Withdrawal of Ranitidine

Summary

- The FDA announced that it is requesting manufacturers withdraw all prescription and over-the-counter (OTC) ranitidine drugs from the market immediately due to contamination with N-Nitrosodimethylamine (NDMA).
- The FDA has found NDMA levels in some ranitidine products increase with time and temperature posing a risk to consumers, and therefore the FDA has requested the withdrawal of all ranitidine products from the U.S. market.
- This differs from past recall actions because this is the first time the FDA is requesting market withdrawal of all ranitidine products.
- Ranitidine products will not be available for new or existing prescriptions or OTC use in the U.S.

Suggested Talking Points to Members

1. **What is ranitidine used for?**
   Prescription ranitidine is used to treat ulcers, gastroesophageal reflux disease (GERD), and conditions where the stomach produces too much acid, such as Zollinger-Ellison syndrome.

   Over-the-counter (OTC) ranitidine is used to prevent and treat symptoms of heartburn.

2. **Why are all ranitidine products being removed from the market?**
   The FDA is requesting that manufacturers remove all prescription and OTC ranitidine products, including tablets, capsules, and liquids, from the market because they may contain an impurity called NDMA – a substance that could cause cancer.

   The FDA has found that NDMA levels in some rantidine products may increase over time and when ranitidine is exposed to temperatures higher than room temperature.

   Ranitidine will not be available for new or existing prescriptions or OTC use in the U.S.

3. **Why are ranitidine products in the news?**
   The FDA is requesting that manufacturers remove all prescription and OTC ranitidine products, including tablets, capsules, and liquids, from the market because they may contain an impurity called NDMA – a substance that could cause cancer.

   The FDA has found that NDMA levels in some rantidine products may increase over time and when ranitidine is exposed to temperatures higher than room temperature.

   Ranitidine will not be available for new or existing prescriptions or OTC use in the U.S.

4. **What are the potential health concerns of taking ranitidine products that contain NDMA?**
   NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables. Ranitidine may contain unacceptable levels of NDMA. NDMA is classified as a substance that could cause cancer based on laboratory tests. Please contact your doctor if you experience any problem that you think might be related to using ranitidine.

5. **Should I continue using the ranitidine that I have?**
   If you are taking **prescription ranitidine**, please talk to your healthcare provider about other treatment options before stopping the medicine. There are multiple medicines approved for the same or similar uses as rantidine that do not contain NDMA.

   If you are taking an **OTC ranitidine product**, stop taking any tablets or liquid that you currently have, dispose of them properly and do not buy more. You may consider using other OTC products.

6. **What should I do with my unused ranitidine?**
   You can disopose of ranitidine in your household trash. Below are some suggestions for disposing the medicine safely:

   1. Mix the pills with an unappealing substance such as dirt, cat litter, or used coffee grounds; do not crush them.
   2. Place the mixture in a container such as a sealed plastic bag.
   3. Throw away the container in your trash at home.
   4. Remove or delete all personal information on the prescription label of empty medicine bottles or packaging, then throw away or recycle them.

7. **What happens if I use ranitidine?**
   Please contact your doctor if you experience any problem that you think might be related to using ranitidine.

8. **Are all ranitidine products being removed from the market?**
   Yes. All prescription and OTC products are being removed from the market. Rantidine will not be available for new or existing prescriptions or OTC use in the U.S.

9. **Are there other types of medicines similar to ranitidine that I can use?**
   Yes. There are other types of medicines similar to ranitidine that are not being removed from the market.

   If you are taking **prescription ranitidine**, please talk to your healthcare provider about other treatment options before stopping the medicine. There are multiple medicines approved for the same or similar uses as rantidine that do not contain NDMA.

   If you are taking an **OTC ranitidine product**, stop taking any tablets or liquid that you currently have, dispose of them properly and do not buy more. You may consider using other OTC products.

   Refer to the table on the last page for a list of alternatives. A new prescription from the member's healthcare provider may be needed.

10. **Who should I contact for medical questions?**
    If you have medical questions, please contact your doctor.

11. **Where can I find more information about this?**
    For more information, please contact your pharmacy or healthcare provider.

Potential Alternative Therapies

H_2-receptor antagonists:	Pepcid (famotidine) and Tagament (cimetidine) Per FDA, these OTC H2-receptor antagonists do not show NDMA impurities at this time. The FDA does not have information on NDMA content of other H2-receptor antagonists at this time.
Proton-pump inhibitors:	Nexium® (esomeprazole), Prevacid® (lansoprazole), and Prilosec® (omeprazole) Per FDA, these OTC proton-pump inhibitors do not show NDMA impurities at this time. The FDA does not have information on NDMA content of other proton pump inhibitors at this time.

- This table does not indicate whether or not the drug is covered by the patient's plan.
- Patients taking **prescription ranitidine** who wish to stop should talk to their healthcare provider about other treatment options.
- Consumers taking **OTC ranitidine**, should stop taking any tablets or liquid they currently have on hand, dispose of them properly and not buy more. They may consider using other OTC products.
- A new prescription from a healthcare provider may be needed if the alternative is a prescription product. Patients should contact their pharmacy to determine whether or not the alternative prescription therapy is covered by their plan.

References (Updated: April 1, 2020):
1. FDA News Release. FDA Requests Removal of All Ranitidine Products (Zantac) from the Market. FDA website. https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market. Accessed April 1, 2020.
5. FDA Questions and Answers: NDMA impurities in ranitidine (commonly known as Zantac). FDA website. https://www.fda.gov/drugs/drug-safety-and-availability/questions-and-answers-ndma-impurities-ranitidine-commonly-known-zantac. Accessed April 1, 2020.

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