

Medication Safety Notice

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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

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UPDATE: Ranitidine – All Products Recalled

Purpose

To provide SA Health staff with an update to the national 'product hold' on all ranitidine products (see [SA Health Medication Safety Notice 03/19](#)).

Summary of Issues

The Therapeutic Goods Administration (TGA) is continuing to perform testing on ranitidine products available in Australia, following identification of N-Nitrosodimethylamine (NDMA) contamination in products internationally. See the [TGA Alert](#).

Product recalls have now been initiated by product sponsors for all ranitidine products (oral, effervescent and injectable) whilst testing continues. All SA Health ranitidine stocks are subject to recall and will be quarantined until further notice.

Alternative treatments now need to be considered for current and new patients.

Guidance for Alternative Therapies

The following information should be considered as general advice only and may not apply to individual patient circumstances (i.e. patients with allergies, renal impairment).

- > Review the indication for ranitidine therapy. If there is no current indication, consider cessation and/or role of dietary and lifestyle modifications.
- > For gastro-oesophageal reflux, consider an alternative H₂ receptor antagonist (e.g. famotidine), antacids or proton pump inhibitors (pantoprazole, omeprazole). See the [Therapeutic Guidelines](#) or [AMH](#) for dosing information.
- > Omeprazole can be used in [neonates](#) and children, and during pregnancy and breastfeeding.
- > Famotidine is considered safe to use in pregnancy (pregnancy category B1).
- > For H₂ blockade in chemotherapy protocols, famotidine may be suitable.
- > Sodium citrate 8.8% (oral) can be used as non-particulate antacid prophylaxis prior to [caesarean section](#).
- > Parenteral administration – consider intravenous omeprazole.

SA Health Action Plan

- > SA Pharmacy has initiated removal all ranitidine products from ward imprests and other hospital storage locations.
- > Sites without an on-site pharmacy should develop an action plan to remove all ranitidine products from imprest and storage locations, and quarantine until further instruction.
- > Clinicians should consider converting current inpatients to alternative treatments in consideration of their clinical requirements and the alternative options available.
- > Contact your pharmacist, SA Pharmacy [Medicines Information Service](#) (ph: 8161 7555) or senior medical staff for further clinical advice.

SA Health will continue to monitor and provide further updates as information becomes available.