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

Section 7:	**Biological Product Information**		**Standard #: 07.200**
Created by:	Provincial Immunization Program		
Approved by:	Provincial Immunization Program		
Approval Date:	January 1, 2017	**Revised:**	June 30, 2023

	Botulism Antitoxin Heptavalent (Equine) Types A, B, C, D, E, F and G
Manufacturer	Emergent BioSolutions Canada Inc.
Biological Classification	Antitoxin
Authorization and Access	**Special authorization and access procedures must be followed:** • The Office of the Chief Medical Officer of Health (OCMOH) must be notified 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 will be determined though discussion amongst the treating physician, the zone Medical Officer of Health (MOH) and Alberta Health Chief Medical Officer of Health.
	  ○ The zone MOH/MOH designate must notify the Office of the Chief Medical Officer of Health (OCMOH) by the fastest means possible of all cases in which botulism antitoxin is required.
	  ○ OCMOH is available on a 24 hour basis by pager at 780-638-3630.
	  ○ 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 two sites.
	For further information about the disease and reporting requirements refer to the Public Health Notifiable Disease Management Guidelines – Botulism

Serology	Blood (serum) 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 Public Health Notifiable Disease Management Guidelines – Botulism)
Schedule	**Treatment:** Infusion depends on age and weight. Refer to product monograph. https://emergentbiosolutions.com/sites/default/files/inline-files/BAT%20Product%20Monograph%20-%20English.pdf
Preferred Use	N/A
Dose	Dose depends on age and weight. Refer to product monograph. https://emergentbiosolutions.com/sites/default/files/inline-files/BAT%20Product%20Monograph%20-%20English.pdf **Note:** • This is a treatment product administered under the direction of a physician in an

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	acute care setting.
Route	Slow IV infusion. Refer to Product Monograph BAT Product Monograph (emergentbiosolutions.com)
Contraindications/ Precautions	**Contraindications:** • None as this is a vital indication due to life-threatening condition. **Precautions:** • 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) may be at increased risk of hypersensitivity reactions and should only receive BAT if the benefits outweigh the risks.[1] Individuals should be closely monitored 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 BAT Product Monograph (emergentbiosolutions.com)
Possible Reactions	**Common:** • Headache, nausea, pruritus and urticaria • Fever, chills, rash and 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 • As with any immunization, 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	• 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. The benefit to the mother and the fetus from receiving heptavalent BAT for botulism should be weighed against the risk of harm from the treatment; decisions should be made on a case-by-case basis.
Lactation	• It is not known whether botulism antitoxin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when botulism antitoxin is administered to a nursing mother. Botulism antitoxin heptavalent may be considered on a case-by-case basis.
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

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	• 5100 U serotype E antitoxin
	• 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	Equine horse serum
Bovine/Porcine Products	None listed in ingredient list
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	The product is to be stored frozen at or below -15°C until used.
	
	Administration:
	1. Bring vial to room temperature prior to use.
	  ○ If frozen, thaw vial by placing in a refrigerator at +2°C to +8°C until the contents are thawed for approximately 14 hours.
	  ○ Product can be thawed 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. BAT vials are for single use only and contain no preservative. Once punctured, use the vial contents to prepare the infusion bag and administer as soon as possible.
	3. Discard any unused portion.
	Refer to product monograph for product preparation of the infusion bag.
	
	Note: If the product does not get used right away after it is thawed it needs to be stored at +2°C to +8°C and the manufacturer should be contacted for stability information.
	
	Date of manufacture, Lot number and Expiry date: 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.
	
	Note: If after receiving the product, a clinician determines that it is not required, the unused product must be shipped back to the Provincial Vaccine Depot, preferably under cold chain with at least twice daily documented storage temperatures. See the shipment package for further details.

Vaccine Code	BA
Antigen Code	BA

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Licensed for	Botulism antitoxin is approved for sale in Canada and is currently only available via CMOH approval and release.

Program Notes

Botulism antitoxin is made from equine plasma; it may carry the risk of transmitting infectious agents, e.g., 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.

Related Resources

- September 2018 - special access program forms no longer required.
- **AHS-Imm-07.200-R01 (January 1, 2017)** Botulism Antitoxin Information Sheet

References

1. Alberta Health, Alberta Immunization Policy (2023 June 30). Botulism Antitoxin Heptavalent (Equine) Types A, B, C, D, E, F and G.
2. Alberta Health. Public Health Disease Management Guidelines - Botulism. In *Public Health Notifiable Disease Guidelines* https://open.alberta.ca/publications/botulism
3. American Academy of Pediatrics. (2018-2021). Red book: 2018-2021 Report of the Committee on Infectious Diseases (31st ed.) Elk Grove, IL: Author.
4. Emergent BioSolutions Canada Inc. (2020 November 17) BAT® Botulism Antitoxin Heptavalent (A, B, C, D, E. F, G) – (Equine). Product Information. https://pdf.hres.ca/dpd_pm/00058874.PDF