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/2019/29
Category:	Class 2: Action With 48 Hours
Title:	Class 2 Drug Alert, Action Within 48 Hours, Rosemont Pharmaceuticals Limited, Ranitidine 150mg/10ml Oral Solution
For Action by:	Dispensing General Practitioners – please ensure this message is seen by all working in your dispensary and retain a copy in your 'locum information pack' Community Pharmacists Hospital pharmacies Chief Pharmacists
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:

Rosemont Pharmaceuticals Limited is recalling all unexpired stock of Ranitidine 150mg/10ml Oral Solution from pharmacies as a precautionary measure due to possible contamination with an impurity N-nitrosodimethylamine (NDMA) which has genotoxic and carcinogenic potential.

This alert is the first alert, out of two, related to ranitidine products issued today (25 October 2019)

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.

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

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

D R U G   A L E R T
CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 25 October 2019   EL (19)A/29   Our Ref: MDR 56-09/19

Dear Healthcare Professional,

Rosemont Pharmaceuticals Limited (part of the Perrigo group)

Product	PL Number
Ranitidine 150mg/10ml Oral Solution	00427/0132

Rosemont Pharmaceuticals Limited is 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.

Medicines & Healthcare products Regulatory Agency

Company contacts for further information

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

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

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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