Indian Health Service
National Pharmacy and Therapeutics Committee
Pharmacovigilance Drug Safety Alert

June 12, 2020

Metformin ER Recall

The Issue:

Metformin is the most widely prescribed anti-hyperglycemic medication for the treatment of type 2 diabetes mellitus around the world. The U.S. Food and Drug Administration recently announced the voluntary recalls of extended release (ER) metformin manufactured by 5 pharmaceutical companies. These manufacturers and their FDA-sponsored webpages are hyperlinked below which provide details including lot numbers effected, company announcement date, NDC numbers, etc.

1. **Apotex Corp.**
2. **Amneal Pharmaceuticals LLC**
3. **Marksans Pharma Limited**
4. **Lupin Pharmaceuticals, Inc.**
5. **Teva Pharmaceuticals USA, Inc.**

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).

Are all metformin products being recalled?

No. Only metformin ER that is made by the companies above have been recalled. Metformin ER manufactured by other pharmaceutical companies and metformin immediate-release (IR) have not been found to contain NDMA.

Should patients stop taking metformin? NO

Metformin continues to be the preferred first-line treatment in the management of type 2 diabetes mellitus, and affords benefits in excess of glycemic control. Prescribers may wish to begin discussing options with patients, including a transition to an immediate release formulation of metformin while supplies of extended release metformin are impacted by the recall. However, continuation of metformin for type 2 diabetics lacking contraindications is strongly advocated.

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.

Reference(s):
1. U.S. Food and Drug Administration. FDA Updates and Press Announcements on NDMA in Metformin. Accessed June 12, 2020.