



Department of

**Health, Social Services
and Public Safety**

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AN ROINN

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÁNNYSTRIE O

**Poustie, Resydènter Heisin
an Fowk Siccar**

From The Chief Pharmaceutical Officer
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For Action: Directors of Pharmaceutical Services of the Boards & CSA
Directors of Pharmaceutical Services of HSC Trusts
Regional Quality Improvement Authority

Our reference: PHC/13/08
Date: 22 August 2008

DRUG ALERT Caution in use

Dear Healthcare Professional,

Baxter Healthcare Ltd
Brevibloc injection 10mg/ml vials **PL 00116/0319**
Esmolol hydrochloride 10mg/ml

The MHRA has been informed that batches of Brevibloc vials, distributed since the start of 2008, have been distributed with an error in the Technical Leaflet (TL) document supplied in the pack. The document title paragraph incorrectly states the strength as 10mg/10ml in two places. Other text in the TL document, pack and product labelling is correct.

The error is likely to affect the majority of stock in the supply-chain and we recommend that all stock is regarded as defective in this respect.

In the meantime we wish to inform healthcare professionals of the potential for patient overdose if the incorrect TL statement is used to calculate a patient dose without reference to the vial or carton label.

Error-free packs are not likely to be supplied to the market before October 2008. Further deliveries over the next few weeks will include packs with this defect.

We understand that Brevibloc 10mg/ml Solution for Infusion (PL 00116/0352) is NOT AFFECTED and is not included within the scope of this notice.

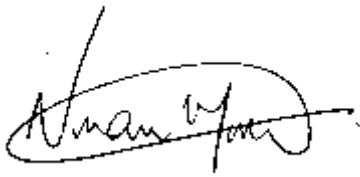
Further Information

For medical enquiries, please telephone Baxter Healthcare Medical Information on 01635 206345. We expect this product is mainly used in a hospital setting but, in view of the nature of this problem, we are alerting primary care practitioners.

Area Boards/RQIA should bring this information to the attention of private hospitals/clinics registered with them, Out of Hours Centres and any other relevant care facilities.

The Central Services Agency is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely



DR NORMAN MORROW
Chief Pharmaceutical Officer

For information:

CMO
CNO
CDO
CISSI
SMO
Director, Health Estates
Public Health Branch
DHSSPS, Library
Extended nurse prescribers

Regional Medicines and Poisons Information Service
Regional Director of Supplies
RPLS
Pharmaceutical Society of NI
Senior Prison Pharmacist
Prison Service, Dundonald House
Nursing Officer, Health Estates
Medical Officer, Castle Buildings
Regional Procurement Pharmacist
NICPPET