



Drug Recall

DATE OF RECALL: June 03, 2020

DRUG NAME: Metformin Hydrochloride Extended-Release Tablets

RECALLING FIRM: Amneal Pharmaceuticals LLC

REASON FOR RECALL: 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 lots within expiry of Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg, out of an abundance of caution.

FDA LINK: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceuticals-llc-issues-voluntary-nationwide-recall-metformin-hydrochloride-extended>

OTHER DETAILS: See FDA link.

RECALLED PRODUCT:

Product Description	NDC Number	Affected Lots	Expiration Date
Metformin HCl Extended Release 500 mg Tablets, 100 Count Bottles	53746-0178-01	All Lots Within Expiry	All Lots Within Expiry
Metformin HCl Extended Release 500 mg Tablets, 500 Count Bottles	53746-0178-05	All Lots Within Expiry	All Lots Within Expiry
Metformin HCl Extended Release 500 mg Tablets, 1000 Count Bottles	53746-0178-10	All Lots Within Expiry	All Lots Within Expiry
Metformin HCl Extended Release 500 mg Tablets, 100 Count Bottles	65162-0178-10	All Lots Within Expiry	All Lots Within Expiry
Metformin HCl Extended Release 500 mg Tablets, 1000 Count Bottles	65162-0178-11	All Lots Within Expiry	All Lots Within Expiry
Metformin HCl Extended Release 500 mg Tablets, 90 Count Bottles	53746-0178-90	All Lots Within Expiry	All Lots Within Expiry
Metformin HCl Extended Release 500 mg Tablets, 90 Count Bottles	65162-0178-09	All Lots Within Expiry	All Lots Within Expiry
Metformin HCl Extended Release 500 mg Tablets, 500 Count Bottles	65162-0178-50	All Lots Within Expiry	All Lots Within Expiry
Metformin HCl Extended Release 750 mg Tablets, 100 Count Bottles	53746-0179-01	All Lots Within Expiry	All Lots Within Expiry
Metformin HCl Extended Release 750 mg Tablets, 100 Count Bottles	65162-0179-10	All Lots Within Expiry	All Lots Within Expiry

