Ascend – Recall of dabigatran etexilate capsules

- On March 22, 2023, Ascend Laboratories announced a consumer-level recall of dabigatran etexilate capsules, 75 mg and 150 mg, due to the presence of a nitrosamine, N-nitroso-dabigatran, above the established FDA acceptable daily intake level.
    - Other dabigatran etexilate capsule products made by other manufacturers that are not being recalled are available for use.
- These lots were distributed nationwide between June 2022 to October 2022.

Product Description	NDC#	Lot# (Expiration Date)
Dabigatran 150 mg capsules	67877-04-7560	22142448 (5/2024); 22142449 (5/2024); 22142450 (5/2024); 22143845 (7/2024)
Dabigatran 75 mg capsules	67877-04-7460	22142462 (5/2024); 22142463 (5/2024); 22142464 (5/2024); 22143000 (6/2024); 22143001 (6/2024); 22143002 (6/2024)

- Dabigatran etexilate is used as an oral anticoagulant to lower the risk of stroke and blood clots.
- 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.
- Patients who are currently using the recalled dabigatran etexilate capsules should continue taking their medication and contact their physician for advice regarding an alternative treatment. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to using these drug products.
- Anyone with an existing inventory of the recalled product should stop use, distribution, and quarantine the product immediately and arrange for return.
- Contact Ascend Laboratories by phone at **1-877-272-7901** for questions regarding this recall.