Rising®
PHARMACEUTICALS

URGENT DRUG RECALL
SECOND NOTICE

Duloxetine DR Capsules USP 20 mg/30 mg/60 mg

April 22, 2025

Marketing Firm:	**Recalling and Manufacturing Firm:**
Rising Health, LLC DBA Rising Pharma Holdings, Inc 2 Tower Center Blvd, 1401A East Brunswick, New Jersey 08816	Aurobindo Pharma Limited Unit-III, Sy No. 313&314, Bachupally Medchal-Malkajgiri Dist. Telangana, India.

Dear Valued Customer,

This is to inform you of a product recall involving the below batches of Duloxetine DR Capsules, USP 20mg, 30mg and 60mg:

NDC Number	Product Name and Dosage Strength	Package Size	Lot Number	Expiration Date
57237-017-60	Duloxetine DR Capsules USP 20mg	60's HDPE Bottle	DT2023003A	Jan-25
			DT2023007A	Jan-25
			DT2023008A	Jan-25
57237-018-99	Duloxetine DR Capsules USP 30mg	1000's HDPE Bottle	DT3023025A	Jan-25
57237-018-30	Duloxetine DR Capsules USP 30mg	30's HDPE Bottle	DT3023051A	Apr-25
57237-019-99	Duloxetine DR Capsules USP 60mg	1000's HDPE Bottle	DT6023002A	Dec-24
			DT6023048A	Jan-25
			DT6023016A	Dec-24
			DT6023036A	Dec-24
57237-019-30	Duloxetine DR Capsules USP 60mg	30's HDPE Bottle	DT6023053A	Jan-25
			DT6023061A	Jan-25
			DT6023068A	Jan-25
			DT6023074A	Jan-25
			DT6023078A	Feb-25
			DT6023076A	Feb-25
			DTC24043A	Dec-25
			DTC24044A	Dec-25

64980-00450-01183116
INDEPENDENT PHARMACY DIST.
1107 W MARKET CENTER DR
HIGH POINT, NC 27260

Rising Health LLC has initiated a voluntary drug product recall for the product Duloxetine DR Capsules USP 20 mg/30 mg/60 mg from USA market ***due to presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso-Duloxetine above the interim acceptable intake limit of 5ppm as stipulated by the FDA.***

This product was shipped between the dates of 03/16/2023 – 10/29/2024 and our records indicate that you purchased this product during the dates it was marketed.

As per product information leaflet, description of the product is as below, and the product label is also included along with this letter for your ease of identification:

Product Name	Description	Package Size
Duloxetine DR Capsules USP 20 mg	Green Opaque / Green opaque, size '4' hard gelatin capsule filled with white to off white pellets and imprinted with "X" on Green opaque cap and "01" on Green opaque body with black ink	60's HDPE bottle
Duloxetine DR Capsules USP 30 mg	Blue Opaque / White opaque, size '3' hard gelatin capsule filled with white to off white pellets and imprinted with "X" on Blue opaque cap and "02" on White opaque body with black ink	30's, and 1000's HDPE bottle.
Duloxetine DR Capsules USP 60 mg	Blue Opaque / Green opaque, size '1' hard gelatin capsule filled with white to off white pellets and imprinted with "X" on Blue opaque cap and "03" on Green opaque body with black ink	30's and 1000's HDPE bottle.

This recall is being conducted at a retail level with the knowledge of the U.S. Food and Drug Administration.

Action to be taken by the Wholesaler/Retailer:

1. Immediately examine your inventory, stop distribution and dispensing this lot, quarantine the product.
2. Please carryout a physical count and record this data on the enclosed business response form.
3. Even if you don't have the recalled product, please email the completed response form to Qualanex, Email: recall@qualanex.com or through Fax: 847-737-3719.
5. Once the business response form is received by Qualanex, a return goods authorization will be sent to you. Please return your product along with the return authorization using the postage paid shipping label included in your return packet.

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If you have further distributed this recalled product to other wholesalers or retailers, please notify the concerned wholesalers or retailers of this recall. If they have any questions regarding the return of this recall product, please have them contact Qualanex, LLC, 1410 Harris Road |Libertyville, IL 60048, Email: recall@qualanex.com or Office (800) 505-9291.

Contact information regarding the recall:

1. If you have any medical questions regarding this recall, please contact Rising's drug safety group at 1-844-874-7464 (8:30 am - 5:00 pm EST).

