Drug Shortage + Recall

Ranitidine oral tablets and suspension

The Issue: Health Canada recently placed a "do not distribute" hold on all new manufacturing of ranitidine in Canada based on global signals of an impurity, NDMA. NDMA is classified as a probable human carcinogen meaning long-term exposure to levels above those considered safe may increase the risk of cancer. It should be noted that NDMA is an environmental contaminant present in low levels in every day life, such as in drinking water, and long-term exposure to these low levels is not expected to cause harm.

Sandoz has voluntarily recalled their oral ranitidine tablets as they did not pass the acceptable level of NDMA in their product. Health Canada has also extended the recall to Apotex, Sanis, Pro-Doc, and some lots of Sivem. The oral suspension is also affected by the recall. Health Canada will provide further information for other vendors as testing results become available.

Practice Implications: Since NH primarily carries the Apotex brand, we will be changing over all patients currently receiving oral ranitidine (suspension and tablets) and provide alternatives to current and new patients as listed below. There will be no change to the injectable product as verbal communication from the manufacturer indicates this product is not affected at this time. ***Clinicians are asked to assess patient suitability for de-escalation of therapy*** (e.g. antacids) before increasing therapy to proton-pump inhibitors (PPIs). Non-medication interventions should also be considered (e.g avoid dietary triggers, elevate head of bed). Further, the ***therapeutic interchange for non-formulary H2-receptor antagonists to ranitidine will be on hold*** until further notice.

Alternatives:**

- Antacids (e.g. TUMS, Gaviscon, Almagel, Pepto-Bismol): consider de-escalation as first line option
- Famotidine 20 mg tablets **restricted** to:
  - pediatric/neonatal patients (including those requiring a compounded oral suspension)
  - patients with allergy or absolute contraindications to PPI
- Ranitidine injectable: **restricted** to patients that are NPO/require IV as per indication, TPN adds, or those that require IV as part of pre-medication regimens (e.g. do not switch all PO ranitidine to IV)
- Pantoprazole (oral and IV): formulary unrestricted
- Esomeprazole/omeprazole/lansoprazole tablets/capsules: see formulary restriction criteria

September 23, 2019

For the information of physicians, nurses and pharmacists
PLEASE POST

Drug Shortage/Recall	√
Formulary change	
Best Practice	
Recall	
Label Change	

For further information contact:
NH Medication Use Management Pharmacists:
Jessica Brecknock (250-267-5940)
Ryan Doerksen (250-565-5956)
mumpharmacist@northernhealth.ca

northern health
the northern way of caring

**Alternates are provided for clinician information and my not be appropriate for all clinical situations. The information provided does not replace clinical judgment.