Botulism Antitoxin Heptavalent

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

Revision Date: November 27, 2018

Rationale for Update:

- Updated to incorporate revised product monograph.
- Incorporated requirements around storage/handling specific to this product.
- Special Access Program forms no longer required.

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)	**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] **Notes:** • Baby BIG® (Baby Botulism Immune Globulin) is the first-line therapy for naturally occurring infant botulism.[2] See Baby BIG®. • Botulism Antitoxin (BAT) Heptavalent is not generally recommended for infants younger than one year of age.[2] • Botulism Antitoxin Heptavalent may be considered for non-type A & B infant botulism, on a case-by-case basis.[2] For further information about the disease and reporting requirements refer to *Public Health Notifiable Disease Management Guidelines – Botulism*.[3]
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. Do not refreeze. Administration: Bring vial to room temperature prior to use. Refer to Product Monograph.[1] *Acceptable Temperature Deviation for BAT* If the product does not get used once it is thawed it needs to be stored at 2 to 8°C. The product remains viable when stored at 2 to 8°C as demonstrated by stability studies for a maximum of 38 months or until 48 months from the date of manufacture, whichever comes first.[4] **Note**: This does not imply or provide permission for the product to be **routinely** stored at 2 to 8°C.) Date of manufacture: The date of manufacture is provided in the 'Certificate of Analysis' release letter which will be included with the product when it is shipped.

References

[1] .Emergent BioSolutions Canada Inc. (2017, May 9). BAT® Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G) Equine. *Product Information*. https://emergentbiosolutions.com/sites/default/files/inline-files/BAT%20Product%20Monograph%20-%20English.pdf

[2] American Academy of Pediatrics. (2018-2021). *Red book: 2018-2021 Report of the Committee on Infectious Diseases* (~~30th~~ 31st ed.) Elk Grove, IL: Author.

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

[4] Emergent BioSolutions Canada Inc. (2018, October 31). Acceptable Temperature Deviation for Botulism Antitoxin (BAT).

