

COMPANY ANNOUNCEMENT

Amneal Pharmaceuticals LLC Issues Voluntary Nationwide Recall of Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg, Due to Detection of N-Nitrosodimethylamine (NDMA) Impurity

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

May 29, 2020

FDA Publish Date:

June 01, 2020

Product Type:

Drugs

Reason for Announcement:

Due to detection of N-Nitrosodimethylamine (NDMA)

Company Name:

Amneal Pharmaceuticals LLC

Brand Name:

Amneal

Product Description:

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

Company Announcement

Amneal Pharmaceuticals LLC Bridgewater, New Jersey (Amneal), is voluntarily recalling all lots of Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg, within expiry to the Retail 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.

To date, Amneal has not received any reports of adverse events that have been confirmed to be directly related to this recall.

Amneal's Metformin Hydrochloride Immediate Release Tablets, USP are not affected by this recall.

Risk Statement: NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant found in water and foods, including meats, dairy products and vegetables.

Metformin HCl Extended Release Tablets, USP, 500 mg and 750 mg, manufactured by Amneal, are prescription, solid oral products that are indicated as an adjunct to diet and exercise to improve blood sugar control in adults with type 2 diabetes mellitus.

The Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg, subject to the recall, are identified by the NDC numbers stated on the product label.

Metformin HCl Extended Release Tablets, USP, 500 mg

53746-178-01	100 count bottles
53746-178-05	500 count bottles
53746-178-10	1000 count bottles
53746-178-90	90 count bottles
53746-178-Bulk	Bulk Box
65162-178-09	90 count bottles
65162-178-10	100 count bottles
65162-178-11	1000 count bottles
65162-178-50	500 count bottles

Metformin HCl Extended Release Tablets, USP, 750 mg

53746-179-01	1000 count bottles
53746-179-Bulk	Bulk Box
65162-179-10	100 count bottles

The affected Metformin Hydrochloride Extended Release Tablets, USP, 500 mg and 750 mg, lots were distributed nationwide in the US directly to Wholesalers, Distributors, Retailers and Repackagers.

Amneal is notifying its direct customers via mail (UPS Standard Overnight) by mailing a recall notification letter and is arranging for return of all the recalled product. Anyone with an existing inventory of the product should quarantine the recalled lots immediately.

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

Retailers who have Metformin Hydrochloride Extended Release Tablets, USP, 500 mg or 750 mg, which are being recalled, should cease dispensing and contact Inmar at 855-532-1851 or via email at Rxcalls@inmar.com (mailto:Rxcalls@inmar.com) Monday – Friday, 8:00 am – 5:00 pm, EST, to arrange for product return.

If you would like to report any adverse reactions or quality problems experienced with the use of this product you may contact Amneal Drug Safety by phone at 1-877-835-5472, Monday - Friday, 8:00 am – 6:00 pm, EST, or via e-mail at DrugSafety@amneal.com (mailto:DrugSafety@amneal.com).


Any 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 (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>)
- Regular Mail or Fax: Download form (</safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>) 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Safe Harbor Statement


Certain statements contained herein, regarding matters that are not historical facts, may be forward-looking statements (as defined in the Private Securities Litigation Reform Act of 1995). Such forward-looking statements include statements regarding management’s intentions, plans, beliefs, expectations or forecasts for the future, including, among other things, future operating results and financial performance, product development and launches, integration strategies and resulting cost reduction, market position and business strategy. Words such as “may,” “will,” “could,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “assume,” “continue,” and similar words are intended to identify estimates and forward-looking statements.


The reader is cautioned not to rely on these forward-looking statements. These forward-looking statements are based on current expectations of future events. If the underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Amneal Pharmaceuticals, Inc. (the “Company”). Such risks and uncertainties include, but are not limited to, risks related to the products and recall thereof described in this press release. A further list and descriptions of these risks, uncertainties and other factors can be found in the Company’s most recently filed Annual Report on Form 10-K for the fiscal year ended December 31, 2019 as supplemented by any subsequently filed Quarterly Reports on Form 10-Q. Copies of these filings are available online at www.sec.gov (www.sec.gov), www.amneal.com (<http://www.amneal.com/>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) or on request from the Company.

Company Contact Information

Consumers:


Amneal

 1-833-582-0812

 AmnealproductrecallDS@amneal.com (<mailto:AmnealproductrecallDS@amneal.com>)

Media:

Candis Edwards

 Information@amneal.com (<mailto:Information@amneal.com>)

Product Photos

NDC 65162-178-10

Metformin Hydrochloride Extended-release Tablets, USP

500 mg

PHARMACIST: Please dispense with attached Patient Information leaflet.



Rx only
100 Tablets



Each extended-release tablet contains:
Metformin Hydrochloride, USP500 mg

Usual Dosage: See enclosed package insert for dosage information.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Dispense in tight, light-resistant container as defined in the USP.

Manufactured by: **Amneal Pharmaceuticals Pvt. Ltd. Oral Solid Dosage Unit**
Ahmedabad 382213, INDIA

Distributed by: **Amneal Pharmaceuticals LLC**
Bridgewater, NJ 08807

Mfg. Lic. No. G/25/2137 Rev. 08-2019-03



NDC 65162-178-09

Metformin Hydrochloride Extended-release Tablets, USP

500 mg

PHARMACIST: Please dispense with attached Patient Information leaflet.



