

Drug Recall

DATE OF RECALL: March 22, 2023

DRUG NAME: Dabigatran Etexilate Mesylate Capsules

RECALLING FIRM: Ascend Laboratories LLC.

REASON FOR RECALL: This recall was issued due to the presence of a nitrosamine, N-nitroso-dabigatran, above the established Acceptable Daily Intake (ADI) level.

FDA LINK: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/ascend-laboratories-llc-issues-voluntary-nationwide-recall-dabigatran-etexilate-capsules-usp-75-mg>

OTHER DETAILS: N/A

RECALLED PRODUCT:

Product Description	NDC Number	Lot Number	Expiration Date
Dabigatran Etexilate Mesylate 150mg Capsules, 60 count	67877-0475-60	22142448	05/2024
		22142449	05/2024
		22142450	05/2024
		22143845	07/2024
Dabigatran Etexilate Mesylate 75mg Capsules, 60 count	67877-0474-60**	22142462	05/2024
		22142463	05/2024
		22142464	05/2024
		22143000	06/2024
		22143001	06/2024
		22143002	06/2024