

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action within 48 Hours

Pharmacy/Wholesaler Level Recall

Dear Healthcare Professional

Creo Pharma Limited (Zentiva Pharma UK Ltd)

Product	PL Number
Ranitidine Oral Solution 30mg/ml	PL 31862/0023

Tillomed Laboratories Limited

Product	PL Number
Ranitidine 150mg Tablets	PL 11311/0138

Creo Pharma Limited and Tillomed Laboratories Limited are 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

Creo Pharma Limited

- For stock control enquiries please contact Zentiva customer service team on +44 (0) 844 8793 188 or GFD-CUSTOMERSERVICES@zentiva.com
- For medical information enquiries please contact Zentiva medical information team on +44 (0) 800 090 2408 or UKMedInfo@zentiva.com

Tillomed Laboratories Limited

- For enquiries please email Tillomed on qa@tillomed.co.uk
- All stock should be returned to following address:
Mawdsley Brooks
Redhouse
Rockingham Way
Adwick-le-Street
Doncaster, DN6 7FB

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

19th November 2019

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