2. If you have any general questions regarding the return of this product, please contact Qualanex, LLC, 1410 Harris Road |Libertyville, IL 60048, Email: recall@qualanex.com or Office 800-505-9291

We regret any inconvenience and appreciate your immediate cooperation.

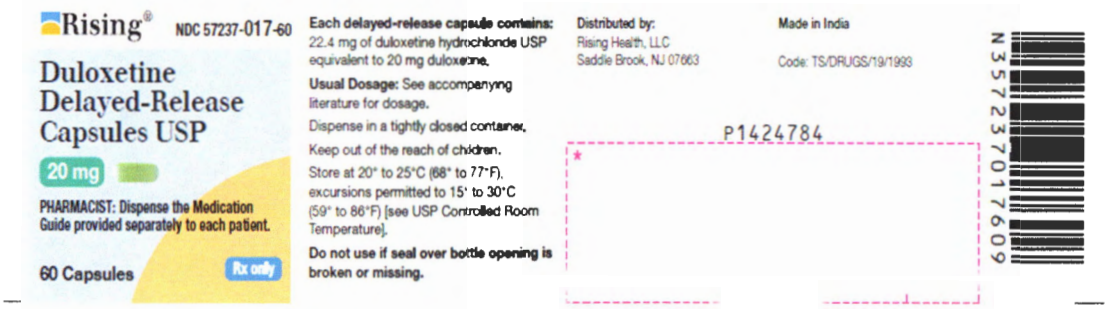
Thank you,

Aishwarya Neti Digitally signed by Aishwarya Neti
Date: 2025.04.22 11:37:31 -04'00'

Aishwarya Neti
Sr. Manager, Quality Assurance
Rising Pharma Holdings, Inc
2 Tower Center Blvd, 14 Fl
East Brunswick, NJ, 08816
Email: aneti@risingpharma.com, qa@risingpharma.com

The product label is as shown below:

Duloxetine DR Capsules USP 20 mg, 60's count



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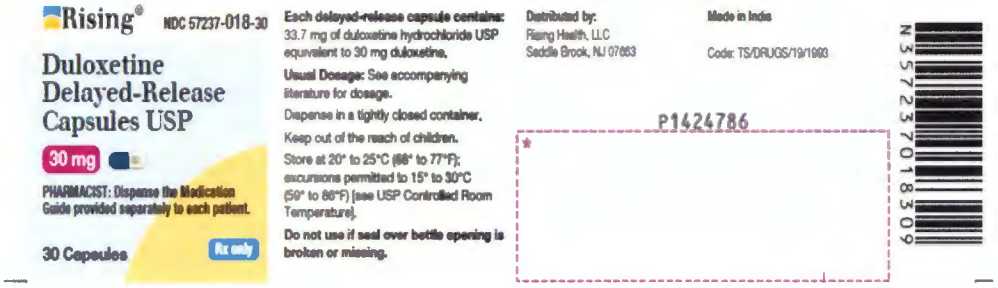
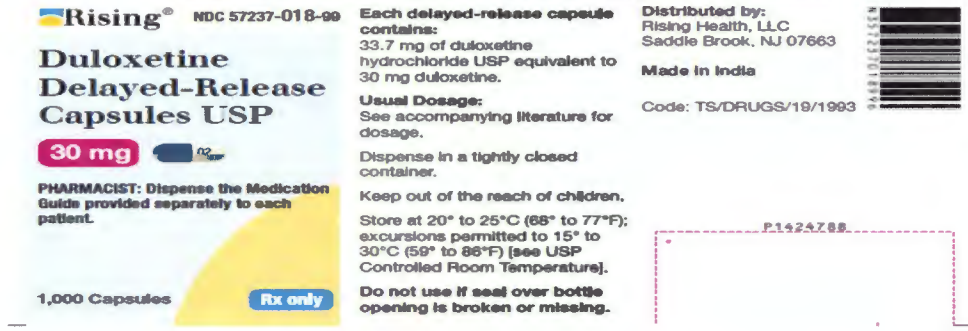
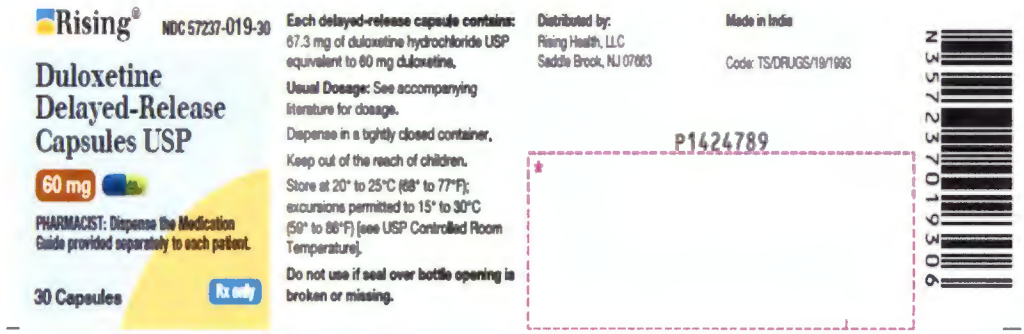
Duloxetine DR Capsules USP 30 mg, 30's count



