

URGENT NOTICE

TYPE: Drug Recall

Product mislabeling by International Laboratories

Drug Name: **Clopidogrel Tablets USP, 75 mg**

NDC# 54458-888-16 Lot# 117099A

Audience: Pharmacy, patient

Date: **01/11/2018**



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.

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).

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