

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

This is to inform you of a product recall involving Dabigatran Etextilate Mesylate (EM) Capsules, 7.5 and 150 mg. Please reference lot-specific information included below.

An out-of-specification (OOS) result was observed during the analysis of Dabigatran Etextilate Mesylate Capsules (150 mg), Batch# 24142462. The observed level of the N-nitroso-dabigatran impurity was found to be 1.48 ppm, exceeding the specified limit of not more than (NMT) 1.33 ppm. As part of the impact assessment, other batches which are within the shelf life were analyzed, including stability-incubated products and finished product batches for different strengths (75 mg, 110 mg, and 150 mg). The analysis identified a total of six OOS findings.

Dabigatran is in a class of anticoagulant medications called direct thrombin inhibitors. Dabigatran is used to decrease the risk of stroke and blood clots in patients with a serious heart rhythm problem called nonvalvular atrial fibrillation. Dabigatran is also used to treat and prevent blood clots (e.g., deep vein thrombosis, pulmonary embolism) from occurring again in patients who already have received other medicines. It is also used to prevent deep vein thrombosis and pulmonary embolism after hip replacement surgery. It works by preventing harmful clots from forming in the blood vessels.

Long-term ingestion of N-nitrosodabigatran may be associated with a theoretical potential increased cancer risk in humans, but there is no immediate risk to patients taking this medication.

Nitrosamines are common in water and foods, including cured and grilled meats, dairy products and vegetables. Everyone is exposed to some level of nitrosamines. These impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time.

Our firm began shipping this product on July 16, 2024. Immediately examine your inventory and quarantine product subject to recall for the lot numbers specified in the table below.

Product	Lot	Initial	Quantity
Name	Number	Distribution Date	Distributed

1	Dabigatran 24142192 150 mg	April 2026	60 capsules/ bottle	67877- September 475-60 17,2024	3,097
	EM Capsules				
2	Dabigatran 24142193 150 mg	April 2026	60 capsules/ Bottle	67877- July 16, 475-60 2024	2,078
	EM Capsules				
3	Dabigatran 24142194 150 mg	April 2026	60 capsules/ Bottle	67877- July 24, 475-60 2024	3,828
	EM Capsules				
4	Dabigatran 24142463 150 mg	May 2026	60 capsules/ Bottle	67877- July 16, 475-60 2024	1,801
	EM Capsules				
5	Dabigatran 24142328 75 mg	May 2026	60 capsules/ Bottle	67877- August 9, 474-60 2024	97
	EM Capsules				
6	Dabigatran 24142329 75 mg	May 2026	60 capsules/ Bottle	67877- July 24, 474-60 2024	73
	EM Capsules				
7	Dabigatran 24142330 75 mg	May 2026	60 capsules/ bottle	67877- August 26, 474-60 2024	1,441
	EM Capsules				
Total Distributed					12,415