



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 16 December 2019

EL (19)A/41

Our Ref: MDR 56-09/19

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.



NHS Regional teams are asked to forward this to relevant clinics, general practitioners and community pharmacists.

Yours faithfully

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