



Safety Alert 005/10

25 June 2010

Extreme Caution - Esmolol hydrochloride 2500mg in 10ml for injection

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Directors of Clinical Operations

Action required by:

- Chief Executives
- Directors of Clinical Governance
- Directors of Clinical Operations

For response by:

- Directors of Clinical Governance

We recommend you also inform:

- Directors of Cardiology
- Directors of Anaesthesia & Surgery
- Directors of Pharmacy
- Directors of Emergency Medicine
- Directors of Intensive Care
- Directors of Neonatal Intensive Care
- Directors of Neonate Emergency Transfer Services
- Directors of Paediatric intensive Care
- Directors of Nursing and Midwifery
- Medical staff
- Nursing staff

Deadline for completion of action

28 June 2010

Expert Reference Group

- MSEAC
- Director of Pharmacy RPA

Clinical Safety, Quality and Governance Branch

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Background

NSW Health has just been advised that supply of Brevibloc® brand Esmolol hydrochloride 100mg in 10ml for injection will be critically short during June and July 2010. Normal supply may resume in August 2010.

To address the shortage, the company supplying Brevibloc® brand, (Phebra) has been granted exemption to import and supply a temporary substitute under Section 19A of the Therapeutic Goods Act 1989.

The substitutes are the generic:

- Esmolol hydrochloride 100mg in 10ml Injection vial (minimal supply); and
- Esmolol hydrochloride **2500mg in 10ml Concentrated Injection ampoule**.

What is Esmolol hydrochloride?

Esmolol hydrochloride is a beta1-selective (cardioselective) adrenergic blocking agent with rapid onset and short duration of action. Half-life after infusion is approximately 9 minutes. Esmolol hydrochloride is indicated for the rapid control of atrial fibrillation, atrial flutter and non-compensatory sinus tachycardia.

Issue

Usually there is only one strength of Brevibloc® brand Esmolol hydrochloride **100mg in 10ml for injection available in Australia**.

Extreme Caution is required when administering Esmolol hydrochloride 2500mg in 10ml concentrated injection ampoule as this is 25 times the strength of the 100mg in 10ml product and rapid infusion could be fatal.

Mandatory actions for Area Health Services

- Immediate review by Chief Pharmacists of current stocks of Brevibloc® brand.
- AHS Drug and Therapeutic Committees to immediately review proposed use of Esmolol hydrochloride **2500mg in 10ml**
- If the 2500mg in 10ml concentrated injection ampoule is to be stocked ensure it is stored separately from the 100mg in 10ml vials.
- Ensure all relevant clinical areas are aware of the risks of using **Esmolol hydrochloride 2500mg in 10ml Concentrated Injection**.

References

- Attachment 1 *Approved product information for Brevibloc Injection – Phebra Pty Ltd Date 10/2008*
- Attachment 2 *Summary Document – Highlighting the Key Differences between the Critical Sections of the Product Information and Summaries of Product Characteristics - Phebra Pty Ltd*

Action required by Area Health Services

1. Immediate review by Chief Pharmacists regarding current use and alternative generic brand and strength.
2. Review which strength of temporary brand to stock.
3. AHS Drug and Therapeutic Committees to immediately review use.
4. Ensure all relevant clinical areas are advised of risks when using **Esmolol hydrochloride 2500mg in 10ml Concentrated Injection**.