Botulism Antitoxin Heptavalent

(Equine) Types A, B, C, D, E, F, & G

Revision Date: June 30, 2023

Rationale for Update

- Updated to include information about returning product that is unused.

Please consult the Product Monograph[1] for further information about the vaccine.	
	Botulism Antitoxin – A, B, C, D, E, F, & G
Manufacturer	Emergent BioSolutions Canada Inc.
Authorization and access	Special authorization and access procedures must be followed: **Botulism Antitoxin** Heptavalent - types A, B, C, D, E, F, & G • 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 use of botulism antitoxins (equine)	**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)[1] For further information about the disease and reporting requirements refer to *Public Health Notifiable Disease Management Guidelines – Botulism*.[2]
Dose	Dose depends on age and weight. Refer to Product Monograph.[1] **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.[1]
Schedule	Treatment: Infusion depends on age and weight. Refer to Product Monograph [1].
Contraindications	None
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. Refer to Product Monograph.[1]
Possible reactions	**Common**: • Headache, nausea, pruritus, urticaria[1] • Fever, chills, rash, edema[1]

	Rare: • Hypersensitivity reactions/allergic reactions[1] • Delayed allergic reactions (serum sickness)[1] • Infusion reactions[1] **Post-Marketing surveillance**: • Hypersensitivity/allergic reactions[1] • Anaphylactic shock[1]
Pregnancy	There are no human or animal data to establish the presence or absence of risk associated with heptavalent BAT.[1] 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 BAT is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when BAT is administered to a nursing mother.[1] Botulism Antitoxin Heptavalent may considered on a case-by-case basis.
Storage and Administration	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 preparation of the infusion bag.[1] Note: If the product does not get used right away after it is thawed it needs to be stored at 2 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.

References

[1] 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

[2] Alberta Health . Botulism. In *Public Health Notifiable Disease Management Guidelines*. www.health.alberta.ca/professionals/notifiable-diseases-guide.html.