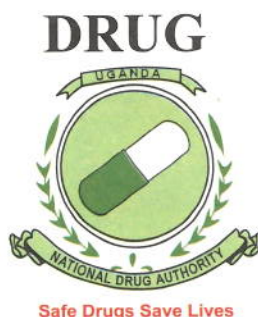


NATIONAL



AUTHORITY

707/NDA/DPS/10/2019

31st October 2019

To: The Prescribers

CIRCULAR NO. 032

Presence of a potentially genotoxic impurity, N-nitrosodimethylamine (NDMA) in Ranitidine

National Drug Authority (NDA) received alerts from the United States Food and Drug Authority that Ranitidine, a histamine H₂ receptor antagonist, prescribed for; Dyspepsia and Gastroesophageal reflux disease (GERD) contains a substance known as N-nitrosodimethylamine (NDMA). N-nitrosodimethylamine at high levels, is a known human carcinogen of genotoxic nature.

NDA has halted the importation and distribution of Ranitidine into the country, pending further regulatory action that will follow conclusion of investigations into the levels of contamination with NDMA in registered brands of Ranitidine.

This communication serves to;

1. Request you to consider alternative treatment options to Ranitidine that are available on the market.
2. Quarantine the available stock of Ranitidine containing products in your possession and a report to NDA.
3. Be vigilant and report any adverse drug reactions associated with the use of Ranitidine containing products directly to National Drug Authority via druginfo@nda.or.ug, or on a toll free line 0800101999.

NDA commits to investigate and accordingly relay any new information, as and when it arises.

Thank you for your continued cooperation.

Victoria Nambasa
FOR: DIRECTOR PRODUCT SAFETY

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OUR MISSION

Promoting and protecting public health
through the effective regulation of human
and animal medicines and healthcare
products

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