

[Retail Level Recall]

[Date: November 19, 2024]

[Notice # 443]

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)	<input type="checkbox"/> Direct Customer (Purchased Directly from MANUFACTURER)
	<input type="checkbox"/> Non-Direct Customer

Customer/Store Name: _____

*DEA #: <i>*DEA # is required in order to process your form</i>	Debit Memo # (If Applicable)
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Address:	City/State/Zip
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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): _____

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	DT2022023A	Nov-24			
	DT2022024A	Nov-24			
	DT2022025A	Nov-24			
	DT2022026A	Nov-24			
	DT2022027A	Nov-24			
	DT2023001B	Jan-25			
	DT2023004A	Jan-25			
	DT2023005A	Jan-25			
57237-018-99	DT2023006A	Jan-25			
	DT3022108A	Nov-24			

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	DT3022107A	Nov-24			
	DT3022106A	Nov-24			
	DT3022111A	Nov-24			
	DT3022109A	Nov-24			
	DT3023001A	Dec-24			
	DT3023003A	Dec-24			
	DT3023024A	Jan-25			
	DT3023020B	Jan-25			
	DT3023027A	Feb-25			
	DT3023028A	Feb-25			
	DT3023034A	Mar-25			
	DT3023049A	Apr-25			
	DT3023095A	Jul-25			
57237-018-30	DT3023019A	Jan-25			
	DT3023050A	Apr-25			
57237-018-90	DT3023022A	Jan-25			
57237-019-99	DT6022160A	Nov-24			
	DT6022165A	Nov-24			
	DT6022162A	Nov-24			
	DT6022164A	Nov-24			
	DT6022163A	Nov-24			
	DT6022171A	Nov-24			
	DT6022169A	Nov-24			
	DT6022170A	Nov-24			
	DT6022173A	Nov-24			
	DT6023009A	Dec-24			
	DT6023007A	Dec-24			
	DT6023008A	Dec-24			
	DT6023011A	Dec-24			
	DT6023034B	Dec-24			
	DT6023067C	Jan-25			
	DT6023114A	Apr-25			
	DTC23243A	Oct-25			
	DTC24040A	Dec-25			
57237-019-90	DT6023108A	Apr-25			
	DTC23201A	Aug-25			
57237-019-30	DT6023059A	Jan-25			

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	DT6023060A	Jan-25			
	DT6023065A	Jan-25			
	DT6023069A	Jan-25			
	DT6023070A	Jan-25			
	DT6023080A	Feb-25			
	DT6023093A	Mar-25			
	DTC24012A	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): _____



URGENT DRUG RECALL

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

November 19, 2024

Marketing Firm: Rising Health, LLC DBA Rising Pharma Holdings, Inc 2 Tower Center Blvd, 1401 East Brunswick, New Jersey 08536	Recalling and Manufacturing Firm: Aurobindo Pharma Limited Unit-III, Sy No. 313&314, Bachupally Medchal-Malkajgiri Dist. Telangana, India.
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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	DT2022023A	Nov-24
			DT2022024A	Nov-24
			DT2022025A	Nov-24
			DT2022026A	Nov-24
			DT2022027A	Nov-24
			DT2023001B	Jan-25
			DT2023004A	Jan-25
			DT2023005A	Jan-25
			DT2023006A	Jan-25
57237-018-99	Duloxetine DR Capsules USP 30mg	1000's HDPE Bottle	DT3022108A	Nov-24
			DT3022107A	Nov-24
			DT3022106A	Nov-24
			DT3022111A	Nov-24
			DT3022109A	Nov-24
			DT3023001A	Dec-24
			DT3023003A	Dec-24
			DT3023024A	Jan-25
			DT3023020B	Jan-25
			DT3023027A	Feb-25
			DT3023028A	Feb-25
			DT3023034A	Mar-25
DT3023049A	Apr-25			



NDC Number	Product Name and Dosage Strength	Package Size	Lot Number	Expiration Date
			DT3023095A	Jul-25
57237-018-30	Duloxetine DR Capsules USP 30mg	30's HDPE Bottle	DT3023019A	Jan-25
			DT3023050A	Apr-25
57237-018-90	Duloxetine DR Capsules USP 30mg	90's HDPE Bottle	DT3023022A	Jan-25
57237-019-99	Duloxetine DR Capsules USP 60mg	1000's HDPE Bottle	DT6022160A	Nov-24
			DT6022165A	Nov-24
			DT6022162A	Nov-24
			DT6022164A	Nov-24
			DT6022163A	Nov-24
			DT6022171A	Nov-24
			DT6022169A	Nov-24
			DT6022170A	Nov-24
			DT6022173A	Nov-24
			DT6023009A	Dec-24
			DT6023007A	Dec-24
			DT6023008A	Dec-24
			DT6023011A	Dec-24
			DT6023034B	Dec-24
			DT6023067C	Jan-25
			DT6023114A	Apr-25
57237-019-90	Duloxetine DR Capsules USP 60mg	90's HDPE Bottle	DTC23243A	Oct-25
			DTC24040A	Dec-25
57237-019-30	Duloxetine DR Capsules USP 60mg	30's HDPE Bottle	DT6023108A	Apr-25
			DTC23201A	Aug-25
			DT6023059A	Jan-25
			DT6023060A	Jan-25
			DT6023065A	Jan-25
			DT6023069A	Jan-25
			DT6023070A	Jan-25
			DT6023080A	Feb-25
DT6023093A	Mar-25			
			DTC24012A	Dec-25

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 March 2023 to August 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, 90'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.
4. Alternatively, you may mail the completed response form to Rising Pharma Holdings, Inc. 2 Tower Center Blvd, Suite 1401A, East Brunswick, New Jersey- 08816.
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.

