SAFETY ALERT: POTENTIAL CONTAMINATION OF RANITIDINE WITH N-NITROSODIMETHYLAMINE

The Food and Drugs Authority (FDA) wishes to bring to your attention new international safety alert regarding the potential contamination of Ranitidine medicine with an impurity called N-nitrosodimethylamine (NDMA), a potential human cancer causing agent.

Ranitidine is a prescription only medicine used to reduce stomach acid and is commonly used to treat heartburn or for treatment and prevention of gastric reflux and ulcers. The Food and Drugs Authority at the moment has not registered for sale and distribution any medicine containing Ranitidine in Ghana.

N-nitrosodimethylamine (NDMA) is a type of N-nitroso compound. N-nitroso compounds are 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.

The health risk the presence of the NDMA poses in the ranitidine depends on the dose consumed and will differ in individual persons. The level of NDMA found in the ranitidine poses very low additional risk and when used for short-term the risk is expected to be extremely low.

Advice for Patients and Consumers
There is no immediate health risk associated with ranitidine as the risks are associated with long-term use. There are similar medicines to ranitidine that can be prescribed for persons who need it. If you are already taking ranitidine, you are advised to continue taking your medicine until you discuss with your pharmacist or doctor alternative treatment as stopping the medicine will cause more harm to your health than the potential contamination with NDMA.

Advice for Healthcare Professionals
While the additional risk posed by NDMA from ranitidine at the levels identified to date is very low, for patients who are currently taking ranitidine these risks may outweigh the clinical benefits. For this reason, doctors who are treating patients with ranitidine should consider alternative management where clinically appropriate, which may include an alternate H receptor antagonist, proton pump inhibitors, and/or diet and lifestyle modification.
Meanwhile, the FDA through its post marketing surveillance activities is investigating if there are any ranitidine medicines available on the Ghanaian market for appropriate regulatory action.

The Food and Drugs Authority will like to advice healthcare professionals and the general public to report all safety issues including adverse drug reactions to all medicines to the FDA by completing the Adverse Reaction Reporting Form or online using the link http://adr.fdaghana.gov.gh/ or call 024 431 0297 or send an email to drug.safety@fdaghana.gov.gh or through the Med Safety Mobile App.

SIGNED

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