Botulism Antitoxin Heptavalent (Equine) Type A, B, C, D, E, F and G

BIOLOGICAL PAGE

Alberta Health Services
Communicable Disease Control

Section 7	Biological Product Information	**Standard # 07.200**	
Created and approved by	Provincial Immunization Program Standards and Quality		
Approval date	January 1, 2017	**Revised**	November 20, 2024

	Botulism Antitoxin Heptavalent (Equine) Types A, B, C, D, E, F and G
Manufacturer	Emergent BioSolutions Canada Inc.
Classification	Antitoxin
Authorization and Access	**Follow special authorization and access procedures:** • Notify the Office of the Chief Medical Officer of Health (OCMOH) by the fastest means possible of all cases for which botulism antitoxin is required. ○ Available on a 24-hour basis from Alberta Health by calling OCMOH pager: 780-638-3630.
Indications for Provincially Funded Vaccine	**Adult, pediatric and infant treatment of botulism** – suspected or confirmed (administer immediately on suspicion of botulism - do not delay treatment waiting for lengthy clinical observations or confirmatory lab results). • Eligibility is determined through discussion amongst the treating physician, the zone Medical Officer of Health (MOH) and Alberta Health Chief Medical Officer of Health. ○ Once eligibility has been determined, OCMOH will authorize release of the product through either the Provincial Vaccine Depot or the Alberta Health Services (AHS) Calgary Vaccine Depot. It is not routinely stocked outside of these 2 sites. • For further information about the disease and reporting requirements refer to the Alberta Public Health Disease Management Guidelines: Botulism.
Serology	Collect blood (serum) to identify the specific toxin before antitoxin is administered. • Administer antitoxin right away. Do not wait for testing results (including lab confirmation). • Refer to the Alberta Public Health Disease Management Guidelines: Botulism.
Schedule	**Treatment:** • Infusion depends on age and weight. Refer to product monograph.
Preferred Use	N/A
Dose	Dose depends on age and weight. Refer to product monograph. **Note:** • This is a treatment product administered under the direction of a physician in an acute care setting.
Route	Slow IV infusion. Refer to product monograph.
Contraindications/ Precautions	**Contraindications:** • None. ○ This is a vital indication due to a life-threatening condition.

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	Precautions:
	• Use caution for individuals who have received previous therapy with an equine-derived antivenom/antitoxin, or have known allergies to horses, or have asthma or get hay fever (seasonal allergies).
	  ○ These individuals may be at increased risk of hypersensitivity reactions and should only receive BAT if the benefits outweigh the risks.
	  ○ Closely monitor during and following administration.
	• Administer BAT in a setting with appropriate equipment, medication, including epinephrine, and personnel trained in the management of hypersensitivity, anaphylaxis and shock.
	• Refer to product monograph.

Possible Reactions	**Common:** • Headache • Nausea • Pruritus • Urticaria • Fever • Chills • Rash • Edema. **Rare:** • Allergic reaction • Infusion reactions (including chills, fever, headaches, nausea and vomiting). Monitoring required. Refer to product monograph. • Serum sickness (fever, urticarial or maculopapular rash, myalgia, arthralgia and lymphadenopathy) may occur following botulism antitoxin administration typically 10-21 days after infusion. • Anaphylaxis • Unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information of possible reactions and recommendations for management of those reactions.
Pregnancy	Consult with the MOH. Decision to use during pregnancy is made on a case-by-case basis. • There are no human or animal data to establish the presence or absence of risk associated with heptavalent BAT. • Trivalent (A, B and E) BAT has been given to pregnant women without causing harm to mother or fetus. Weigh the benefit to the person who is pregnant and fetus from receiving heptavalent BAT for botulism against the risk of harm from the treatment.
Lactation	Consult with the MOH. Decision to use for people who are breast/chest feeding is made on a case-by-basis. • It is not known whether botulism antitoxin is excreted in human milk. • Exercise caution when using in a person who is breast/chest feeding.
Composition	**Each single use vial (regardless of size or fill volume) contains a minimum antitoxin potency of:** • Sterile solution of purified F(ab')2 plus F(ab')2-related immune globulin fragments derived from equine plasma, containing antitoxin activity to botulinum neurotoxins A, B, C, D, E, F, G • 4500 U serotype A antitoxin • 3300 U serotype B antitoxin • 3000 U serotype C antitoxin • 600 U serotype D antitoxin • 5100 U serotype E antitoxin

