Public Health Link

From the Chief Medical Officer for Wales

Distribution:	As Appendix 2
From:	Chief Pharmaceutical Officer, Andrew Evans
Date:	17 October 2019
Reference:	CEM/CPhA/2019/27
Category:	Class 2: Action With 48 Hours
Title:	Class 2 Drug Alert, Action Within 48 Hours, Teva Uk Limited Trading As Ratiopharm Gmbh, Ranitidine Effervescent Tablets 150mg And 300mg
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:

Teva UK Limited, trading as Ratiopharm GmbH, is recalling all unexpired stock of Ranitidine Effervescent Tablets 150mg and 300mg from pharmacies 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

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

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy Level Recall

Date: 17 October 2019 EL (19)A/27 Our Ref: MDR 56-09/19

Dear Healthcare Professional,

Teva UK Limited trading as ratiopharm GmbH is recalling all unexpired stock of Ranitidine Effervescent Tablets from pharmacies.

Ranitidine Effervescent Tablets 150mg PL 15773/066

Batch Number	Expiry Date	Pack Size	First Distributed
17007672	30/04/2020	1 x 60	01/09/2017
17011546	30/06/2020	1 x 60	19/12/2017
17017838	30/09/2020	1 x 60	28/03/2018
18001231	31/12/2020	1 x 60	15/08/2018
18006590	31/03/2021	1 x 60	20/11/2018
18006591	31/03/2021	1 x 60	03/12/2018
18010644	30/06/2021	1 x 60	06/11/2018
18010645	30/06/2021	1 x 60	05/06/2019

Ranitidine Effervescent Tablets 300mg PL 15773/067

Batch Number	Expiry Date	Pack Size	First Distributed
17001878	31/01/2020	1 x 30	27/06/2017
17011702	30/06/2020	1 x 30	09/07/2018

Generic Name: Ranitidine

Teva UK Ltd 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

- Please stop supplying the above products immediately. Kindly quarantine all remaining stock without delay 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

For stock control enquiries please contact Teva Customer Solutions team on 0800 590502 or customer.services@tevauk.com

For medical information enquiries please contact Teva UK Medical Information Department on 0207 540 7337 or UK.Safety@tevauk.com

Recipients of this Drug Alert 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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