



Department of
**Health, Social Services
and Public Safety**

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AN ROINN

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÄNNYSTRIE O

**Poustie, Resydènter Heisin
an Fowk Siccar**

From The Chief Pharmaceutical Officer
Dr Norman Morrow
Castle Buildings
Upper Newtownards Road
Belfast BT4 3SJ

Telephone: 028 90 523219
Facsimile: 028 90 522335

E-Mail: norman.morrow@dhsspsni.gov.uk

For Action: Assistant Director Pharmacy and Medicines Management
HSC Board & BSO
Directors of Pharmaceutical Services of HSC Trusts
Regional Quality Improvement Authority

Our Ref: PHC/36/09

Date: 26 November 2009

DRUG ALERT MEDICINES RECALL

Dear Healthcare Professional

Aurum Pharmaceuticals Limited

**Acetylcysteine 200mg/ml Injection
(Acetylcysteine)**

PL 12064/0026

Aurum Pharmaceuticals Limited have informed us that there is an error in the patient information/professional leaflet contained in all batches of Acetylcysteine 200mg/ml Injection 10ml currently on the market. The error concerns the dose to be given to children weighing 20kg or more and appears in the third stage of dosing which is infused over 16 hours.

The incorrect leaflet text reads:

	Dose/dilution in infusion fluid	Time
Followed by (3):	100mg in 500ml intravenously	over 16 hrs

The leaflet text should read:

	Dose/dilution in infusion fluid	Time
Followed by (3):	100mg/kg in 500ml intravenously	over 16 hrs

To avoid stock disruption, distribution of affected stock will continue. The leaflet is being amended and it is anticipated that stock containing the corrected version will be supplied to the market by April 2010. Once corrected stock is available, distribution of product containing the affected leaflet will cease.

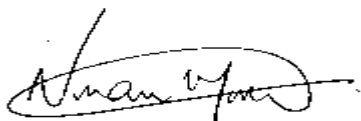
Further information

For further enquiries, please telephone Carol Akinola, Pharmacovigilance and Medical Information Manager, Aurum Pharmaceuticals Limited on 01708 382791.

HSC Board/RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation 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
NICPLD