



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.

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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

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

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