



MS_Prozesszuordnung PPT - Fachzentrum Pharmazie MS_Dok-Bez. BE-Betriebs-dok

Detail zur Dok-Art FORMULAR

Titel Factsheet zu BAT Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G)-(Equine) Sterile Solution for Injection

Freigabe der Vorlage (Master) im DVS:

Erstellt D. Guillet Prüfung und Freigabe F. Vrtic

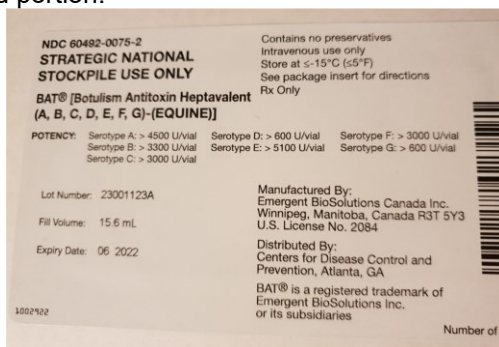
- ⇒ Dieses Factsheet basiert auf der Fachinformation zu BAT®
- ⇒ Ce Factsheet s'appuie sur les informations professionnelles de BAT®

Storage:

- Store frozen at or below ≤-15° C until used.
- Once thawed, Botulism Antitoxin Heptavalent may be stored at 2-8°C for a maximum of 36 months or until 48 month from the date of manufacture, whichever comes first. **Do not refreeze!**
- 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. Discard any unused portion.

Preparation:

1. **Bring vial to room temperature:**
If frozen, thaw vial by placing in a refrigerator at 2 to 8 °C until the contents are thawed for approxi-mately 14 hours. The 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. Inspect vial to ensure, there is no damage to the seal or vial. If damaged, discard the vial.
3. Do not shake the vial during preparation to avoid foaming.
4. Dilute 1:10 in 0.9% Sodium Chloride Injection by adding BAT solution from the vial to the appropriate amount of saline in an IV bag. Do not use any other diluents. As the fill volume per vial varies by lot number (approximately 10 to 26 milliliters per vial), 90 to 235 milliliters of saline will be required. Withdraw the entire contents of the vial to obtain the total volume in the vial. If a partial vial is required (for pediatric dosage), the entire content of the vial should be withdrawn to ensure accurate calculation of the dosage.
5. Visually inspect the product for particulate matter and discoloration prior to administration. Do not use if the solution is turbid, cloudy, or contains particles other than a few translucent-to-white proteinaceous particulates.
6. Use an intravenous line with constant infusion pump. Use a 15 micron sterile, non-pyrogenic, low protein binding in-line filter.
7. 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.
8. Discard any unused portion.



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