

Public Health Link

from the Chief Medical Officer for Wales

Distribution:	As Appendix 2
From:	Chief Pharmaceutical Officer, Andrew Evans
Date:	20 November 2019
Reference:	CEM/CPhA/2019/36
Category:	Class 2: Action With 48 Hours
Title:	Class 2 Drug Alert, Action Within 48 Hours, Creo Pharma Limited (Zentiva Pharma Uk Ltd), Ranitidine Oral Solution 30mg/MI And Tillomed Laboratories Limited, Ranitidine 150mg Tablets
For Action by:	<p>Dispensing General Practitioners – Ensure all working in your dispensary see this alert and a copy is held on your locum file – Action as below.</p> <p>Community Pharmacies – Action as below</p> <p>Hospital pharmacies – Action as below.</p> <p>Chief Pharmacists - Action as below.</p>
For Information:	See Annex 2 – Distribution List
What is this about:	Full details are set out below.
Why has it been sent:	For your information, action and to pass on to colleagues.

Issue:

Creo Pharma Limited and Tillomed Laboratories Limited are recalling all unexpired stock of the above products as a precautionary measure due to possible contamination with an impurity N-nitrosodimethylamine (NDMA) which has genotoxic and carcinogenic potential.

Full details of the drug alert are included in the attached PDF file. Please forward to listed recipients. This information is also published on the MHRA website <https://www.gov.uk/drug-device-alerts>.

Appendix 1

- To: Chief Executives of Health Boards and NHS Trusts
- To: Medical Directors of Health Boards
- To: Nurse Directors Health Boards
- To: Directors of Public Health
- To: Hospital Principals and Chief Pharmacists to action as per alert

To: **NHS Wales Shared Services Partnership to forward to:**

Dispensing General Practitioners – Ensure all working in your dispensary see this alert and a copy is held on your locum file.

Community Pharmacies

Deputising services

HB Prescribing Advisers

Independent/Private clinics and Hospitals and Hospices throughout Wales



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

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