

U.S. Food and Drug Administration

FDA Medical Bulletin * Summer 1997 * Volume 27 Number 2

MEDICATION ERRORS

Medication errors can be a source of significant morbidity and mortality in the health care setting. Therefore, it is important that medication errors be monitored so that similar incidents can be prevented in the future. Problems associated with devices that lead to medication errors should also be reported. FDA reviews each medication error report and, if warranted, takes appropriate action on labeling and packaging problems. In some cases, changing the design, name, or packaging of a product can help prevent medication errors.

Medication errors or potential errors may be reported in confidence to FDA's medWatch program (call 1-(800) FDA-1088 or fax the medWatch form to 1-(800) FDA-0178). When reporting a medication error to medWatch, the "Product Problem" portion of the form should be completed with a description of the packaging, labeling, or device problem. FDA knows that confidentiality is extremely important, especially in the area of reporting errors. Current federal regulations protect the identities of reporting individuals and institutions from disclosure.

Confusion with Brevibloc Injection Dosage Forms

Esmolol HCl (Brevibloc Injection) is available in dilute form for direct intravenous injection and concentrated form for preparation of intravenous infusion solutions. Despite the manufacturer's and FDA's warnings against confusing the two products, FDA continues to receive reports that the concentrated form is being injected directly, sometimes with fatal outcomes resulting from cardiac arrest and severe hypotension.

Esmolol HCl is indicated for the rapid control of ventricular rate in patients with atrial fibrillation or atrial flutter in the perioperative, postoperative, or other emergent circumstances when short-term control of ventricular rate with a short-acting agent is desirable. It is also indicated in noncompensatory sinus tachycardia when in the physician's judgment the rapid heart rate requires specific intervention and for the treatment of tachycardia and hypertension that occur during induction and tracheal intubation during surgery, on emergence from anesthesia, and in the postoperative period. Most esmolol HCl use occurs in the operating room, often under emergent circumstances.

Esmolol HCl is available in a 10 mg/mL, 10-mL vial (100 mg total) to be used for direct intravenous (IV) administration. This vial is used to administer an appropriate loading dose while the maintenance infusion is being prepared.

Esmolol HCl is also available in a 250 mg/mL, 10-mL ampul (2,500 mg total) to be used ONLY for the preparation of IV infusion solutions. Serious adverse events (and deaths) have occurred when the more concentrated product, intended ONLY for preparation of infusion solutions, was used instead of the less concentrated product intended for bolus doses, giving a 25-fold overdose. Causes of these errors include improper storage, (*e.g.*, the two dosage forms being stored in proximity), failure to read the label properly, and imprecise ordering by the prescribing physician (*e.g.*, ordering the product as 10 mL or 1 vial rather than 100 mg).

In 1995, in response to adverse events resulting from the mix-up of the two dosage forms of esmolol HCl, Ohmeda Pharmaceutical Products Division, in conjunction with FDA, instituted several labeling and packaging changes. The strength on the concentrated product marketed in an ampul was expressed in mg and grams, and the "Must Be Diluted" warning statement was boxed and printed in red ink. A red warning flag stating "MUST BE DILUTED" was also applied directly to the upper tip of the ampul bulb. The adhesive used for this sticker is such that the flag cannot be separated from the ampul without breaking off the bulb. (All ampuls currently in use should have the adhesive red flag

on them.) A "Dear Hospital Pharmacist and Health Care Professional" letter was issued in July 1995 warning the medical community of the potential infusion error and impending changes in labeling.

Despite the above measures, bolus use of the concentrated product continues to be reported. Ohmeda is currently evaluating ready-to-use formulations, including premixed infusion bags or Monovials (a system designed to transfer the contents of a vial directly into an IV bag) to replace the concentrated ampuls. Until such a change is made, however, practitioners must be aware of the importance of using the concentrated product properly (*i.e.*, as a dilute solution). Hospital pharmacists should ensure that all operating room personnel are instructed in the proper use of each dosage form. The concentrated ampul form of the drug should not be stored near the less concentrated form. Physicians who order the product must also be aware of the possibility of error. All doses should be ordered in mg (not mL), and the dose should be confirmed before administration.

REPORT SERIOUS ADVERSE EVENTS AND PRODUCT PROBLEMS TO MEDWATCH
1-800-FDA-1088

[Table of Contents](#) | [FDA Home Page](#) | [Search](#) | [A-Z Index](#) | [Site Map](#) | [Contact FDA](#)

FDA/Website Management Staff

U.S. Food and Drug Administration

FDA Medical Bulletin * June 1996 * Volume 26 Number 2

ALERT ON ESMOLOL (BREVIBLOC) INJECTION:

FDA has received reports of several deaths when the wrong concentration (2500 mg/10-mL) of BREVIBLOC (Esmolol Hydrochloride Injection) was administered. Two concentrations are available.

The **CONCENTRATE**, available in a 10-mL ampule containing 2500 mg (2.5 grams) of Esmolol, is intended for **DILUTION ONLY**. The product is also available in a 10-mL vial (100 mg) intended for direct bolus injection.

The manufacturer has changed the labeling of the ampule to include a red warning sticker on the neck. As an additional safety measure, we recommend that access to the ampule be restricted to personnel who normally prepare the solutions.

**REPORT SERIOUS ADVERSE EVENTS AND PRODUCT PROBLEMS TO MEDWATCH
1-800-FDA-1088**

[Return to Medication Errors](#)

[TABLE OF CONTENTS](#)

[FDA HOME PAGE](#)