June 8, 2020

Urgent: Amneal Pharmaceuticals LLC issues voluntary market withdrawal of Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg

Dear ASD Healthcare Customer:

Amneal Pharmaceuticals is initiating a voluntary market withdrawal of Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg with the knowledge of the U.S. Food and Drug Administration (FDA). The affected lot information is listed below.

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.

Amneal provided the following affected NDC information:

Please refer to page 2 of the official Amneal notice in the following pages for specific lot information.

<table>
<thead>
<tr>
<th>Product Description</th>
<th>NDC</th>
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</table>
To comply with the withdrawal, we ask for your cooperation in taking the following action:

- Please examine your stock immediately to determine if you have the above-mentioned lot on hand. If you have product from this lot, cease use immediately and quarantine the affected product.
- **Please contact Inmar directly at 855-532-1851 or E-mail to:** [RxRecalls@inmar.com](mailto:RxRecalls@inmar.com) **to request a Product Return Kit.**
- A Return Kit and prepaid shipping label will be sent to you by Inmar for the product return.
- Include a copy of the Recall Response Form indicating the product to be returned within the product return kit. Appropriate credit for product returns will be issued upon receipt of said product with the return kit. All recalled product returned without a return kit may delay the issuance of your credit.

For the full recall notice, please view the attached document on the following pages.

If you have any questions or concerns, please contact ASD Healthcare’s customer service at **800.746.6273.**
URGENT MARKET RECALL – CONSUMER LEVEL - INITIATED 06/03/2020

Metformin Hydrochloride Extended Release Tablets, USP
500 mg and 750 mg

Dear Valued Customer:

AMNEAL PHARMACEUTICALS LLC is voluntarily recalling Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg to the Consumer Level. 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. Further scientific evaluations are ongoing at Amneal.

Customers who purchased the affected product directly from Amneal may call Amneal at 1-833-582-0812 or email AmnealProductRecallDS@amneal.com, Monday – Friday, 8:00 am – 5:00 pm, EST, for further information.

The NDC numbers provided below are included in this recall. A listing of the Metformin Hydrochloride Extended Release, USP, Tablet 500 mg and 750 mg lots that are affected by this recall are included with this recall notification package.

500 mg strength: First Distribution Date: 12/10/2019

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750 mg strength: First Distribution Date: 10/4/2019

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<td>Bulk Box</td>
</tr>
<tr>
<td>65162-179-10</td>
<td>100 count bottles</td>
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</table>

Please perform the following activities:

- Examine your inventory immediately for the NDC numbers specified above and immediately cease distribution of this product being recalled.
- Promptly complete the attached Recall Stock Response Form even if you have no product to return.
- Wholesalers/Distributors are requested to provide their customer list to Amneal in Excel format to MetforminERRRecall@amneal.com within 48 hours from receipt of this letter.
Amneal will send Dear Retailer, Recall Notification Letters by UPS to retail pharmacies providing information respective to this recall and with instructions for product returns from Retailers and Consumers.

- Submit the completed Recall Stock Response form(s) by any of the below methods:
  - Fax to: 631-983-2597
  - Email to: MetforminERRRecall@amneal.com
  - Mail to: Amneal Pharmaceuticals, Recall Coordinator, 50 Horseblock Rd, Brookhaven, NY 11791 using the prepaid envelope included in the recall package.

**Product to return**

Customers who have inventory of the affected lots of Metformin HCl ER Tablets, USP 500 mg or 750 mg to return should contact Inmar directly at 855-532-1851 or by E-mail RxRecalls@inmar.com, Monday – Friday, 8:00 am – 5:00 pm, EST, to arrange for product return.

A Return Kit and prepaid shipping label will be sent to you for product return. Appropriate credit for product returns will be issued upon receipt of said product with the return kit. All recalled product returned without a return kit may delay the issuance of your credit.

This recall is being conducted with the knowledge of the U.S. Food & Drug Administration. Your cooperation and prompt response to this notice is appreciated.

**Medical Inquiries, Adverse Event Reporting or Quality Concerns**

For Medical Inquiries or to report Adverse Events, or quality problems experienced with the use of this product, please contact Amneal Drug Safety by phone at 1-877-835-5472, Monday - Friday, 8:00 am – 6:00 pm, EST, or e-mail at DrugSafety@amneal.com.

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

- Complete and submit the report Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- **Regular Mail or Fax:** Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

**Recalled Lots**

The following is a listing of the Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg lots associated with this recall.

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