URGENT: DRUG RECALL
INTERNAL RECALL #: 505

June 04, 2026

51991-00505-01183116
INDEPENDENT PHARMACY DISTRIBUTOR
1107 W MARKET CENTER DR
HIGH POINT, NC 27260

To Whom It May Concern:

Please be advised that ***Breckenridge Pharmaceutical, Inc.*** (Breckenridge) is voluntarily performing a Retail Level Recall of **Duloxetine Delayed-Release Capsules, USP, 60mg**, manufactured by Towa Pharmaceutical Europe, S.L. Refer to accompanying image of the capsules and labels. This Retail Level Recall affects **the lots in the accompanying Attachment A.**

Only the lots listed in Attachment A are being recalled due to presence of Nitrosamine Drug Substance Related Impurity (NDSRI), 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**.

Please examine your stock, determine if you have any of the affected product lot numbers on hand and place affected product into quarantine. If you have any of the affected lots, please complete the "Business Recall Response Form" and return to Breckenridge's designated recall service provider – Qualanex LLC. Once Qualanex receives your completed response form, they will send you a Return Authorization which should be included with your recall return. Even if you do not have any of the affected lots, please complete the "Business Recall Response Form" with that information. You will also receive a Return Label (if you have not already received one) which you can use to return your recalled product.

Return Authorization requests can be made by email at recall@qualanex.com, via telephone at 1-800-505-9291, or by Fax at 1-847-737-3719.

Please take the following actions:

1) **Check your inventory to see if you have any of the recalled product in stock, from the lots listed in the table above. If so, place the product under quarantine, and do not distribute.**
2) **Complete the enclosed 'Business Recall Response Form" and return via facsimile to Qualanex, LLC at 1-847-737-3719 or via email at recall@qualanex.com.**
3) **If the product was further distributed, please notify sub-accounts to the retail level.**

Please contact Qualanex at 1-800-505-9291, Monday – Friday from 9AM – 5PM (EST), should you have any questions or concerns regarding this recall.

