions to subsequent administration of blood products that contain IgA.
- BabyBIG® is made from human plasma. Products made from human plasma may contain infectious agents that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, testing for the presence of certain current viral infections and inactivating and/or removing certain viruses. Despite these measures, such products can still potentially transmit disease.

**Possible Reactions**
Serious adverse reactions were not observed in clinical trials using Baby BIg.
- The most common adverse reaction observed was a skin rash.
- Other reactions such as chills, muscle cramps, back pain, fever, nausea, vomiting and wheezing were the most frequent reactions observed during the clinical trials.
- As with any immunization, unexpected or unusual side effects can occur. Refer to the product prescribing information for more detailed information of possible reactions and recommendations for management of those reactions.

**Pregnancy**
- Not applicable

**Lactation**
- Not applicable

### Composition
- **Each 1 mL contains:**
  - 15 I.U. Type A botulism antitoxin
  - 2.7 I.U. Type B botulism antitoxin
  - Sucrose
  - Human albumin
  - Sodium
  - Sterile water for reconstitution

**Blood/Blood Products**
- Made from pooled adult plasma from individuals who were immunized with pentavalent botulinum toxoid

**Bovine/Porcine Products**
- None listed in ingredient list

**Latex**
- None listed in ingredient list

**Interchangeability**
- N/A

**Administration with Other Products**
- Administer separately from other drugs or medications.
  - The passive transfer of antibodies may interfere with the response to live viral vaccines. Consult zone MOH if live vaccine is indicated following administration of Baby BIg.

**Appearance**
- Reconstituted product should be colorless and translucent.

**Storage**
- Store at +2°C to +8°C.
- Once reconstituted use within 2 hours.
**Botulism Immune Globulin Intravenous (Human) – Baby Blg**

- Do not freeze.
- Do not use beyond the labeled expiry date.
- Store in original packaging when possible to protect from light.

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<tr>
<th>Vaccine Code</th>
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<tr>
<td>Antigen Code</td>
<td>BAIG</td>
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**Licensed for**

Botulism immune globulin intravenous is not approved for sale in Canada and is currently only available via Health Canada’s Special Access Program (SAP).

**Notes:**

**Related Resources:**

- Botulism Immune Globulin (Baby Blg) Information Sheet (October 7, 2014).
- Process for the [Approval and Release of Botulism Immune Globulin Intravenous (Human) - BabyBIG®](#)

**References:**


