ATTENTION PHARMACISTS and PHYSICIANS

- Enclosed is a dosage of BabyBIG® per your order; this treatment is intended for administration to the patient named on the Invoice and Purchase Agreement (IPA) and may not be used for other purposes. If your treatment plan for the patient has changed, please notify the IBTPP immediately at 510-231-7600 (24/7).

- **BabyBIG® may not be returned for a refund**. Once the treatment dose is received, the full dose should be given to the patient for whom it was ordered without delay. The fee for BabyBIG® is per treatment (not per vial) and no portion may be returned for a refund.

- Promptly forward a copy of the completed IPA to the Accounts Payable Department of your institution so that they may arrange for fee payment. The fee is due within five (5) business days after ordering BabyBIG®.

Patient care:

- Ensure that the stool or enema specimen is promptly collected and sent to the appropriate testing laboratory for establishing the diagnosis of infant botulism. Refer to your state public health department/laboratory for specimen collection and submission information. Fecal specimens for infant botulism diagnostic testing can be collected before or after antitoxin administration. BabyBIG® does not neutralize botulinum toxin present in the lumen of the intestine, nor does it kill or prevent the growth of *Clostridium botulinum* or inhibit the formation of botulinum toxin in the infant's large intestine.
  - For California hospitals, please refer to our website www.infantbotulism.org under the "For Lab Scientists" link for specimen collection and submission instructions.
  - **Please note that the shipping costs for the diagnostic stool or enema specimen submission are the responsibility of your institution as specified in the IPA for BabyBIG®.**

BabyBIG® vials: If there is a suspect vial or remaining vial that was not reconstituted for administration, please:
1) immediately call the Program's 24/7 number 510-231-7600 and
2) ensure that the vial is held in a restricted-access, temperature-controlled, monitored refrigerator at 2-8°C.

Returning unused or residual BabyBIG: If possible, please save the insulated box that BabyBIG was shipped in, so that only vials which contain >0.5 mL of residual medicine or not reconstituted vials (if any) may be returned. Do not return empty vials or vials with less than 0.5 mL of product remaining. If questions, call during CDPH/IBTPP business hours: 8:00 a.m. - 5:00 p.m., Mon-Fri, Pacific Time.

- Following infusion: Residual BabyBIG ≤0.5 mL should be disposed of according to your hospital protocol. Vials containing >0.5 mL of BabyBIG may be returned in an insulated box using conditioned coldpacks to the address listed below via **standard overnight** courier:

  Infant Botulism Laboratory - IBTPP
  California Department of Public Health
  Specimen Receiving, Room B106
  850 Marina Bay Parkway
  Richmond, CA 94804
  Attn: IBTPP / 510-231-7600

BabyBIG general information:

- To learn more about the efficacy and history of BabyBIG®, please visit www.infantbotulism.org

Last updated: April 2021

BabyBIG® PREPARATION / ADMINISTRATION

- Enclosed is a single treatment dosage of BabyBIG®; this treatment is intended for administration to the patient for whom it was ordered and may not be used for other purposes. If your treatment plan for the patient has changed, please notify us immediately at 510-231-7600 (24/7).

- **BabyBIG® may not be returned for a refund**. Once the treatment dose is received, the full dose should be given to the patient for whom it was ordered without delay. The fee for BabyBIG® is per treatment (not per vial) and no portion may be returned for a refund.

BabyBIG Preparation:

- Upon receipt of the BabyBIG® medicine, all vials should be stored in a restricted-access, temperature-controlled, and monitored refrigerator at 2-8°C.

- Once I.V. access has been established and the patient is ready to receive the medicine the **pharmacist** should be notified to reconstitute the vials of lyophilized BabyBIG®. Please follow Sections 2.1 and 2.3 of the Package Insert regarding preparation and administration. Infusion must begin within two (2) hours of reconstitution. See www.infantbotulism.org for more information.

- After reconstitution, the **pharmacist** will draw up in a **20 mL syringe** (see page 1 of Hemo-Nate® Syringe Filter Instructions For Use brochure) the reconstituted product to total the full treatment volume and send the medicine to the floor/PICU along with the package-enclosed minimum volume tubing, 18-micron filter, BabyBIG® package insert, and Hemo-Nate® Syringe Filter Instructions For Use brochure.

BabyBIG Administration:

- Prior to administering the medicine, the **personnel responsible for administration** will obtain the necessary tubing, 18-micron filter, and Hemo-Nate® Syringe Filter Instructions For Use brochure which are included in the shipment. Review the Hemo-Nate® Syringe Filter Instruction For Use brochure for the proper method of infusion administration and prime the filter with saline solution. When attaching the tubing, filter and syringe, ensure the luer-lock connections are secure. Avoid overtightening the connections, which can result in cracking the filter hub. To avoid excessive pressure on the filter-tubing luer-lock connection during priming, please utilize a 20 mL syringe and slowly apply gentle pressure to administer the priming solution. The Hemo-Nate® Syringe Filter Instructions For Use brochure and the FDA-approved BabyBIG® package insert contain information on the proper syringe size and infusion administration instructions, respectively. If an incorrect syringe size is used, leakage from the filter may result.

