

Botulism Immune Globulin Intravenous (Human)- BabyBIG® Biological Page

Section 7:	Biological Product Information	Standard #: 07.201
Created by:	Province-wide Immunization Program Standards and Quality	
Approved by:	Province-wide Immunization Program Standards and Quality	
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Botulism Immune Globulin Intravenous (Human) – BabyBIG®	
Manufacturer	Baxalta Inc. and Cangene bioPharma Inc. distributed by FFF Enterprises for Infant Botulism Treatment and Prevention Program, California Department of Public Health
Biological Classification	Immune Globulin
Indications for Provincially Funded Vaccine	<p>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.</p> <p>Eligibility must be approved and accessed via the Zone Medical Officer of Health (MOH) as per the Alberta Health Public Health Notifiable Disease Management Guidelines – Botulism.</p> <p>For further information about the disease and reporting requirements refer to the Alberta Health Public Health Notifiable Disease Management Guidelines – Botulism.</p>
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	Refer to Product Prescribing Information
Preferred Use	N/A
Dose	Refer to Product Prescribing Information
Route	<ul style="list-style-type: none"> • Intravenous infusion • Refer to Product Prescribing Information
Contraindications/Precautions	<p>Contraindications:</p> <ul style="list-style-type: none"> • Refer to Product Prescribing Information <p>Precautions:</p> <ul style="list-style-type: none"> • Refer to Product Prescribing Information • 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. <ul style="list-style-type: none"> ○ A signed <i>Consent for Treatment/Procedure</i> is required before administering immune globulin products: http://www.albertahealthservices.ca/frm-09741.pdf.

Botulism Immune Globulin Intravenous (Human) – BabyBIG®	
Possible Reactions	Refer to Product Prescribing Information
Pregnancy	N/A
Lactation	N/A
Composition	Refer to Product Prescribing Information
Blood/Blood Products	Made from pooled adult plasma from individuals who were immunized with recombinant botulinum vaccine for serotypes A and B.
Bovine/Porcine Products	None listed in ingredient list
Latex	None listed in ingredient list
Interchangeability	N/A
Administration with Other Products	<ul style="list-style-type: none"> 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 BabyBIG®.
Appearance	Refer to Product Prescribing Information
Storage	<ul style="list-style-type: none"> Store at +2°C to +8°C. Once reconstituted use within 2 hours. Do not freeze. Do not use beyond the labeled expiry date. Store in original packaging when possible to protect from light.
Vaccine Code	BAIg
Antigen Code	BAIG
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).
Related Resources:	
<ul style="list-style-type: none"> Botulism Immune Globulin (BabyBIG®) Information Sheet Alberta Health Public Health Notifiable Disease Management Guidelines – Botulism 	
References:	
<ol style="list-style-type: none"> Alberta Health, Public Health and Complicance Division. Alberta Immunization Policy Biological Products (2018, Sept 17). <i>Botulism Immune Globulin Intravenous (Human) - BabyBIG®</i>. Alberta Health. (2019, August). Public Health Notifiable Disease Management Guidelines. <i>Botulism</i>. American Academy of Pediatrics. (2015). <i>Red Book: 2015 Report of the Committee on Infectious Diseases</i>. Elk Grove, IL: American Academy of Pediatrics. California Department of Public Health. (2015, September). <i>Botulism Immune Globulin and Intravenous (Human) - BabyBIG</i>. Infant Botulism Treatment and Prevention Program. http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/ucm089339.htm. 	