**Ranitidine Products are Recalled Following Detection of Possibly Carcinogenic Substance**

On September 13, 2019 the FDA found that samples of ranitidine contained N-nitrosodimethylamine (NDMA), which is a nitrosamine impurity that is a probable human carcinogen. Ranitidine is a common over-the-counter medicine used by individuals with acid reflux. Sandoz, a manufacturer of prescription ranitidine capsules, voluntarily pulled 14 lots of product from the market on September 24, 2019.[1]

N-Nitrosodimethylamine (NDMA) is a volatile, oily, liquid substance that belongs to a group of chemicals called nitrosamines. NDMA breaks down when it is exposed to heat or light and releases toxic gases.[2] Other sources that could lead to human exposure of this chemical are tobacco smoke, chewing tobacco, shampoos and cleansers, some rubbers, detergents, and pesticides. NDMA is not a product that is intentionally added to foods or medications, but instead is the biproduct when alkylamines are broken down during the production or manufacturing of products. NDMA can cause illnesses that affect the liver primarily at both short high-level exposures and long low-level exposures. Liver disease has been seen in poisoned individuals and both humans and animals who were exposed to the chemical. While there haven't been any documented reports of cancer caused by NDMA exposure in humans, it is reasonable to expect that exposure could cause cancer. It is unknown what the threshold is for this chemical that would cause it to be harmful in humans.[3] The FDA has recently notified all manufacturers of ranitidine that they must perform laboratory testing on their products to send to the FDA in order to determine the amount of NDMA in the product. Individuals taking ranitidine containing products should follow the recall instructions provided by their company. At this time, there is no reason to discontinue use if the specific manufacturer or lot of the medication has not been recalled. Patients taking over-the-counter ranitidine could consider using a different medication for their condition.[1]

References:


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2. National Cancer Institute staff. NCI Thesaurus: N-Nitrosodimethylamine (Code C44417). National Institute of Health. Available at: https://ncit.nci.nih.gov/ncitbrowser/pages/concept_details.jsf?dictionary=NCI_Thesaurus&version=19.08d&code=C44417&ns=NCI_Thesaurus&type=properties&key=null&b=1&n=0&vse=null. Accessed September 30, 2019.
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