

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

Only the lots listed below are being recalled due to presence of Nitrosamine Drug Substance Related Impurity (NDSRJ), N-nitroso-duloxetine, at elevated levels close to 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 Name	NDC	Lot #	Exp Date	Pack Size
Duloxetine Delayed Release Capsules, 60mg	51991-748-10	240978C	April 2027	1000 count
Duloxetine Delayed Release Capsules, 60mg	51991-748-10	241052C	April 2027	1000 count
Duloxetine Delayed Release Capsules, 60mg	51991-748-90	241074C	May 2027	90-count
Duloxetine Delayed Release Capsules, 30mg	51991-747-10	241180C	April 2027	1000-count

Duloxetine Delayed Release Capsules, 60mg	51991-748-90	240317	February 2027	90-count
Duloxetine Delayed Release Capsules, 60mg	51991-748-90	240318	February 2027	90-count
Duloxetine Delayed Release Capsules, 60mg	51991-748-90	240316	January 2027	90-count
Duloxetine Delayed Release Capsules, 60mg	51991-748-90	240315C	February 2027	90-count
Duloxetine Delayed Release Capsules, 60mg	51991-748-90	240373C	February 2027	90-count
Duloxetine Delayed Release Capsules, 60mg	51991-748-90	232311	November 2026	90-count
Duloxetine Delayed Release Capsules, 60mg	51991-748-90	240370C	February 2027	90-count
Duloxetine Delayed Release Capsules, 60mg	51991-748-90	240375C	February 2027	90-count
Duloxetine Delayed Release	51991-748-90	240413C	February 2027	90-count

Capsules, 60mg

***\*\*Distribution Range: April 11, 2024 – July 31, 2025***