

PRESCRIPTION MEDICATION RECALL



Metformin Hydrochloride Extended Release tablets

About this recall.

Your safety, health and well-being are important to us. We want to let you know that U.S. Food and Drug Administration (FDA) recently announced voluntary, nationwide recalls of Metformin Hydrochloride Extended Release tablets. The affected products are made and/or distributed by Amneal Pharmaceuticals LLC, Apotex Corp. AvKARE, Granules Pharmaceuticals Inc., Lupin Pharmaceuticals Inc. and Teva Pharmaceuticals USA, Inc.

Amneal Pharmaceuticals LLC – all lots (as of May 29, 2020)

MEDICATION NAME/STRENGTH	NDC NUMBER
Metformin Hydrochloride Extended Release 500 mg tablets	53746-178-01, 53746-178-05, 53746-178-10, 53746-178-90, 65162-178-09, 65162-178-10, 65162-178-11, 65162-178-50
Metformin Hydrochloride Extended Release 750 mg tablets	53746-179-01, 53746-0179-05, 65162-179-10

Apotex Corp. – all lots (as of May 27, 2020)

MEDICATION NAME/STRENGTH	NDC NUMBER
Metformin Hydrochloride Extended Release 500 mg tablets	60505-0260-1

AvKARE – all lots (as of June 4, 2020)

MEDICATION NAME/STRENGTH	NDC NUMBER
Metformin Hydrochloride Extended Release 500 mg tablets	42291-0610-90, 42291-0610-18, 42291-0610-36, 42291-0610-10, 50268-0531-15
Metformin Hydrochloride Extended Release 750 mg tablets	42291-0611-90, 42291-0611-18, 42291-0611-50

Together, all the way.®



Granules Pharmaceuticals, Inc. – 12 lots (as of July 3, 2020)

MEDICATION NAME/STRENGTH	LOT NUMBER*	NDC NUMBER
Metformin Hydrochloride Extended Release 750 mg tablets (100 count bottles)	4920003A, 4920004A, 4920005A, 4920009A, 4920010A, 4920011A, 4920012A, 4920013A, 4920014A, 4920015A, 4920016A	70010-492-01
Metformin Hydrochloride Extended Release 750 mg tablets (500 count bottles)	4920005B	70010-492-05

Lupin Pharmaceuticals, Inc. – all lots (as of July 8, 2020)

MEDICATION NAME/STRENGTH	NDC NUMBER
Metformin Hydrochloride Extended Release 500 mg tablets	68180-338-01, 68180-336-07
Metformin Hydrochloride Extended Release 1000 mg tablets	68180-339-09, 68180-337-07

Teva Pharmaceuticals USA, Inc. – 14 lots (as of June 2, 2020)

MEDICATION NAME/STRENGTH	LOT NUMBER*	NDC NUMBER
Metformin Hydrochloride Extended Release 500 mg tablets	1329548A, 1338302M, 1348968M, 1348969M, 1348970M, 1376339M	62037-571-01
	1323460M, 1330919M, 1338300A, 1341135M, 1391828M	62037-571-10
Metformin Hydrochloride Extended Release 750 mg tablets	1333338M, 1333339A	62037-577-01
	1354471A	62037-577-10

Why this medication was recalled.

Several lots were found to contain a substance called N-nitrosodimethylamine (NDMA), which may cause cancer in humans.

What this medication is used to treat.

Metformin Hydrochloride Extended Release is used to improve blood sugar levels in adults with type 2 diabetes mellitus, in addition to diet and exercise.

Check the label on your medication to find out if it was recalled.

Look for the information listed above. If everything matches, your medication was recalled. If it doesn't match, your medication wasn't recalled. If you need help finding this information, you can contact the pharmacy that filled your prescription.

Here's what you can do if your medication was recalled.

- › Contact the company that made and/or distributed the medication to find out what you should do with it.
 - **Amneal:** Call 833.582.0812, Monday-Friday, 8:00 am-5:00 pm EST or email AmnealProductRecallDS@amneal.com.
 - **Apotex Corp.:** Call 800.706.5575, Monday-Friday, 8:30 am-5:00 pm EST or email UScustomerservice@Apotex.com.
 - **AvKARE:** Call 931.908.0014, Monday-Friday 8:00 am-5:00 pm CST or email drugsafety@avkare.com or customerservice@avkare.com.
 - **Granules:** Contact Inmar, a company that manages the return of recalled prescription medications, at 888.985.9117, Monday-Friday, 9:00 am-5:00 pm EST or email rxrecalls@inmar.com. They'll send you materials and instructions for how to return your medication and request a refund.
 - **Lupin:** Contact Inmar, a company that manages the return of recalled prescription medications, at 855.532.1856, Monday-Friday, 9:00 am-5:00 pm EST. They'll send you materials and instructions for how to return your medication and request a refund.
 - **Teva:** Contact Inmar, a company that manages the return of recalled prescription medications, at 855.532.1850, Monday-Friday, 9:00 am-5:00 pm EST or email tevarecalls@inmar.com. They'll send you materials and instructions for how to return your medication and request a refund.
- › Call your doctor's office to find out how this affects your health and/or treatment, and/or if you've had any recent problems with this medication. We've also let your doctor know that you may have been affected by this recall.
- › Go to the U.S. Food and Drug Administration (FDA)'s website to learn more about the recall and next steps.
 - [Apotex recall](#)
 - [Amneal recall](#)
 - [Granules recall](#)
 - [Lupin recall](#)
 - [Teva recall](#)

* The lot number is either on the label printed by the pharmacy or stamped onto the bottle (or package) itself. It may or may not be listed as "LOT."



Para obtener ayuda en español llame al número en su tarjeta de Cigna.

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