

December 6, 2019

There are no recalls for Metformin in the United States

The purpose of this Drug Safety Alert is to:

- 1) Inform you that the FDA is investigating the presence of contaminants such as NDMA and other nitrosamines in metformin.
- 2) Clarify that there are no recalls for metformin.
- 3) Stress the importance for patients to continue taking their metformin as prescribed.

The Issue: Metformin is the most widely prescribed anti-hyperglycemic medication for the treatment of Type 2 Diabetes around the world. Some countries outside of the United States have reported metformin tablets that have been contaminated with small amounts of NDMA. The levels reported are the similar to those occurring naturally in some foods and water.

The FDA is working with drug companies to test samples of metformin in the United States to ensure that there are no products with elevated NDMA levels.

As of December 6, 2019, there are no metformin recalls in the United States

What is NDMA? N-nitrosodimethylamine is a chemical that has been classified as a probable human carcinogen based on laboratory test results when ingested in large amounts. Small amounts of NDMA can be found in water and foods (e.g., meats, dairy products and vegetables).

Should patients stop taking metformin? NO

The FDA recommends that patients should continue taking metformin. It could be dangerous for patients with diabetes to stop taking their metformin without first talking to their health care provider. Additionally, FDA recommends providers to continue to prescribe metformin when appropriate.

The FDA will continue to investigate the purity of metformin and other medications and will provide alerts and guidance if any actions are deemed necessary.

The full [FDA statement can be found online](#).