pharmpIX

Voluntary Recall: Pravastatin Sodium Tablets by International Laboratories - Mislabeling

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform you that on August 10, 2017 the FDA issued a statement notifying the voluntary retirement of one lot of Pravastatin Sodium Tablets USP 40 mg packaged in bottles of 30 tablets manufactured by International Laboratories, LCC due to mislabeling. The product is labeled as Pravastatin Sodium Tablets 40mg but contained Bupropion Hydrochloride XL 300mg tablets. The affected lots are detailed in the following table.

| Product | Affected Lot | NDC |
|--------------------------------|--------------|--------------|
| Pravastatin Sodium Tablets USP | 115698A | 54458-925-16 |
| 40mg | | |

The Pharmacy must:

- 1. Identify if they have the product in inventory and immediately stop using and dispensing the product.
- For questions regarding this recall can contact International Laboratories, LCC at 727-322-7146 or e-mail address <u>sutka.veselinovic@internationallabs.com</u> on Monday – Friday 8AM - 5PM EST.

For additional information visit:

https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm571066.htm

Department of Clinical Pharmacy

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