Medical Xpress

Two more heartburn meds recalled due to possible carcinogen

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(HealthDay)—The U.S. Food and Drug Administration is adding to a list

of recalled lots of popular heartburn medications—including generic forms of Zantac—because the pills might contain small amounts of a suspected carcinogen.

The substance, called N-Nitrosodimethylamine (NDMA), is an environmental contaminant that can be found in water and foods and has been classified as a "probable human carcinogen" by the World Health Organization.

The presence of NDMA in minute quantities has already led to the recall of multiple types of blood pressure medications, such as valsartan and losartan.

NDMA's potential presence in Zantac and generic versions of the drug were first announced in September.

The new recalls were announced Thursday by the FDA and include "all quantities and lots" of ranitidine hydrochloride capsules manufactured by Appco Pharma in the 150 milligram (mg) and 300 mg size with expiration dates of April/May 2021; and "all unexpired lots," in the same dosages, of ranitidine tablets manufactured by Northwind Pharmaceuticals. Neither company has yet received any reports of "adverse events" tied to the medicines.

Ranitidine decreases the amount of acid created by the stomach. Over-the-counter ranitidine is approved to prevent and relieve heartburn, and prescription ranitidine is approved for a number of uses, including treatment and prevention of ulcers of the stomach and intestines, and treatment of gastroesophageal reflux disease (GERD).

Speaking at the time of the initial Zantac recall, one gastroenterologist said patients may want to switch their meds.

"Drug impurities remain a major national concern," said Dr. David Robbins, associate chief of endoscopy at Lenox Hill Hospital in New York City. "While Zantac may prove safe in the long run, this latest statement adds confusion and concern, so my interim advice to patients is simple: switch to another drug… and, of course, confirm with your doctor the need for an antacid."

In the meantime, scientists at one California lab believe they may be getting closer to understanding why NDMA is showing up in ranitidine tablets.

"What we found out was that NDMA is being generated as a result of heating of ranitidine," chemist Ron Najafi, of Emery Lab, told *CBS News*.

His team found that, at room temperature, NDMA levels in tablets remain at about 25 nanograms—far below the threshold level of 96 nanograms that's deemed unsafe by the FDA.

But heat changes that. When a pill was heated to 158 degrees Fahrenheit, NDMA levels rose to 142 nanograms.

"So if someone were to keep their ranitidine, Zantac, in their car, for example, and in the middle of summertime, that product is going to get heated up and it's going to generate this compound," Najafi told *CBS*. "So NDMA in this case… is not an impurity in the drug, it's being formed from the drug itself."

Najafi suspects that ranitidine tablets might be exposed to ambient heat somewhere in the long transport process between manufacturing plants and drugstore shelves.

The Emery lab has submitted their findings to the FDA and is

advocating that pills be shipped under controlled temperatures.

Dr. Janet Woodcock, who directs drug evaluation and research at the FDA, responded to the lab results.

It does appear that some NDMA can form with significant heat, she told *CBS*. "However, these are pretty high temperatures, so the question about whether ranitidine would need to be kept cold to keep it from converting is something that still hasn't been answered," she added.

In the meantime, Woodcock stressed that at the levels found in recalled pills, the risk to users remains very small.

"For most of these contaminants that we're talking about, the level of NDMA—or nitrosamine—in there is not much more than your daily diet, especially if you ate a lot of meat," Woodcock said.

More information: The U.S. Agency for Toxic Substances & Disease Registry has more on NDMA.

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