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: 2024.11.19 14:33:48
-05'00'

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



Rising[®] NDC 57237-017-60
**Duloxetine
Delayed-Release
Capsules USP**
20 mg
PHARMACIST: Dispense the Medication
Guide provided separately to each patient.
60 Capsules **Rx only**

Each delayed-release capsule contains:
22.4 mg of duloxetine hydrochloride USP
equivalent to 20 mg duloxetine.
Usual Dosage: See accompanying
literature for dosage.
Dispense in a tightly closed container.
Keep out of the reach of children.
Store at 20° to 25°C (68° to 77°F);
excursions permitted to 15° to 30°C
(59° to 86°F) [see USP Controlled Room
Temperature].
**Do not use if seal over bottle opening is
broken or missing.**

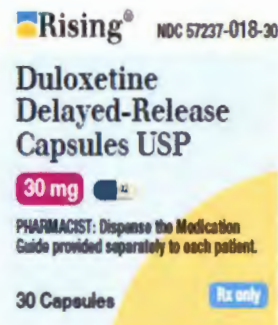
Distributed by:
Rising Health, LLC
Saddle Brook, NJ 07863

Made in India
Code: TS/DRUGS/19/1993

P1424784



Duloxetine DR Capsules USP 30 mg, 30's count



Rising[®] NDC 57237-018-30
**Duloxetine
Delayed-Release
Capsules USP**
30 mg
PHARMACIST: Dispense the Medication
Guide provided separately to each patient.
30 Capsules **Rx only**

Each delayed-release capsule contains:
33.7 mg of duloxetine hydrochloride USP
equivalent to 30 mg duloxetine.
Usual Dosage: See accompanying
literature for dosage.
Dispense in a tightly closed container.
Keep out of the reach of children.
Store at 20° to 25°C (68° to 77°F);
excursions permitted to 15° to 30°C
(59° to 86°F) [see USP Controlled Room
Temperature].
**Do not use if seal over bottle opening is
broken or missing.**

Distributed by:
Rising Health, LLC
Saddle Brook, NJ 07863

Made in India
Code: TS/DRUGS/19/1993

P1424786





Duloxetine DR Capsules USP 30 mg, 90's count

Rising® NDC 57237-018-90

**Duloxetine
Delayed-Release
Capsules USP**

30 mg

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

90 Capsules

Rx only

Each delayed-release capsule contains: 33.7 mg of duloxetine hydrochloride USP equivalent to 30 mg duloxetine.
Usual Dosage: See accompanying literature for dosage.
Dispense in a tightly closed container.
Keep out of the reach of children.
Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Do not use if seal over bottle opening is broken or missing.

Distributed by:
Rising Health, LLC
Saddle Brook, NJ 07663

Made in India

Code: TS/DRUGS/19/1993



P1424787

Duloxetine DR Capsules USP 30 mg, 1000's count

Rising® NDC 57237-018-99

**Duloxetine
Delayed-Release
Capsules USP**

30 mg

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

1,000 Capsules

Rx only

Each delayed-release capsule contains: 33.7 mg of duloxetine hydrochloride USP equivalent to 30 mg duloxetine.
Usual Dosage: See accompanying literature for dosage.
Dispense in a tightly closed container.
Keep out of the reach of children.
Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Do not use if seal over bottle opening is broken or missing.

Distributed by:
Rising Health, LLC
Saddle Brook, NJ 07663

Made in India

Code: TS/DRUGS/19/1993



P1424788

Duloxetine DR Capsules USP 60 mg, 30's count

Rising® NDC 57237-019-30

**Duloxetine
Delayed-Release
Capsules USP**

60 mg

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

30 Capsules

Rx only

Each delayed-release capsule contains: 67.3 mg of duloxetine hydrochloride USP equivalent to 60 mg duloxetine.
Usual Dosage: See accompanying literature for dosage.
Dispense in a tightly closed container.
Keep out of the reach of children.
Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Do not use if seal over bottle opening is broken or missing.

Distributed by:
Rising Health, LLC
Saddle Brook, NJ 07663

Made in India

Code: TS/DRUGS/19/1993



P1424789



Duloxetine DR Capsules USP 60 mg, 90's count

Rising® NDC 57237-019-90

Duloxetine Delayed-Release Capsules USP

60 mg

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

90 Capsules

Rx only

Each delayed-release capsule contains:
67.3 mg of duloxetine hydrochloride USP equivalent to 60 mg duloxetine.
Usual Dosage: See accompanying literature for dosage.
Dispense in a tightly closed container.
Keep out of the reach of children.
Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Do not use if seal over bottle opening is broken or missing.

Distributed by:
Rising Health, LLC
Saddle Brook, NJ 07663

Made in India

Code: TS/DRUGS/19/1993



N357237019900

P1424790

Duloxetine DR Capsules USP 60 mg, 1000's count

Rising® NDC 57237-019-99

Duloxetine Delayed-Release Capsules USP

60 mg

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

1,000 Capsules

Rx only

Each delayed-release capsule contains:
67.3 mg of duloxetine hydrochloride USP equivalent to 60 mg duloxetine.
Usual Dosage: See accompanying literature for dosage.
Dispense in a tightly closed container.
Keep out of the reach of children.
Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Do not use if seal over bottle opening is broken or missing.

Distributed by:
Rising Health, LLC
Saddle Brook, NJ 07663

Made in India

Code: TS/DRUGS/19/1993



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