

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action within 48 Hours

Pharmacy and Wholesaler Level Recall

Dear Healthcare Professional

Medley Pharma Limited

Product	PL Number
Ranitidine 150mg Tablets BP	43870/0026
Ranitidine 300mg Tablets BP	43870/0027

Generic Name: Ranitidine

Medley Pharma Limited is recalling all unexpired stock of the above products from pharmacies and retail stores as a precautionary measure due to possible contamination with an impurity N-nitrosodimethylamine (NDMA) which has genotoxic and carcinogenic potential.

Advice for healthcare professionals and retail stores

- Stop supplying the above products immediately and remove from the shelves within your store. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.
- If you receive queries about this issue from patients, advise them to contact their GP, pharmacist or healthcare professional to review ongoing treatment.

This is an on-going issue and the MHRA is actively involved with the European Medicines Agency and with other medicines regulators to determine any possible



impact. An investigation into other potentially impacted products is continuing and further updates will be provided as the investigation progresses.

Company contacts for further information

For stock control enquiries please contact Customer Service team on 01515214527 or sales@medleypharma.co.uk

For medical information enquiries please contact Jo Bunyan Pharmacovigilance Department on 07946548344 or jo@callisto-consulting.co.uk

Recipients should bring it to the attention of relevant contacts by copy of this letter.

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.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

TO ALL CHEMISTS, DOCTORS ON THE LISTS

Pharmaceutical Services
2 Franklin Street
BELFAST
BT2 8DQ

Telephone No. 028 9536 0333

16th December 2019

Pharmaceutical website: <http://www.hscbusiness.hscni.net>