

Drug Recall

DATE OF RECALL: January 7, 2022

DRUG NAME: Metformin HCl ER 750 mg Tablets

RECALLING FIRM: Viona Pharmaceuticals, Inc

REASON FOR RECALL: This recall was issued due to the detection of N-Nitrosodimethylamine (NDMA) levels above the Acceptable Daily Intake Limit in one lot (M008132) in long term stability condition at a 17-month(s) time point interval.

FDA LINK: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/viona-pharmaceuticals-inc-issues-voluntary-nationwide-recall-metformin-hcl-extended-release-tablets-0>

OTHER DETAILS: N/A

RECALLED PRODUCT:

Product Description	NDC Number	Affected Lots	Expiration Date
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M008130	06/2022
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M008131	06/2022
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M008132	06/2022
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M008133	06/2022
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M010080	07/2022
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M010081	07/2022
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M011029	08/2022
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M011030	08/2022
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M011031	08/2022
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M011032	08/2022

Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M011304	08/2022
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M013394	09/2022
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M013395	09/2022
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M013396	09/2022
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M013966	09/2022
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M013967	09/2022
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M100831	12/2022
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M100832	12/2022
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M100833	01/2023
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M100834	01/2023
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M101267	01/2023
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M102718	01/2023
Metformin HCl ER 750 mg Tablets, 100 count	72578-0036-01	M102719	01/2023