Sincerely,

Jacqui Hibbert
Vice President, Quality Assurance

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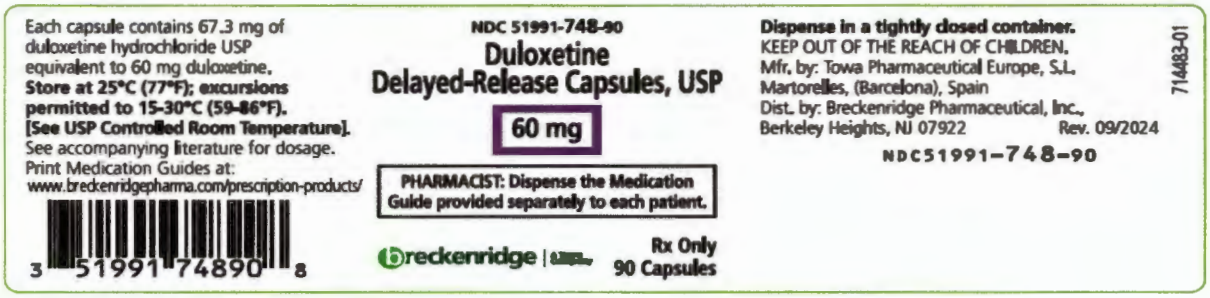
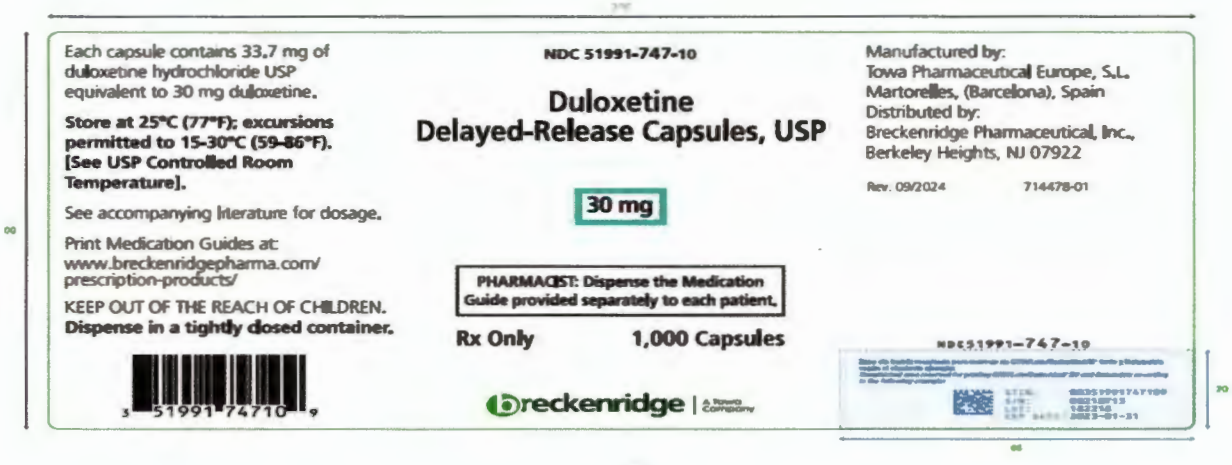
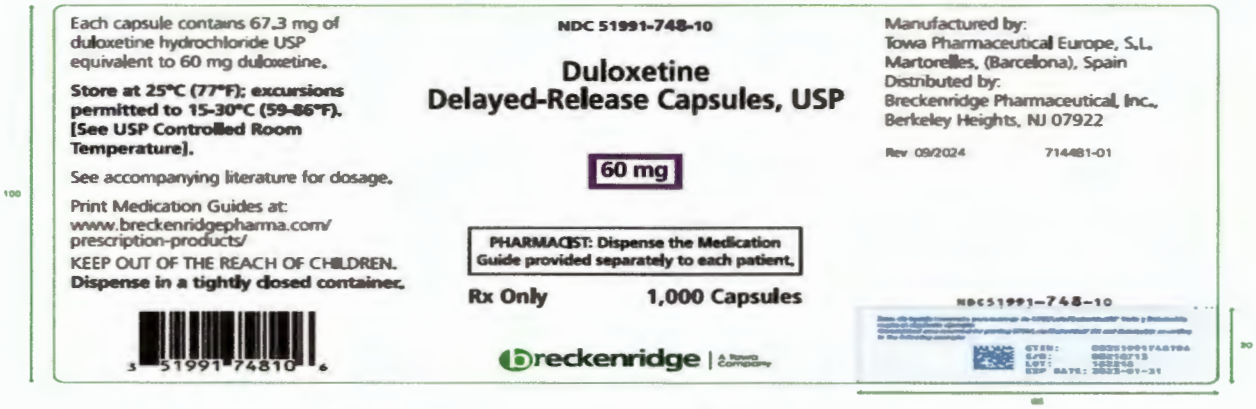
Duloxetine Delayed-Release Capsules USP, 60 mg

Duloxetine Delayed-Release Capsules USP, 30 mg

Product Labels







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ATTACHMENT A (to Drug Recall Notification Form)

List of batches in the scope of Recall (Internal Recall # 505)

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 Capsules, 60mg	51991-748-90	240413C	February 2027	90-count

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

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BUSINESS RECALL RESPONSE FORM
URGENT: DRUG RECALL
Internal Recall # 505

Product Name	Pack Size	NDC Number	Lots involved
Duloxetine Delayed-Release Capsules USP, 60 mg	90-count	51991-748-90	**Refer to Attachment A for list of lots and expiry dates.**
Duloxetine Delayed-Release Capsules USP, 60 mg	1000-count	51991-748-10	
Duloxetine Delayed-Release Capsules USP, 30 mg	1000-count	51991-747-10	

This recall is being carried out at retail level.

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the recall instructions and have taken the appropriate action.

Customer Facility Name	
Address	
City, State, Zip	
Contact name	
Contact, Phone, Fax, Email	
Wholesaler Name and Address	

[ ] I have read and understand the recall instructions provided on the recall notification letter dated June 04, 2026

[ ] I have checked my stock for the recalled lots listed in **Attachment A**:

[ ] Do not have any stock of the recalled items.

OR

[ ] I have quarantined and listed in the table below the quantity of recall units I will be returning to QUALANEX as soon as possible.

Upon receipt of this Response Form, QUALANEX will issue a Return Authorization to be included with the product.

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NDC	Lot #	Qty. Sealed bottles	Qty. Partial bottles	Notes

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online by completing and submitting the form at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm.

FOR WHOLESALERS ONLY:

# of Retail Pharmacies to be notified: _____

Please return a copy of this completed response form via facsimile to Qualanex, LLC at 1-847-737-3719 or via email at recall@qualanex.com.

Completed by:_____ Date:_____