

Public Health Link

from the Chief Medical Officer for Wales

Distribution:	As Appendix 2
From:	Chief Pharmaceutical Officer, Andrew Evans
Date:	21 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/Retail Store Level Recall

Date: 21 November 2019

EL (19)A/37

Our Ref: MDR 56-09/19

Dear Healthcare Professional,

OTC Concepts Limited

Product	PL Number
Ranitidine 75mg Tablets	PL 20338/0020

Relonchem Limited

Product	PL Number
Relonchem Ranitidine 75mg Tablets (6)	PL 20395/0079
Relonchem Ranitidine 75mg Tablets (12)	PL 20395/0079
Bells Healthcare Ranitidine 75mg Tablets (12)	PL 20395/0079
Numark Ranitidine 75mg Film Coated Tablets (12)	PL 20395/0079
Tesco Heartburn and Indigestion Relief 75mg Film Coated Tablets (12)	PL 20395/0079

Noumed Life Sciences Limited

Product	PL Number
Noumed Indigestion Relief 75mg Film-Coated Tablets	PL 44041/0027
Gavilast Heartburn and Indigestion 75mg Film-Coated Tablets	PL 44041/0028
Ranitidine 75mg Film-Coated Tablets	PL 44041/0028



Medreich PLC

ASDA Ranitidine 75 mg Tablets (12)		PL 21880/0022	
Batch Number	Expiry Date	Pack Size	First Distributed
370190	31/01/2020	1 x 12	August 2017

Peach Ethical Indigestion Relief Ranitidine 75mg Film Coated Tablets (12)		PL 21880/0022	
Batch Number	Expiry Date	Pack Size	First Distributed
370049	31/12/2019	1 x 12	October 2017

Sainsbury's Indigestion Relief Tablets (12)		PL 21880/0022	
Batch Number	Expiry Date	Pack Size	First Distributed
370065	31/12/2019	1 x 12	May 2017
370066	31/12/2019	1 x 12	May 2017

Tesco Indigestion Relief Ranitidine 75mg film-coated tablets		PL 21880/0022	
Batch Number	Expiry Date	Pack Size	First Distributed
370050	31/12/2019	1 x 12	March 2017
370051	31/12/2019	1 x 12	March 2017
370052	31/12/2019	1 x 12	April 2017
370064	31/12/2019	1 x 12	May 2017

Generic Name: Ranitidine

OTC Concepts Ltd, Relconchem Ltd and Noumed Life Sciences Ltd are recalling all unexpired batches of the above products from pharmacies and retail stores as a precautionary measure due to possible contamination with an impurity N-nitrosodimethylamine (NDMA) which has genotoxic and carcinogenic potential.

Medreich Plc are recalling specific batches of the above products from pharmacies and retail stores 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

OTC Concepts Limited

- For stock control enquiries please contact Customer Service team on +44 (0) 1484 665733 or Warehouse@dalkeithlabs.co.uk
- For medical information enquiries please contact Pharmacovigilance Department on +44 (0) 1525 292344 or RanitidinePV@dalkeithlabs.co.uk

Relonchem Limited

- For stock control enquiries please contact Relonchem Customer Service team on +44 (0) 151 422 1200 or sales@relonchem.com
- For medical information enquiries please contact Relonchem Pharmacovigilance Department on +44 (0) 151 556 1857 or medicalinformation@relonchem.com

Noumed Life Sciences Limited

- For stock control enquiries please contact Noumed Life Sciences Limited Customer Service team on +44 (0) 2033998900 or nicole.mascowe@noumed.co.uk
- For medical information enquiries please contact Noumed Life Sciences Limited Pharmacovigilance Department on Tel +44 (0) 2033998960 or akhtarhms@skayedzan.co.uk

Medreich PLC

- For stock control enquiries please contact Medreich Plc. Customer Service team on +44 (0) 20 8831 1580 or cs_team@medreich.co.uk
- For medical information enquiries please contact Medreich Plc. Pharmacovigilance Department on +44 (0) 20 8831 1580 or gagroup@medreich.co.uk

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.



Medicines & Healthcare products
Regulatory Agency



Yours faithfully

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