



Drug Recall

DATE OF RECALL: July 01, 2020

DRUG NAME: Metformin HCl Extended-Release 500mg Tablets

RECALLING FIRM: PD-Rx Pharmaceuticals, Inc

REASON FOR RECALL: This recall was issued due to CGMP deviations. The FDA analysis detected N-Nitrosodimethylamine (NDMA) impurity above the acceptable intake level.

FDA LINK: <https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=181853>

OTHER DETAILS: See FDA Link

RECALLED PRODUCT:

Product Name	NDC #	Affected Lots
Metformin HCl ER 500mg Tablets 30 Count	72789-0009-30	A20B02 exp. 12/31/2020 I19D03 exp. 12/31/2020 J19A98 exp. 12/31/2020 K19E32 exp. 12/31/2020 L19C86 exp. 12/31/2020
Metformin HCl ER 500mg Tablets 60 Count	72789-0009-60	I19D55 exp. 12/31/2020 I19F50 exp. 12/31/2020 K19A18 exp. 12/31/2020 K19D87 exp. 12/31/2020 L19B34 exp. 12/31/2020 L19D23 exp. 12/31/2020 L19E74 exp. 12/31/2020
Metformin HCl ER 500mg Tablets 90 Count	72789-0009-90	I19E91 exp. 12/31/2020 I19F33 exp. 12/31/2020 J19B88 exp. 12/31/2020 J19E70 exp. 12/31/2020 K19D26 exp. 12/31/2020 L19A65 exp. 12/31/2020
Metformin HCl ER 500mg Tablets 180 Count	72789-0009-93	I19C21 exp. 8/21/2020 I19C57 exp. 12/31/2020 J19C21 exp. 12/31/2020 J19C67 exp. 12/31/2020 K19B53 exp. 12/31/2020 L19C77 exp. 12/31/2020 L19E44 exp. 12/31/2020