

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, 30mg and 60mg**, manufactured by Towa Pharmaceutical Europe, S.L. This Retail Level Recall affects **the lots in the table below.**

Only the lots listed in the table 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	Size	NDC Number	Affected Lot #	Exp Date
Duloxetine Delayed-Release Capsules USP, 60 mg	1000-count	51991-748-10	240987C	04/2027
Duloxetine Delayed-Release Capsules USP, 60 mg	1000-count	51991-748-10	241014C	04/2027
Duloxetine Delayed-Release Capsules USP, 30 mg	90-count	51991-747-90	230201C	01/2026
Duloxetine Delayed-Release Capsules USP, 30 mg	90-count	51991-747-90	230471C	01/2026

Duloxetine Delayed-
Release Capsules USP,
30 mg

1000-
count

51991-
747-10

230288C

01/2026