breckenridge | A Towa Company

URGENT: RETAIL LEVEL RECALL NOTIFICATION
INTERNAL RECALL #: 456

March 26, 2025

51991-00456-01214506
INDEPENDENT PHARM DIST
1107 W MARKET CENTER DRIVE
HIGH POINT, NC 27260

To Whom It May Concern:

Please be advised that ***Breckenridge Pharmaceutical, Inc.*** (Breckenridge) is voluntarily performing a Retail Level Class II Recall of **Duloxetine Delayed-Release Capsules, USP, 30mg**, manufactured by Towa Pharmaceutical Europe, S.L. Refer to accompanying image of the capsules. This Retail Level Recall affects **the lot in the table below.**

Only the lot listed in the table below is being recalled due to presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-nitroso-duloxetine, above the proposed interim limit.

Product	Size	NDC Number	Affected Lot #	Exp Date
Duloxetine Delayed-Release Capsules USP, 30 mg	1000-count	51991-747-10	240909C	03/2027

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.

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 "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. 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 lot listed in the table above. If so, place the product under quarantine, and do not distribute.**
2) **Complete the enclosed '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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BUSINESS RESPONSE FORM
URGENT DRUG RECALL
Internal Recall # 456

Product Name	Pack Size	NDC Number	Lots involved
Duloxetine Delayed-Release Capsules USP, 30mg	1000-count	51991-747-10	240909C

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 March, 26, 2025

[ ] I have checked my stock for the recalled lots listed in the above table:

[ ] 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.

NDC	Lot #	Qty. Sealed bottles	Qty. Partial bottles	Notes
51991-747-10	240909C			

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BUSINESS RESPONSE FORM
URGENT DRUG RECALL
Internal Recall # 456

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:_____