

**HN (NI) 2002/02**  
**DATE: 19 March 2002**



HEALTH ESTATES  
ESTATE POLICY

**For Attention and Action by:**  
**Chief Executive of each HSS Trust**  
**General Manager/Chief Executive of each HSS Board**  
**Chief Executive of each Agency**

**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

**TITLE:**

**LMA PRO-SEAL<sup>®</sup> INSTRUCTION MANUAL:  
DRUG DOSAGE ERROR**

**MANUFACTURER/SUPPLIER**

Intavent

**PROBLEM**

Intavent have issued the attached Technical Bulletin correcting the dosage of midazolam stated in the Instruction Manual for this laryngeal mask airway.

**DISTRIBUTION**

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Device Managers
- Directors of Anaesthetics
- Medical Directors
- Ambulance Staff and Paramedics
- Maternity Wards
- Dental Practitioners
- Operating Theatre Managers
- Operating Theatre Staff
- Accident & Emergency Departments
- General Dental Practitioners
- Trust Pharmacy Managers
- Adult & Paediatric Intensive Care
- Private Clinics
- Supplies Staff

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

**IMMEDIATE ACTION**

- Device users should be aware of the attached Technical Bulletin correcting the dose of midazolam stated in the original Instruction Manual
- Midazolam should be administered in accordance with its product data sheet

**BACKGROUND**

The Medical Devices Agency (MDA) has been informed by the manufacturer of a potentially serious typographical error in the Instruction Manual; the attached Technical Bulletin (Annex A) corrects the text to read **Midazolam 2-5mg intravenously**. Intavent has requested the publication of this Notice to ensure the rapid distribution of the Bulletin to all users of the product.

MDA consider it unlikely that clinicians would administer midazolam in the potentially fatal dose originally stated in the Instruction Manual. However this cannot be completely excluded.

**MIDAZOLAM  
NOTICE**



HEALTH ESTATES  
ESTATE POLICY

**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

**HAZZARD  
NOTICE**

Users of the product should ensure immediate replacement of manufacturers' instructions in accordance with Device Bulletin DB 9904 (NI): "Medical Device and Equipment Management for Hospital and Community Based Organisation", Section 4.1. This recommends user organizations to have systems in place for replacing existing manufacturers instructions with revised versions.

Guidance booklet "Devices in Practice" provides practical guidance concerning medical device management for health and social care service professionals involved in primary care.

## **ENQUIRIES**

Enquiries to the manufacturer should be addressed to:

Mr. David Wardle  
Quality Assurance Manager  
Intavent Ltd  
The Old Forge  
Tidmarsh  
Reading  
Berkshire  
RG8 8ER

Tel: 0118 984 1212  
Fax: 0118 984 1414

Enquires to the NIAIC should quote the reference number HN(NI) 2002/02 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US  
Marked for the attention of Mr Brian Godfrey

Tel: 02890 523714  
Fax: 02890 523900  
Email: [brian.godfrey@dhsspsni.gov.uk](mailto:brian.godfrey@dhsspsni.gov.uk)

Brian Godfrey  
NIAIC Manager

### **HOW TO REPORT ADVERSE INCIDENTS**

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in Safety Notice SN (NI) 2002/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety  
Áisíneacht Feidhmeannach don Roinn Sláinte, Serbhísí Sóisialta agus Sábháilteacht Phoiblí*