

Put Concerns About Ranitidine and Drug Safety in Perspective

Headlines about a probable carcinogen in some Rx and OTC ranitidine products will raise questions about the safety of generic and brand meds.

The buzz is about N-nitrosodimethylamine (NDMA)...the impurity that first sparked recalls of irbesartan, losartan, and valsartan.

Now FDA is investigating how much NDMA is in ranitidine...whether it poses any risk...and the source. In fact, one independent analysis used high temps to test ranitidine...and the test itself generated NDMA.

Expect all this to spur more questions about med safety...and where meds are coming from. Help patients see the big picture.

Point out that everyone is exposed to NDMA...and small amounts are present in water and common foods (bacon, grilled meats, dairy, etc).

Explain that most generic AND brand meds are made from or include ingredients from overseas...but they all must meet the same FDA standards.

Educate patients that meds have clear benefits for many conditions.

For example, explain that treating hypertension reduces the risk of stroke and other CV events. In contrast, FDA estimates 8,000 patients would need to take the highest contaminated ARB dose daily for 4 years to possibly lead to one additional lifetime diagnosis of cancer...at MOST.

And acid-suppressing meds help heal peptic ulcers, esophagitis, etc.

But these meds may not be needed long-term. Use the hype as an opportunity to re-evaluate use of H2-blockers...and work with prescribers.

For now, consider famotidine if an H2-blocker is needed...or an antacid (*Tums*, etc) as an alternative for quick relief.

Caution that PPIs (omeprazole, etc) come with their own risks. For example, chronic use is linked to fractures, *C. diff*, pneumonia, etc.

Continue to emphasize lifestyle changes (small meals, etc).

Stay tuned...FDA is testing other H2-blockers and PPIs for NDMA.

Share our *How Safe Are My Generic Drugs?* patient handout to answer questions and put concerns about NDMA into perspective.

Key References:

- www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine (10-14-19)
- www.fda.gov/drugs/drug-safety-and-availability/questions-and-answers-ndma-impurities-ranitidine-commonly-known-zantac (10-14-19)
- www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf (10-14-19)
- www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin

Cite this document as follows: Article, Put Concerns About Ranitidine and Drug Safety in Perspective, Pharmacist's Letter, November 2019

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ii-receptor-blocker-arb-recalls-valsartan-losartan (10-14-19)
Pharmacist's Letter, November 2019, No. 351101

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