

Patient Safety Alert

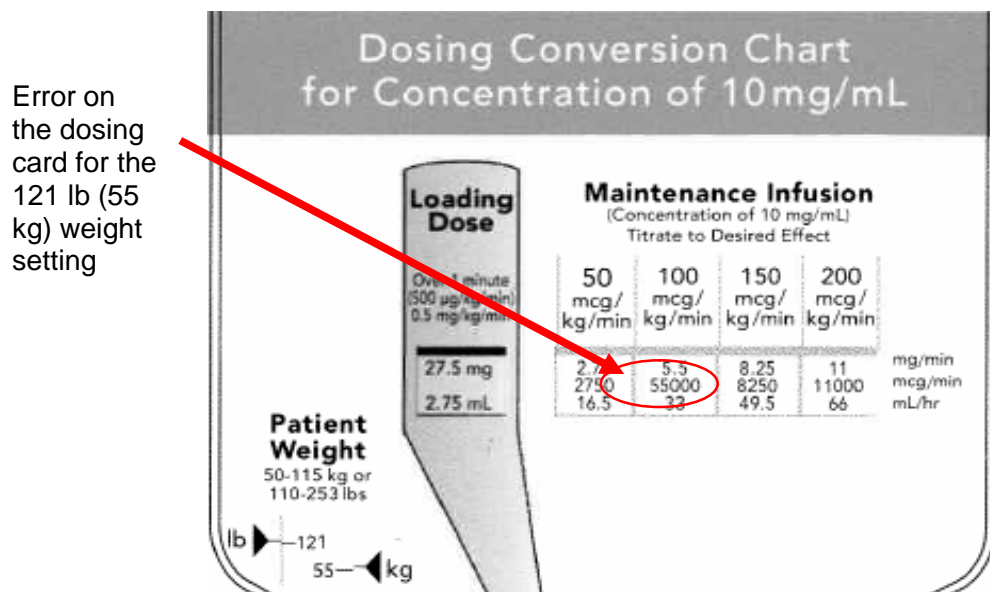
Veterans Health Administration Warning System
Published by VA Central Office

AL09-03

October 27, 2008

Item: Baxter Single Strength Dosing Card for BREVIBLOC Premixed Injection (esmolol HCl) 2,500 mg/250 mL (10 mg/mL) Ready-to-use-Bags, 250 mL bags

Specific Incident: There is an error in the 121 lb (55 kg) patient weight setting on the Single Strength Dosing Card for Baxter's BREVIBLOC Premixed Injection (esmolol HCl) 2,500 mg/250 mL (10 mg/mL) Ready-to-use-Bags, 250 mL bags. **The Maintenance Infusion listed under 100 mcg/kg/min for the mcg/min setting is listed as 55000 (see below); it should read 5500.** Baxter reports that the other rates listed on the dosing card are correct. The dosing cards were distributed to clinicians by Baxter pharmaceutical sales representatives.



Using the incorrect maintenance infusion value (55000 mcg/min) could cause a patient receiving the infusion to have an adverse clinical outcome. Baxter sent an Important Correction of Drug Information letter to Directors of Nursing and Directors of Pharmacy on August 27, 2008, to inform them of error within the dosing card.

Actions: By close of business November 3, 2008:

1. Chief Nursing Officer (or designee), Chief of Staff (or designee) and Chief of Pharmacy (or designee) will ensure that all nurses, physicians, and pharmacists, respectively, are informed of this Patient Safety Alert and that clinical departments under their management control locate

the incorrect dosing cards. The incorrect dosing cards can be identified by the product number **748762 4/07** on the back of the card as shown in the Attachment.

Note: Be sure to look in all areas where these cards may be located in your facility. These cards often find their way into pharmacists', physicians' or nurses' pockets and are often posted on desks or walls in areas such as, but not limited to, cath labs, critical care areas, emergency departments, operating rooms, pharmacy, post-anesthesia care units, and telemetry monitoring units.

2. **Under no circumstances may these dosing cards be used in their current form.** Nurses, physicians, pharmacists and department managers must either destroy or correct the incorrect dose cards.

Additional Information: There are currently no replacement dosing cards available from Baxter, and Baxter could not provide an estimated completion date when corrected dosing cards would be ready to be distributed. Clinicians may however contact their Baxter pharmaceutical sales representative to be put in the queue for a replacement card.

While correction of the dosing cards doesn't meet Baxter's recommendation, included in the Important Correction of Drug Information letter sent August 27, 2008, to Directors of Nursing and Directors of Pharmacy, to remove and destroy the affected BREVIBLOC Single Strength Dosing Cards, use of this corrected cognitive aid should improve patient safety compared to manually calculating doses (which clinicians would need to do if the cards were to be destroyed).

Source: Risk and Safety Management Alert System (RASMAS)

Attachment: Reverse side of the Single Strength Dosing Card for Baxter's BREVIBLOC Premixed Injection (esmolol HCl) 2,500 mg/250 mL (10 mg/mL) Ready-to-use-Bags, 250 mL bags, showing the product number of the incorrect cards

Contact: Product Inquiry at Baxter Healthcare Corporation, 1 (800) 262-3784 or Keith Trettin or Lori King at the National Center for Patient Safety, (734) 930-5890.

ATTACHMENT

Reverse side of the Single Strength Dosing Card for Baxter's BREVIBLOC Premixed Injection (esmolol HCl) 2,500 mg/250 mL (10 mg/mL) Ready-to-use-Bags, 250 mL bags, showing the product number of the incorrect cards

TACHYCARDIA • SVT • HYPERTENSION

Indications
Brevibloc (esmolol HCl) is indicated for the rapid control of ventricular rate in patients with atrial fibrillation or atrial flutter in perioperative, postoperative, or other emergent circumstances where short term control of ventricular rate with a short-acting agent is desirable. Brevibloc (esmolol HCl) is not intended for use in chronic settings where transfer to another agent is anticipated. Brevibloc (esmolol HCl) is also indicated for intraoperative and postoperative tachycardia and/or hypertension.

Safety Information
Contraindicated in patients with sinus bradycardia, heart block greater than first degree, cardiogenic shock, and overt cardiac failure.
Use with caution and monitor carefully during infusion for patients with LV dysfunction, CHF, hypotension, reactive airway disease, and diabetes. In general, patients with bronchospastic disease should not receive beta blockers. Due to the relative beta₁-selectivity and titratability, esmolol HCl may be used with caution in patients with bronchospastic disease. Titrate to the lowest possible dose.
Should not be used for treatment of hypertension due primarily to vasoconstriction associated with hypothermia or to prevent tachycardia and/or hypertension.
The most common side effect was hypotension; asymptomatic (25%) and symptomatic (12%), mainly dizziness and diaphoresis. Hypotension usually reverses within 30 minutes of decrease of dose or termination of infusion. Infusion site reactions (8%).

Please see accompanying full Prescribing Information.

Baxter Healthcare Corporation • 95 Spring Street • New Providence, NJ 07974

Affix PI Here

**For product inquiry:
1-800-ANA-DRUG (1-800-262-3784)
www.baxter.com**

NO VARNISH

Baxter, Brevibloc and Brevibloc Premixed are registered trademarks of Baxter International Inc.
748762 4/07 ADK

Baxter

Product number

