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Baxter

August 20, 2007

Dear Healthcare Professional:

We are writing to inform you that after careful consideration, Baxter Healthcare Corporation (Baxter) has decided to cease the manufacture and distribution of **Brevibloc Concentrate** (esmolol HCl) 250 mg/mL, 10 mL ampul (NDC 10019-025-18 for the pack and NDC 10019-025-73 for the ampul). Baxter intends to discontinue only the 250 mg/mL ampul due to a higher risk of medication errors that may potentially result in serious outcomes. This decision was made after thorough review of adverse event reports, clinical usage studies, input from clinicians, and in support of initiatives to reduce medication errors.

The **Brevibloc Concentrate 250 mg/mL ampul** will remain available through pharmacies and wholesalers until current supplies are depleted. The ampul remains safe and effective when used according to the package insert instructions. Careful dilution of the 250 mg/mL ampul is required prior to use. The majority of adverse events reported were the result of improper dilution and dosage of the **Brevibloc Concentrate 250 mg/mL ampul**. Despite warning flags, label changes, and other measures taken by Baxter to warn about the possibility of medication errors, errors continued to be reported.

Baxter will continue to manufacture and distribute **Brevibloc** product presentations in ready-to-use vials and premixed bags. These provide a safe, convenient alternative to the concentrate, while also meeting clinical needs. The available options are:

- Brevibloc Premixed Injection 2500 mg/250 mL (10 mg/mL) Ready To-Use Bag
- Brevibloc Premixed Double Strength Injection, 2000 mg/100 mL (20 mg/mL) Ready-To-Use Bag
- Brevibloc Injection, 100 mg/10 mL (10 mg/mL) Vial
- Brevibloc Double Strength Injection, 100 mg/5 mL (20 mg/mL) Vial

Patient safety has long been a priority for Baxter, and we continue to seek ways to help clinicians reduce the risk of medication errors. If you have any questions or concerns regarding the above action, please call our Professional Services Department at 1-800-ANA-DRUG (262-3784).

Sincerely,

Paula Dimopoulos, PharmD Senior Director, Medical Affairs

Baxter Anesthesia & Critical Care