- Administer the reconstituted BabyBIG® antitoxin according to the dosages (50 mg/kg) and flow rates specified in the FDA-approved package insert.

Product Description: The Hemo-Nate® filter is a small volume, disposable syringe filter having stainless steel filter media, bi-directional supported and bubble point tested for absolute retention and removal of harmful micro-debris (particulates) of 18 microns and larger that are present in AHF concentrates and cryoprecipitates. [1, 2, 3]

Indications For Use: For the filtration of stored blood, blood components and other fluids indicated for filtration. Infusion rates set by each individual hospital and /or physician's usual clinical procedures.

Important: Follow these instructions for aseptic technique.

Lot Numbers: Are demonstrated on lidding of each tray.

Contraindications: None Known (see precautions).

Cautions:
- Carefully read and follow all instructions prior to use.
- Federal (USA) law restricts this device to sale by or on the order of a physician.

Precautions:
- Intended for single patient use. Do not reuse or resterilize. Reuse of this sterile device poses a significant risk of cross contamination and sepsis and/or dependence on an unvalidated process. This device is not structurally designed or validated for reuse.
- **Sterile**, non-pyrogenic unless package is damaged or opened. Sterilized by Ethylene oxide. Examine the package carefully prior to opening to confirm sterility. If package is opened or damaged, do not use the device.
- Follow Universal Precautions.
- Peer group studies* have indicated no damage to cellular components in blood volumes up to 50cc (whole blood).
- **Excessive force may damage blood cells. If resistance is encountered, change filter and proceed. For infusion, use 20 cc syringe or larger.**
- Use of packed cells may limit volumes to about 20 cc.
- Age of blood and/or debris concentration per unit volume may have an effect of the capacity of the filter.

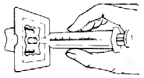
* Warren, et al, PERINATOLOGY-NEONATOLOGY Vol 4, No 5. P. 41 Sept/Oct 1980

For use with **Whole Blood and Packed Cells**

Instructions For Use (Aseptic Technique)

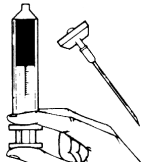
Note: With filter media bi-directionally supported, filtration can be effected in either direction - depending upon what is being filtered. It is recommended that fluids with cellular components be aspirated through the **Hemo-Nate** filter prior to infusion.

Spike container with Hemo-Tap® blood bag spike.



Place **Hemo-Nate** filter on syringe and 18 Ga. needle on male luer adaptor of filter.

Enter **Hemo-Tap** injection site and remove the desired amount of fluid.



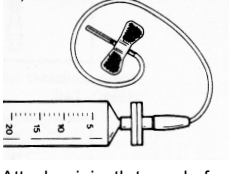
Withdraw from injection site, remove filter and needle and administer per standard clinical procedure.

For use with **AHF Concentrates/Cryoprecipitates**

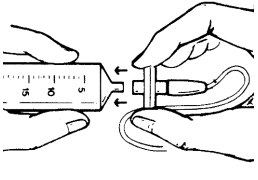
Instructions For Use

FOR AHF CONCENTRATES: Reconstitute the factor, fill the syringe or syringes and proceed as follows:

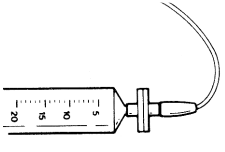
Attach **Hemo-Nate** filter to syringe filled with concentrate



Attach minicath to end of syringe. Infuse concentrate



Disconnect empty syringe from filter - press tubing against filter with thumb.



Attach next syringe of concentrate and continue infusing.

FOR CRYOPRECIPITATES: Employing the usual method of delivery, attach **Hemo-Nate** to distal end of administration set, proximal to patient, as a final filter. Attachment can be made either by a Luer-Slip or Luer-Lock.

NOTE: Due to the wide variations in viscosity of Cryoprecipitates, it is recommended that the **Hemo-Nate** be used in conjunction with a standard I.V. pump for administration rather than gravity flow. The use of a pump will also reduce infusion time and afford a much more accurate delivery.

References:

1. M.E. EYSTER, et al, TRANSFUSION, Sept-Oct 1978 Vol 18, No. 5
2. M.J. INWOOD, et al, TRANSFUSION, Nov-Dec 1978 Vol 18, No. 6
3. G.A. ROCK, et al, CANADIAN MEDICAL ASSOC JOUR., Feb. 15, 1983 Vol. 128

Procedure acknowledgment to Orthopedic Hospital, Hemophilia Rehab. Center, Los Angeles, CA.

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UTAH MEDICAL PRODUCTS INC.

Hemo-Nate® Syringe Filter

For Use With:

- **Whole Blood and Packed Cells**
- **AHF Concentrates Cryoprecipitates**

Instructions For Use