Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 19th November 2019 EL (19)A/36 Our Ref: MDR 56-09/19

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.

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

Yours faithfully

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