

*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, 20mg, 30mg, 60mg**, manufactured by Towa Pharmaceutical Europe, S.L.

The lots listed below are being recalled due to presence of Nitrosamine Drug Substance Related Impurity (NDSRJ), 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.

NDC	Product Name	Batch #	Exp. Date	Pack Size
51991-746-05	Duloxetine Delayed Release Capsules, USP 20mg	220456	Feb-25	500's bottle
51991-747-90	Duloxetine Delayed Release Capsules, USP 30mg	220265	Feb-25	90's bottle
51991-747-90	Duloxetine Delayed Release Capsules, USP 30mg	220088	Nov-24	90's bottle
51991-747-90	Duloxetine Delayed Release Capsules, USP 30mg	220267	Feb-25	90's bottle
51991-747-10	Duloxetine Delayed Release Capsules, USP 30mg	220256	Feb-25	1000's bottle
51991-747-10	Duloxetine Delayed Release Capsules, USP 30mg	220225	Jan-25	1000's bottle
51991-747-10	Duloxetine Delayed Release Capsules, USP 30mg	220269	Feb-25	1000's bottle
51991-748-90	Duloxetine Delayed Release Capsules, USP 60mg	230028C	Nov-25	90's bottle
51991-748-90	Duloxetine Delayed Release Capsules, USP 60mg	230106C	Dec-25	90's bottle
51991-748-90	Duloxetine Delayed Release Capsules, USP 60mg	230170C	Dec-25	90's bottle

51991-748-90	Duloxetine Delayed Release Capsules, USP 60mg	220039	Dec-24	90's bottle
51991-748-90	Duloxetine Delayed Release Capsules, USP 60mg	220363	Feb-25	90's bottle