Clopidogrel Tablets USP, 75 mg by International Laboratories: Recall - Product Mislabeling

[Posted 01/10/2018]

AUDIENCE: Pharmacy, Patient

ISSUE: International Laboratories, LLC is voluntarily recalling Lot# 117099A of Clopidogrel Tablets, USP 75 mg, packaged in bottles of 30 tablets, to the consumer level due to mislabeling. The product is labeled as Clopidogrel Tablets USP, 75 mg but may contain Clopidogrel 75mg or Simvastatin Tablets USP 10 mg.

Missed doses of Clopidogrel increases the risk of heart attack and stroke which can be life threatening. Patients should not stop taking clopidogrel without talking to their prescribing physician. Additionally, unintentional consumption of simvastatin could include the common side effects associated with its use and may cause fetal harm when administered to a pregnant woman. Simvastatin occasionally causes myopathy which is a disease of the muscles. Finally, allergic reactions are also possible and could also be life threatening.

- NDC# 54458-888-16
- Lot# 117099A

BACKGROUND: Clopidogrel Tablets USP 75 mg are a platelet inhibitor (blood thinner) indicated for the use in patients with acute coronary syndrome, recent myocardial infarction (MI), recent stroke, or established peripheral arterial disease. Clopidogrel tablets have been shown to reduce the rate of MI and stroke.

The product was distributed nationwide and delivered to the distribution centers in Arkansas, Georgia, Indiana, California and Maryland, and distributed to retail stores in all US States.

RECOMMENDATION: International Laboratories, LLC is notifying distributors and customers by letter and is arranging for return of all recalled products. Consumers who have purchased this product should stop using and return the product to the location of purchase for a full refund. For questions regarding return of product please call Inmar at 855-258-7280 or via email internationallabs@inmar.com or by using mailing address

Recall Coordinator, 635 Vine St., Winston Salem, NC 27101. Inmar's business hours are (Monday – Friday 9 AM – 5 PM EST).

Consumers should also contact their physician or healthcare provider if they are experiencing any health concerns that may be related to taking or using this drug product.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form 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

[01/10/2018 - Press Release - International Laboratories]