Rising®
PHARMACEUTICALS

[Carbidopa, Levodopa, Entacapone Tablets 25 mg/100 mg/200 mg, 100's count, Lot / Batch No. CS25070]

[Retail Level Recall]

[October 7, 2025]
[Notice # 480]

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):

☐ ***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 Bottles to be returned	Qty. Partial Bottles to be returned
16571-691-01	CS25070	03/2027			

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 VOLUNTARY DRUG RECALL

Carbidopa, Levodopa, Entacapone Tablets 25 mg/100 mg/200 mg, 100's count Bottle pack
Batch # CS25070

Date: 10/07/2025

Marketing and Distribution Firm:	**Manufacturing & Recalling Firm:**
Rising Pharma Holdings. Inc, DBA Rising Pharmaceuticals 2 Tower Center Blvd, #1401 East Brunswick, NJ 08816	Suven Pharmaceuticals Limited Plot Nos. 262 To 271, IDA Pashamylaram Sangareddy, Telangana, India, 502307

Product Name	NDC(s)	Lot(s)	Exp. date	Distribution Quantity	Distribution dates
Carbidopa, Levodopa, Entacapone Tablets 25 mg/100 mg/200 mg	16571-691-01	CS25070	03/2027	2,064 bottles	June 11th 2025 to July 28th 2025

Dear Valued Wholesaler/Retailer,

Rising Pharma Holdings. Inc, is initiating a voluntary recall to the Retail Level on Carbidopa, Levodopa, Entacapone Tablets 25 mg / 100 mg / 200 mg (ANDA# 213212) batch # CS25070 manufactured by Suven Pharmaceuticals Limited located in Telangana, India and marketed by Rising Pharma Holdings, Inc., USA. Our records indicate that you purchased this product on the dates it was distributed.

This voluntary recall has been initiated following a product complaint received from a pharmacy, where a pharmacist reported that sealed medication bottle contained Carbidopa, Levodopa, and Entacapone film-coated tablets (37.5 mg/150 mg/200 mg) instead of labelled lower strength Carbidopa, Levodopa, and Entacapone film-coated tablets (25 mg/100 mg/200 mg).

Suven Pharmaceuticals Limited has conducted an investigation into the reported complaint and determined that the issue is attributable to a low-level packaging defect, limited to a small number of units. A health hazard assessment performed by Rising Pharma Holdings, Inc. concluded that the presence of higher-strength Carbidopa, Levodopa, and Entacapone tablets in place of the lower-strength tablets is unlikely to pose a significant risk of adverse health outcomes. Based on the available data, no safety concerns for patients are anticipated.

This batch was distributed between June 11th 2025 to July 28th 2025. For ease of identification, a specimen of the product label is enclosed with this letter for your reference.

This recall is being conducted 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, and quarantine the product.
2. Please carry out a physical count and record this data on the enclosed 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 Fax: 847-737-3719
4. 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 recall 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.

This action applies only to Carbidopa, Levodopa, Entacapone Tablets 25 mg/100 mg/200 mg, Batch # CS25070, 100 tablets, NDC 16571-691-01.

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,

Sivaprasad Bachina

Digitally signed by Sivaprasad Bachina
Date: 2025.10.07 13:49:41 -04'00'

Thanks and Regards,

Sivaprasad Bachina
Manager– Quality Assurance

2 Tower Center Blvd, Suite 1401A
East Brunswick, N.J. 08816
Email: sbachina@risingpharma.com, qa@risingpharma.com
Phone: +1 315 742 0604

Product Bottle Label (NDC: 16571-691-01):