

DRUG ALERT
CLASS 2 MEDICINES RECALL
Action within 48 Hours
Pharmacy/Wholesaler Level Recall

Dear Healthcare Professional

Rosemont Pharmaceuticals Limited (part of the Perrigo group)

Product	PL Number
Ranitidine 150mg/10ml Oral Solution	00427/0132

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

Advice for healthcare professionals

- Stop supplying the above products immediately. 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 not to stop taking their medication as the health risk of discontinuing the medicine is higher than the potential risk presented by the contaminant. A treatment review is not necessary until the next routine appointment.

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 Perrigo Customer Service team on +44 (0)1226 704711 or customerservice@perrigouk.com

For medical information enquiries please contact Perrigo Pharmacovigilance Department on +44 (0)203 598 9603 or UKLOCustomerService@perrigo.com

Recipients 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

28th October 2019

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