

*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 Recall of **Duloxetine Delayed-Release Capsules, USP, 40mg**, manufactured by Towa Pharmaceutical Europe, S.L. **Only the lot listed below** are being recalled due to presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-nitroso-duloxetine, above the proposed interim limit.

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:** Duloxetine Delayed-Release Capsules USP, 40 mg 30 count

**NDC NUMBER:** 51991-750-33

**LOT NUMBER:** 230199

**EXPIRATION DATE:** 01/2026