Diabetes ECHO
Questions about Metformin Recall

June 11, 2020

“Patients calling concerned about cancer from metformin”

FDA NEWS RELEASE
For Immediate Release:
May 28, 2020

FDA Alerts Patients and Health Care Professionals to Nitrosamine Impurity Findings in ***Certain Metformin Extended-Release Products***
Agency Continues Investigations of Nitrosamine Impurities in Drug Products

https://www.fda.gov/news-events/press-announcements/fda-alerts-patients-and-health-care-professionals-nitrosamine-impurity-findings-certain-metformin

Recall due to NDMA contaminant not metformin itself

- The cancer concerns with metformin is not with metformin itself but with a contaminate in the pill.

- Metformin itself helps reduce the risk of many cancers including pancreatic cancer and liver cancer.

- The contaminant, NDMA, is the same contaminant that was in some pills for a BP med and in ranitidine, both of which were recalled due to NDMA
- NDMA is also in meat, especially if cured or grilled, and some other foods – in environment

- It is believed to be cancer causing in large amounts, but this is not certain
  - TV media bursts and the attorney ads make it seem like it is a certain risk

Extended Release tablets of metformin from 5 firms – recommended to recall

- The recall is ***extended-release*** tablets of metformin
- The agency is in contact with five firms to recommend they voluntarily recall their products.
  - Actavis Pharma Inc.,
  - Amneal Pharmaceuticals, LLC,
  - Apotex Corp.,
  - Lupin Pharma and
  - Marksans Pharma Ltd.

- The agency is also asking all manufacturers of metformin containing ER products to evaluate the risk of excessive NDMA in their product and to test each batch before it is released into the U.S. market.
  - If testing shows NDMA above the acceptable intake limit, the manufacturer should inform the agency and should not release the batch to the U.S. market.

Continue Metformin – Replace with unaffected Lot

- Patients should **continue taking metformin tablets** even after recalls occur**, until they consult with their health care professional who can prescribe a replacement**.
  - Patients with type 2 diabetes could face dangerous health risks if they stop taking their prescribed metformin.
- The FDA recommends that health care professionals **continue to prescribe metformin** when clinically appropriate
- FDA testing has **not shown NDMA in immediate release (IR) metformin products** (the most commonly prescribed type of metformin).

Resources

- https://www.fda.gov/drugs/drug-safety-and-availability/questions-and-answers-ndma-impurities-metformin-products
  - Frequently asked questions about NDMA in metformin.
    - It's worth noting that the findings have so far only been in extended release products.
- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts
  - FDA's recalls page where patients and providers can search to see if their product has been part of a recall.

Date	Brand Name(s)	Product Description	Product Type	Recall Reason Description	Company Name
06/01/2020	Amneal	Metformin Hydrochloride Extended-Release Tablets, USP 500mg and 750mg	Drugs,	Due to detection of N-Nitrosodimethylamine (NDMA)	Amneal Pharmaceuticals LLC
05/28/2020	Apotex Corp	Metformin Hydrochloride Extended-Release Tablets, USP 500mg	Drugs,	Due to detection of N-Nitrosodimethylamine (NDMA)	Apotex Corp