*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.*

Please be advised that Breckenridge Pharmaceutical, Inc. (Breckenridge) is performing a Retail Level Class II Recall of Duloxetine Delayed-Release Capsules, USP, 60mg, manufactured by Towa Pharmaceutical Europe, S.L. This Retail Level Recall affects the lots in the table below.

Only the lots in the table below are being recalled due to presence of Nitrosamine Drug Substance Impurity (NDSRI), N-nitroso-duloxetine, above the proposed interim limit.

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. To date, Breckenridge is not aware of reports of adverse events that have been assessed to be related to this recall.

This recall is being initiated with the knowledge of the Food and Drug Administration and should be carried out to the **Retail Level.**

| Product | Size | NDC Number | Affected Lot | Exp Date |
|---|---|---|---|---|
| Duloxetine Delayed -Release Capsules USP, 60 mg | 90-count | 51991-748-90 | 230035C | 11/2025 |
| Duloxetine Delayed-Release Capsules USP, 60 mg | 90-count | 51991-748-90 | 230101C | 12/2025 |