

Public Health Link

from the Chief Medical Officer for Wales

Distribution:	As Appendix 2
From:	Chief Pharmaceutical Officer, Andrew Evans
Date:	25 October 2019
Reference:	CEM/CPhA/2019/30
Category:	Class 2: Action With 48 Hours
Title:	Class 2 Drug Alert, Action Within 48 Hours, Omega Pharma Limited Trading As Perrigo, Zantac 75 Tablets, Zantac 75 Relief Tablets And Galpharm International Limited (Part Of The Perrigo Group), Ranitidine 75mg Tablets (Various Liveries)
For Action by:	<p>Dispensing General Practitioners – please ensure this message is seen by all working in your dispensary and retain a copy in your 'locum information pack'</p> <p>Community Pharmacists</p> <p>Hospital pharmacies</p> <p>Chief Pharmacists</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:

Omega Pharma Limited and Galpharm International Limited are recalling all unexpired stock of Ranitidine Tablets (various liveries) 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.

This alert is the second alert, out of two, related to ranitidine products issued today (25 October 2019). This has been issued as a separate alert as it relates to particular ranitidine products that can be supplied without a prescription.

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

Community Pharmacists

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: 25 October 2019

EL (19)A/30

Our Ref: MDR 56-09/19

Dear Healthcare Professional,

Omega Pharma Limited trading as Perrigo

Product	PL Number
Zantac 75 Relief Tablets	02855/0081
Zantac 75 Tablets	02855/0082

Galpharm International Limited (part of the Perrigo Group)

Product (GSL)	PL Number
Galpharm Indigestion Relief 75mg Tablets	16028/0122
Boots Heartburn & Indigestion Relief 75mg Tablets	16028/0122
Kirkland Indigestion Relief 75mg Tablets	16028/0122
Morrisons Indigestion & Heartburn Relief 75mg Tablets	16028/0122

Product (P)	PL Number
Boots Heartburn & Indigestion Relief 75mg Tablets	16028/0123

Generic Name: Ranitidine

Omega Pharma Limited and Galpharm International Limited are recalling all unexpired stock 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

For stock control enquiries please contact Perrigo Customer Service team on +44 (0)1226 704711 or customerservice@perrigo.co.uk

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

Omega Pharma Ltd (Zantac Products):

Please contact the Alloga UK Credits team via telephone on 01773 515172 or via email AllogaUK.Credit.Claims@Alloga.co.uk to arrange collection of any stock subject to this recall.

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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