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2 October 2019

IMPORTANT NOTIFICATION
ZANTAC (ranitidine) All dosage forms and strengths
All batches within expiry

TGA Ref: RC-2019-RN-01448-1

Dear Doctor,

Aspen Pharmacare Australia Pty Ltd, in consultation with the Therapeutic Goods Administration (TGA), is conducting a retail level recall of Zantac (ranitidine) tablets, effervescent tablets, syrup and ampoules.
The TGA has not requested that a Dear Doctor letter be sent for this retail level product recall.
We are informing you as the potentially affected product may have been supplied to your clinic or hospital, or you may have prescribed or recommended Zantac to your patients.

A retail level recall means that all retail outlets stocking Zantac will remove the product from sale. Outlets include retail and hospital pharmacies, grocery stores and wholesalers.

The issue
Aspen Pharmacare has initiated the retail level recall following the confirmation of trace amounts of N-Nitrosodimethylamine (NDMA) as being present, which is consistent with several other products globally. NDMA is classified as a probable human carcinogen based on results from laboratory tests. It is also a known environmental contaminant found in water and foods, including meats, dairy products, and vegetables. This is a global anomaly that affects more than one type and brand of ranitidine.

The actual health risks depend on dose and will vary from person to person. While long-term exposure, over years, can increase an individual's risk of developing cancer, the risks from short-term use are expected to be extremely low.

What Health Care Practitioners should do
Review the TGA ranitidine alert at https://www.tga.gov.au/alert/ranitidine

If you believe your workplace has any Zantac packs including starter packs, please conduct an inspection and remove all impacted product, in line with your normal destruction procedures, to prevent further distribution and / or use.

What consumers should do
This is not a consumer level recall. Patients in possession of Zantac do not need to return their pack to the pharmacy or grocery store they purchased it from. There is no immediate risk associated with the use of ranitidine as the risks are associated with long term use. Patients and customers who wish to use a substitute medicine should speak to their doctor or pharmacist in the first instance. For patients that have been prescribed ranitidine, the risks of sudden cessation and/or not treating their condition at all, will likely pose a greater risk to their health than what this anomaly poses. Therefore, these individuals should not stop taking ranitidine until they have spoken to their doctor or pharmacist about alternative treatments.

For further information, please see the link below to the TGA alert:
https://www.tga.gov.au/alert/ranitidine

We appreciate your understanding and thank you for your assistance in helping us to manage this issue. If you do have any questions, please contact the Aspen Contact Centre Tel: 1300 659 646.

Aspen Pharmacare Australia Pty Ltd sincerely regrets any inconvenience caused to you or your organisation.

Yours sincerely,

Cathie Hilton

Head of Prescription Business