Dabigatran Recalled Over Potential Carcinogen

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Ascend Laboratories LLC is recalling 10 lots of the oral anticoagulant dabigatran etexilate capsules (75 mg and 150 mg) because of unacceptable levels of a potential carcinogen.

The nationwide recall, to the consumer level, is due to the detection of the nitrosamine impurity, N-nitroso-dabigatran, which may increase the risk of cancer with prolonged exposure to levels higher than acceptable.

To date, Ascend Laboratories has not received any reports of adverse events related to this recall.

The recalled product was distributed nationwide to wholesalers, distributors, and retailers in the United States from June 2022 to October 2022.

Complete details of the recalled product, including national drug code, lot numbers, expiration dates, and configuration/counts, are provided in a company announcement that was posted on the US Food and Drug Administration (FDA) website.

The company is advising patients who have any dabigatran that has been recalled to continue taking their medication and to contact their physician for advice regarding an alternative treatment.

Wholesalers/distributors and pharmacies with an existing inventory of the affected lots should stop use and distribution and quarantine the product immediately. Wholesalers and distributors should also recall the distributed product.

Questions regarding this recall can call Ascend Laboratories LLC at 877.272.7901 (24 hours, 7 days a week).

Problems with this product should be reported to the FDA through MedWatch, its adverse event reporting program.

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