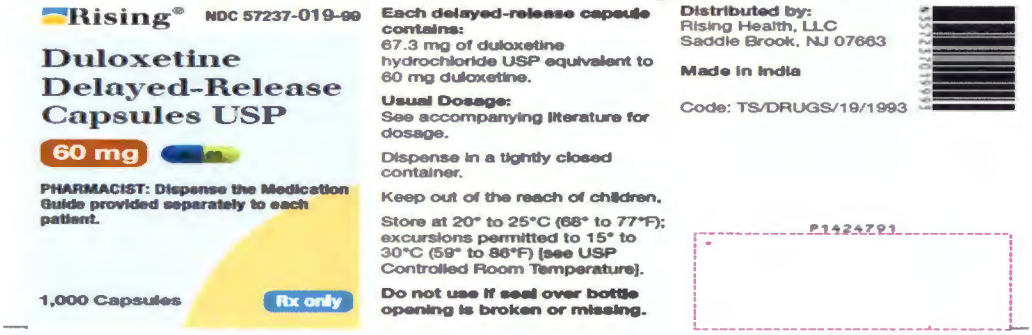
Duloxetine DR Capsules USP 30 mg, 1000's count



Duloxetine DR Capsules USP 60 mg, 30's count



Duloxetine DR Capsules USP 60 mg, 1000's count



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Rising® PHARMACEUTICALS

[Duloxetine DR Capsules, USP 20mg, 30mg and 60mg]

[Retail Level Recall]

[Date: April 22, 2025]

[Second Notice # 450]

VOLUNTARY RECALL RESPONSE FORM

Date Form Completed _____

Please fill out this form completely, by doing so this will acknowledge that you have read and understand the recall notice and have taken the appropriate action. Once complete please return your response form by any one of these means to Qualanex, Attn: Recall Team: EMAIL: recall@Qualanex.com FAX: 1-847-737-3719

This Response Form is for (Check One)	☐ **Direct Customer (Purchased Directly from MANUFACTURER)** ☐ **Non-Direct Customer**
Customer/Store Name:	
*DEA #: ***DEA # is required in order to process your form***	Debit Memo # (If Applicable)
Address:	City/State/Zip
Contact Name (please print):	Email Address: Telephone #: Fax #:

Please mark your answer - I have checked my stock and:

☐ I ***do*** have stock of the recalled item(s) **(Complete Below Table)** **OR** ☐ I ***do not*** have stock of the recalled item(s).

Direct Customers

Does your response include **all** your DC locations? ☐ YES ☐ NO

Have you notified your customers of this recall down to the appropriate level? ☐ YES ☐ NO

Non-Direct Customers

Name of Wholesaler/Distributor and address the product(s) in this recall were purchased from (Please include DEA):

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[Retail Level Recall]

[Date: April 22, 2025]

[Second Notice # 450]

☐ ***I have quarantined and listed in the table below the quantity of recall units I will be returning to Qualanex.***

If additional space is needed please make copies of this form.

NDC	Lot #	Exp. Date	Qty. Case to be returned	Qty. Sealed to be returned	Qty. Partial Bottles to be returned
57237-017-60	DT2023003A	Jan-25			
	DT2023007A	Jan-25			
	DT2023008A	Jan-25			
57237-018-99	DT3023025A	Jan-25			
57237-018-30	DT3023051A	Apr-25			
57237-019-99	DT6023002A	Dec-24			
	DT6023048A	Jan-25			
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	DT6023068A	Jan-25			
	DT6023074A	Jan-25			
	DT6023078A	Feb-25			
	DT6023076A	Feb-25			
	DTC24043A	Dec-25			
	DTC24044A	Dec-25			

Any Adverse Events Associated with this recalled product? ☐ No ☐ Yes (if yes please attach additional sheet and explain)

Please indicate the number of (additional) shipping labels that you need to return the recalled product(s): _____

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