Rising® PHARMACEUTICALS

[FUROSEMIDE TABLETS USP 40 mg, 1000's count Bottle pack,

Batch # FUB125042G, Exp date: 2027/05/13]

[Retail Level Recall]

[January 10th, 2026]
[Notice # 486]

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
64980-563-10	FUB125042G	05/2027			

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): _____

Graviti

RECALL LETTER

FUROSEMIDE TABLETS USP 40 mg, 1000's count Bottle pack, Batch # FUB125042G, Exp date: 2027/05/13

Date: 01/10/2026

Manufacturing & Recalling Firm:	**Marketing & Distribution Firm:**
Graviti Pharmaceuticals Private Limited, Survey No. 621/E & 621/EE, Isnapur Village, Patancheru Mandal, Sangareddy, Telangana – 502307, India.	Rising Pharma Holdings. Inc, DBA Rising Pharmaceuticals 2 Tower Center Blvd, #1401 East Brunswick, NJ 08816

Product Name	NDC(s)	Lot(s) / Exp. date	Distribution dates
Furosemide Tablets, USP 40 mg	64980-563-10	Batch # FUB125042G, Exp date: 2027/05/13	Sep 17, 2025 to Sep 23,2025

Dear Valued Wholesaler/ Retailer,

Graviti Pharmaceuticals Private Limited (Graviti) is initiating a voluntary recall to the Retail level on Furosemide Tablets, USP 40 mg (ANDA# 216629) batch # FUB125042G manufactured by Graviti and marketed by Rising Pharma Holdings, Inc. USA.

This voluntary recall is being initiated based on one customer complaint received by Graviti through Rising Pharma concerning a foreign black object embedded in a tablet of Furosemide Tablets USP 40 mg prior consumption by the patient. To date Graviti has not received reports of any relevant adverse events associated with this issue for the batch.

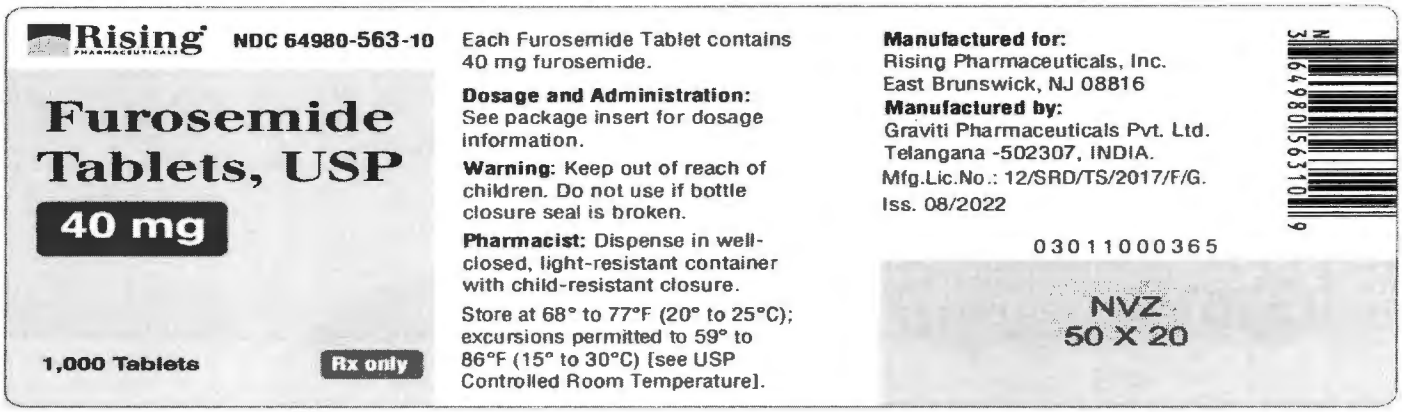
Graviti conducted a comprehensive health hazard assessment and detailed investigation. The assessment concluded that the potential risk is limited and transient, with a remote probability of adverse events. Based on these findings, the market complaint is assessed to pose a low risk to patient safety.

This product was shipped between the dates of 09/17/25 to 09/23/25, and our records indicate that you purchased this product during the dates it was marketed.

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

Description: Furosemide Tablets, USP 40 mg are white, round, flat face, beveled edge scored tablets debossed with "17" on one side and plain on other side.

Product Label:



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 Email: recall@qualanex.com or through 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/distributors, please notify them that they must further notify their retailers (hospitals, pharmacy, clinics, etc.) accordingly. If they have any questions regarding the return of this recall product, please have them contact: recall@qualanex.com or phone # 800-505-9291.

This action applies only to Furosemide Tablets, USP 40 mg, Batch # FUB125042G, 1000's count HDPE bottle pack, NDC 64980-563-10. Only the product from this batch will be accepted under the terms of this recall. **No other batches of Furosemide Tablets, USP 40 mg are affected by this 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, at email: recall@qualanex.com

We regret any inconvenience and appreciate your immediate cooperation.

Umesh Baikunje Golithadka

Digitally signed by Umesh Baikunje Golithadka
Date: 2026.01.10 12:33:18 +05'30'

Umesh Baikunje
Head- Quality

Address:
Graviti Pharmaceuticals Private Limited,
Survey No. 621/E & 621/EE,
Isnapur Village, Patancheru Mandal,
Sangareddy, Telangana – 502307, India.