Medication Safety Notice

Issued by Medicines and Technology Programs, SA Health
www.sahealth.sa.gov.au/medicationsafety

A medication **Safety Notice** strongly advises the implementation of particular recommendations or solutions to improve quality and safety.

We recommend you inform:

- General Managers
- Pharmacy Directors
- Medical Directors
- Clinical Directors
- Nursing Directors
- Drug and Therapeutics Committees
- Medication Safety Committees
- Safety and Quality Units
- Clinical Governance

Contact details:

T: (08) 8204 1944
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Government of South Australia | Health
Department for Health and Wellbeing

Ranitidine – 'Product Hold' initiated by TGA

Purpose

To inform SA Health staff of a current national 'product hold' on all ranitidine products.

Summary of Issues

The Therapeutic Goods Administration (TGA) has initiated a 'product hold' on all ranitidine products (all brands, all dosage forms) following identification of N-Nitrosodimethylamine (NDMA) contamination in products internationally. The product hold means that sponsors of ranitidine products are no longer supplying stock from their warehouses (See the TGA Alert.).

The TGA is undertaking extensive testing of ranitidine products available in Australia. The preliminary results have shown that some products are of concern, consistent with what is being seen overseas. The product hold will allow time for product testing to be completed, however is **likely to result in shortages of ranitidine products and potentially shortages of ranitidine alternatives.**

NDMA is a known environmental contaminant and is commonly found in low levels in a variety of foods, particularly smoked and cured meats, as well as in some drinking water and in air pollution. It is the same contaminant recently identified in 'sartan' medicines. The levels of NDMA identified in ranitidine products is considered to be low however any contamination is considered unacceptable for quality use of medicines.

The TGA advises there is no **immediate health risk associated with these products, however** long-term exposure to NDMA can increase an individual's risk of developing cancer. The risk of exposure must be balanced with changing therapy for each individual patient. At this time, the TGA is not calling for individuals to stop taking ranitidine.

One company, Sandoz, has implemented a voluntary recall of their ranitidine products, including **Mylanta® ranitidine**, **Ranitidine Sandoz®**, **Ranitidine GH®**, **Ranital®** and **Ranital Forte®**. Further sponsor initiated recalls are also likely.

SA Health Action Plan

SA Pharmacy has reviewed pharmacy stocks and ward imprest holdings across sites, and has procured an alternative brand.

Staff should ensure to seek replacement stock for any Sandoz ranitidine products that may have moved beyond imprests.

It is expected that ranitidine stock in SA Health sites may become in short supply within the next two weeks.

Prescribers should consider the risks associated with potential NDMA exposure, noting for some patients, the risks of not treating their condition may pose a greater health risk.

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A range of alternative treatments options are available including other H2 receptor antagonists (eg nizatadine, famotidine), proton pump inhibitors (eg pantoprazole, omeprazole), and/or diet and lifestyle modification. These should be considered where clinically relevant.

Famotidine like ranitidine is pregnancy category B1 and is considered safe to use in pregnancy. It has a more rapid onset of action than PPIs and may be more appropriate for as needed (PRN) dosing.

Ranitidine (Zantac®) is the only H2 antagonist available in injectable form. A proton pump inhibitor may be necessary for patients requiring parenteral administration.

Patients taking ranitidine should be made aware of the issue, and concerns about continued use and other options should be discussed with their prescriber, pharmacist or other members of their health care team.

SA Health will continue to monitor the 'product hold' and further updates will be provided as information becomes available.

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