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: 08 October 2019 EL (19)A/24 Our Ref: MDR 56-09/19

Dear Healthcare Professional,

GlaxoSmithKline trading as Glaxo Welcome UK Ltd

Product	PL Number
Zantac Syrup 150mg/10ml	10949/0108
Zantac Injection 50mg/2ml	10949/0109
Zantac Tablets 150mg	10949/0042
Zantac Tablets 300mg	10949/0043

Generic Name: Ranitidine

GlaxoSmithKline 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 a developing 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 refer to https://gskpro.com/en-gb/ or contact 0800-221-441.

For medical information enquiries please contact ukmedinfo@gsk.com, via the Live Chat facility on https://hcp.gsk.co.uk/contact-us/live-chat.html or on 0800 221 441 (option 2).

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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