Amneal Pharmaceuticals LLC Issues Voluntary Nationwide Recall of Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg

Amneal Pharmaceuticals LLC is voluntarily recalling all unexpired lots of Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg.

Amneal was notified by the U.S. FDA that the Agency's testing of seven lots of Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg, showed N-Nitrosodimethylamine (NDMA) amounts above acceptable FDA levels. FDA recommended the recall of the seven tested lots. Amneal has agreed to this recall and has further decided to extend the recall to all unexpired lots of Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg, out of an abundance of caution.

To date, Amneal has not received any reports of adverse events that have been confirmed to be directly related to this recall.

NDMA 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 found in water and foods, including meats, dairy products and vegetables.

What you should do:

- Patients should continue taking their medication and contact their prescriber for guidance and/or alternative therapy.
- Patients may report any adverse reactions or quality problems experienced with the use of this drug by contacting Amneal Drug Safety by phone at **1-877-835-5472, Monday - Friday, 8:00 am – 6:00 pm, EST, or via e-mail at DrugSafety@amneal.com.**
- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems related to the use of this product may be reported to FDA's MedWatch Adverse Reporting program online, by regular mail or by fax.

- **Online:** http://www.fda.gov/MedWatch/report.htm
- **Regular Mail:** Use postage-paid, pre-addressed Form FDA 3500 available at: http://www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- **Fax:** 1-800-FDA-0178

The Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg, subject to the recall, are identified by the NDC numbers stated on the product label.

Recalled Product information: The products that are being recalled are as follows:

Product Description	NDC#	Lot#	Expiry Date
Metformin HCl Extended Release 500 mg Tablets	53746-0178-01	All Unexpired Lots	All Unexpired Dates
Metformin HCl Extended Release 500 mg Tablets	53746-0178-05		
Metformin HCl Extended Release 500 mg Tablets	53746-0178-10		
Metformin HCl Extended Release 500 mg Tablets	53746-0178-90		
Metformin HCl Extended Release 500 mg Tablets	65162-0178-09		
Metformin HCl Extended Release 500 mg Tablets	65162-0178-10		
Metformin HCl Extended Release 500 mg Tablets	65162-0178-11		
Metformin HCl Extended Release 500 mg Tablets	65162-0178-50		
Metformin HCl Extended Release **750 mg** Tablets	53746-0179-01		
Metformin HCl Extended Release **750 mg** Tablets	65162-0179-10		

Sincerely,
Your Local Walmart & Sam’s Club Pharmacy