



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

Our reference: PHC/15/09
Date: 11 June 2009

DRUG ALERT MEDICINES RECALL

Dear Healthcare Professional

**Niche Generics Ltd and Actavis UK Ltd
Oxybutynin Hydrochloride Tablets 5mg**

PL 19611/0027

Product distributed in both Niche and Actavis liveries

Livery	Batch No.	Expiry Date	Pack Size	First Distributed
Niche	09D02	12/2011	84	16/04/2009
Niche	09D04	12/2011	84	16/04/2009
Actavis	146401	12/2011	56	05/05/2009
Actavis	146402	12/2011	56	22/05/2009

Niche Generics Ltd, the product marketing authorisation holder, are recalling all remaining stock of the above batches due to the possible inclusion of undispersed active ingredient which has the potential to result in patient overdose. The above marketing authorisation number has been used for stock distributed in Niche Generics and Actavis liveries.

We understand that the undispersed active ingredient has been found during the early stages of production and may not reach the finished tablet. Work is ongoing to obtain more information, but in the interim all remaining stock is being recalled as a precautionary measure.

Both companies have requested that patients should be contacted and supplied with replacement stock from unaffected batches.

Medical information (for both liveries) can be obtained from the Niche Medical Information Department (Dr Vineet Kacker) on 07753 606357 or vineet.kacker@apcpharma.co.uk.

All unused stock of the listed batches should be quarantined and returned for credit via the original supplier. For returns and credit enquiries, please contact Niche Customer Services on 01462 633816 or csuk@nichegenerics.com or Actavis Customer Services on 0800 373 573.

HSC Board/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 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