August 21, 2020 **COM-2020-059**

RECALL NOTIFICATION

FDA PUBLICATION DATE: August 20, 2020

DRUG NAME: Metformin Hydrochloride Extended-Release 500mg and 750mg

COMPANY: Bayshore Pharmaceuticals, LLC.

REASON: Detection of N-Nitrosodimethylamine (NDMA)

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate you with the latest up-to-date information on drug safety. It is for this reason that we are notifying you that on August 20, 2020, the U.S. Food and Drug Administration (FDA) published a safety communication for Metformin Hydrochloride Extended=Release (500mg and 750mg) indicating the detection of N-Nitrosodimethylamine (NDMA) in excess.

Affected Product	Strengths	NDC	Lot
Metformin Hydrochloride Extended-release tablets USP	500mg	76385-128-10	18641
	750mg	76385-129-01	18657

Pharmacy required actions(s):

- Identify if the product is inventory and immediately stop using and dispensing it.
- Contact all members that in the previous 90 days received the recalled medication.
- Advise patients to continue taking their medication and contact their physician for advice regarding an alternative treatment, and if they have experienced any problems that may be related to taking or using the recalled drug product.

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Contact information:

- Bayshore Pharmaceuticals, LLC to the phone: (**877)-372-6093**.
    - If the patient wants to return the product, may contact Bayshore's product recall processor Qualanex, LLC at (**888)-504-2013.**

Remember, you can report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download FDA Form 3500 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.

Additional information can be found at:

- MedWatch: The FDA Safety Information and Adverse Event Reporting Program
- https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-metformin

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference:

- Center for Drug Evaluation and Research. (2020, August 20). Bayshore Pharmaceuticals, LLC Issues Voluntary Nationwide Recall of Metformin Hydrochloride Extended-Release Tablets USP, 500 mg and 750 mg Due to the Detection of N-Nitrosodimethylamine (NDMA) Impurity. Retrieved August 21, 2020, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bayshore-pharmaceuticals-llc-issues-voluntary-nationwide-recall-metformin-hydrochloride-extended

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