Metformin Hydrochloride Extended Release Tablets – Nostrum Laboratories

On November 2, 2020 the U.S. Food and Drug Administration (FDA) announced that Nostrum Laboratories is voluntarily recalling two lots of Metformin HCl Extended Release Tablets, 750mg to the consumer level. The tablets have been found to contain levels of nitrosamine impurities above the ADI (acceptable daily intake) limit.

NDMA (N-Nitrosodimethylamine) is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables. Nostrum Laboratories, Inc. has not received any reports of adverse events related to this recall.

The product is indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus. The affected Metformin HCl Extended Release Tablets, USP 750 mg lots are listed in the table below.

Product Description	NDC	Lot Numbers	Expiry Dates
Metformin HCl Extended Release Tablets, USP 750 mg	29033-056-01	MET200101	05/2022
		MET200301	05/2022

Consumers should consult a healthcare professional to obtain a replacement or a different treatment option. It could be dangerous for patients with type 2 diabetes to stop taking their metformin without first talking to their healthcare professional. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking this drug product.

Consumers with medical questions regarding this recall can contact Nostrum Laboratories, Inc. Medical Affairs at phone number 816-308-4941 or email quality@nostrumpharma.com (mailto:quality@nostrumpharma.com) Monday through Friday from 8am – 5 pm CST. Consumers should contact their physician or pharmacy for further medical advice.