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	• 3000 U serotype F antitoxin
	• 600 U serotype G antitoxin
	• No preservative
	• Clinically relevant non-medicinal ingredients:
	  ○ 10% maltose
	  ○ 0.03% polysorbate 80.

Blood/Blood Products	Contains equine horse serum.
Bovine/Porcine Products	Does not contain bovine or porcine products.
Latex	Does not contain latex.
Interchangeability	N/A
Administration with Other Products	Must not be mixed with other medicinal products in a single container.
Appearance	Thawed product is a clear or slightly opalescent liquid, free of turbidity and foreign particles. • Visually inspect the product for particulate matter and discolouration prior to administration. • Do not use the solution if it is turbid or contains particles, other than a few translucent to white proteinaceous particulates.

Storage	**Storage:**
	Store product frozen at or below -15°C until used.
	Administration:
	1. Bring vial to room temperature prior to use.
	  ○ Thaw vial by placing in a refrigerator at +2°C to +8°C until the contents are thawed. This takes approximately 14 hours.
	  ○ Alternatively, thaw rapidly by placing at room temperature for one hour followed by a water bath at +37°C until thawed.
	  ○ Do not thaw this product in a microwave oven.
	  ○ Do not refreeze the vial.
	2. Once punctured, use the vial contents to prepare the infusion bag and administer as soon as possible.
	  ○ BAT vials are for single use only and contain no preservative.
	  ○ Refer to product monograph for infusion bag preparation.
	3. Discard any unused portion.
	Note:
	• If the product does not get used right away after it is thawed, store at +2°C to +8°C and contact the manufacturer for stability information.
	• The date of manufacture, lot number and expiry date are provided in the 'Certificate of Analysis' release letter which will be included with the product when it is shipped.
	• If clinician determines that product is not required, ship the unused product back to the Provincial Vaccine Depot or AHS Calgary Vaccine Depot.
	  ○ Ship under cold chain with at least twice daily documented storage temperatures. See the shipment package for further details.

Vaccine Code	BA
Antigen Code	BA
Licensed for	Botulism antitoxin is approved for sale in Canada and is currently only available via OCMOH approval and release.

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Notes	• Botulism antitoxin is made from equine plasma. It may carry the risk of transmitting infectious agents such as viruses. • The equine plasma pools are screened for the presence of certain infectious agents and the manufacturing process for botulism antitoxin includes measures to inactivate and remove certain viruses. Despite these measures these products can potentially transmit disease. • No cases of transmission of viral diseases have been associated with the use of botulism antitoxin. • Refer to product monograph. • 2018 September: special access program forms no longer required.
Related Resources	• Botulism Antitoxin Heptavalent (Equine) Type A, B, C, D, E, F and G Vaccine Information Sheet

References

Alberta Health. (2023 June 30). Botulism Antitoxin Heptavalent (Equine) Types A, B, C, D, E, F and G. In *Alberta Immunization Policy: Biological Products* (2023). Government of Alberta.

Alberta Health. (2023, August). Botulism. In *Alberta Public Health Disease Management Guidelines.* Government of Alberta.

Committee on Infectious Diseases, American Academy of Pediatrics. (2018). *Red book: 2018-2021 Report of the Committee on Infectious Disease (31st ed.)* American Academy of Pediatrics.

Emergent BioSolutions Canada Inc. (2020 November 17) BAT® Botulism Antitoxin Heptavalent (A, B, C, D, E. F, G) – (Equine). Health Canada drug product database. https://pdf.hres.ca/dpd_pm/00058874.PDF