



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy and Wholesaler Level Recall

Date: 05 December 2019

EL (19)A/40

Our Ref: MDR 56-09/19

Dear Healthcare Professional,

Accord Healthcare

Product	PL Number
Ranitidine 150mg Film-Coated Tablets	PL 20075/0063
Ranitidine 300mg Film-Coated Tablets	PL 20075/0064

Generic Name: Ranitidine

Brief description of the problem

Accord Healthcare are recalling all unexpired stock of the above products from pharmacies and wholesalers 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 Accords Customer Service team on 0800 373573

For medical information enquiries please contact Accords Pharmacovigilance Department on 01271 385257 or medinfo@accord-healthcare.com



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

**Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574**