Rx only
90 Tablets



Each extended-release tablet contains:
Metformin Hydrochloride, USP500 mg

Usual Dosage: See enclosed package insert for dosage information.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Dispense in tight, light-resistant container as defined in the USP.

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Bridgewater, NJ 08807

Mfg. Lic. No. G/25/2137 Rev. 08-2019-03



NDC 65162-178-50

Metformin Hydrochloride Extended-release Tablets, USP

500 mg

PHARMACIST: Please dispense with attached Patient Information leaflet.



Rx only
500 Tablets



Each extended-release tablet contains:
Metformin Hydrochloride, USP500 mg

Usual Dosage: See enclosed package insert for dosage information.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Dispense in tight, light-resistant container as defined in the USP.

Manufactured by: **Amneal Pharmaceuticals Pvt. Ltd. Oral Solid Dosage Unit**
Ahmedabad 382213, INDIA

Distributed by: **Amneal Pharmaceuticals LLC**
Bridgewater, NJ 08807

Mfg. Lic. No. G/25/2137 Rev. 08-2019-03



NDC 53746-178-90

Metformin Hydrochloride Extended-Release Tablets, USP

500 mg

PHARMACIST: PLEASE DISPENSE WITH ATTACHED PATIENT INFORMATION LEAFLET

Rx only
90 TABLETS



Each extended-release tablet contains: Metformin Hydrochloride, USP 500 mg

Usual Dosage: See enclosed package insert for dosage information.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Dispense in tight, light-resistant container as defined in the USP.

Distributed by: **Amneal Pharmaceuticals LLC**
Bridgewater, NJ 08807

Rev. 03-2018-02



NDC 65162-178-11

Metformin Hydrochloride Extended-release Tablets, USP

500 mg

PHARMACIST: Please dispense with attached Patient Information leaflet.

Rx only
1000 Tablets



Each extended-release tablet contains: Metformin Hydrochloride, USP500 mg

Usual Dosage: See enclosed package insert for dosage information.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

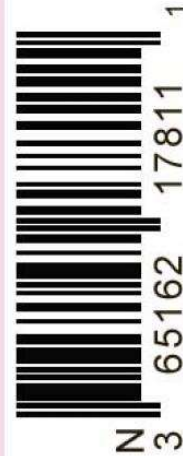
Dispense in tight, light-resistant container as defined in the USP.

Manufactured by:
Amneal Pharmaceuticals Pvt. Ltd.
Oral Solid Dosage Unit
Ahmedabad 382213, INDIA

Distributed by:
Amneal Pharmaceuticals LLC
Bridgewater, NJ 08807

Mfg. Lic. No. G/25/2137

Rev. 08-2019-03



NDC 65162-178-11

Metformin Hydrochloride Extended-release Tablets, USP

500 mg

PHARMACIST: Please dispense with attached Patient Information leaflet.

 Rx only
1000 Tablets



Each extended-release tablet contains:
Metformin Hydrochloride, USP500 mg

Usual Dosage: See enclosed package insert for dosage information.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Dispense in tight, light-resistant container as defined in the USP.

Manufactured by:
Amneal Pharmaceuticals Pvt. Ltd.
Oral Solid Dosage Unit
Ahmedabad 382213, INDIA

Distributed by:
Amneal Pharmaceuticals LLC
Bridgewater, NJ 08807

Mfg. Lic. No. G/25/2137
Rev. 08-2019-03


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NDC 53746-178-05

Metformin Hydrochloride Extended-Release Tablets, USP

500 mg

PHARMACIST: PLEASE DISPENSE WITH ATTACHED PATIENT INFORMATION LEAFLET

 Rx only
500 TABLETS



Each extended-release tablet contains:
Metformin Hydrochloride, USP 500 mg

Usual Dosage: See enclosed package insert for dosage information.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Dispense in tight, light-resistant container as defined in the USP.

Distributed by: **Amneal Pharmaceuticals LLC**
Bridgewater, NJ 08807

Rev. 03-2018-02


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NDC 53746-178-10

Metformin Hydrochloride Extended-Release Tablets, USP

500 mg

PHARMACIST: PLEASE DISPENSE WITH ATTACHED PATIENT INFORMATION LEAFLET

 Rx only
1000 TABLETS



Each extended-release tablet contains:
Metformin Hydrochloride, USP 500 mg

Usual Dosage: See enclosed package insert for dosage information.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Dispense in tight, light-resistant container as defined in the USP.

Distributed by: **Amneal Pharmaceuticals LLC**
Bridgewater, NJ 08807

Rev. 03-2018-02


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NDC 53746-179-10

Metformin Hydrochloride Extended-Release Tablets, USP

750 mg

PHARMACIST: PLEASE DISPENSE WITH ATTACHED PATIENT INFORMATION LEAFLET

Rx only
1000 TABLETS

amneal

Each extended-release tablet contains:
Metformin Hydrochloride, USP 750 mg

Usual Dosage: See enclosed package insert for dosage information.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Dispense in tight, light-resistant container as defined in the USP.

Distributed by: **Amneal Pharmaceuticals LLC**
Bridgewater, NJ 08807

Rev. 03-2018-02



NDC 65162-179-10

Metformin Hydrochloride Extended-release Tablets, USP

750 mg

PHARMACIST: Please dispense with attached Patient Information leaflet.

Rx only
100 Tablets

amneal

Each extended-release tablet contains:
Metformin Hydrochloride, USP750 mg

Usual Dosage: See enclosed package insert for dosage information.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Dispense in tight, light-resistant container as defined in the USP.

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