URGENT VOLUNTARY DRUG RECALL
CONSUMER LEVEL RECALL

Cetirizine Hydrochloride Tablets USP 5 mg, 100 count

Batch No. GY825029, GY825030, GY825031 and GY825032, Exp date: 10/2028

Date: 07/17/2026

Marketing and Distribution Firm:	**Manufacturing & Recalling Firm:**
Rising Pharma Holdings. Inc, DBA Rising Pharmaceuticals 2 Tower Center Blvd, #1401 East Brunswick, NJ 08816	Unique Pharmaceutical Laboratories (A Division of J. B. Chemicals & Pharmaceuticals Limited). Plot No. 4, Phase IV, GIDC Industrial Estate, Panoli, Bharuch-394116, Gujarat, India.

Product Name	NDC(s)	Lot(s) / Exp. date	Distribution dates
Cetirizine Hydrochloride Tablets USP 5 mg	16571-401-10	GY825029 Exp.: 10/2028	April 2026 to May 2026
Cetirizine Hydrochloride Tablets USP 5 mg	16571-401-10	GY825030 Exp.: 10/2028	May 2026
Cetirizine Hydrochloride Tablets USP 5 mg	16571-401-10	GY825031 Exp.: 10/2028	May 2026 to June 2026
Cetirizine Hydrochloride Tablets USP 5 mg	16571-401-10	GY825032 Exp.: 10/2028	May 2026 to June 2026

Dear Valued Wholesaler/ Retailer / Consumer,

Rising Pharma Holdings, Inc is initiating a voluntary recall at the **Consumer Level** for **Cetirizine Hydrochloride Tablets USP 5 mg**, manufactured by Unique Pharmaceutical Laboratories for Batch No's. **GY825029, GY825030, GY825031 and GY825032**, 100's count Bottle pack due to cross contamination with Ranitidine.

As a part of investigation, Finish product retain samples testing for four batches (Batch No. GY825029, GY825030, GY825031, and GY825032) have been carried out and two batches (GY825030 and GY825031) failed to comply in Related substances (By HPLC) (Unspecified degradation products & Total degradation products). In an abundance of caution and in accordance with our commitment to product quality and patient safety, a voluntary recall has been initiated for all four batches.

After the failure of two batches in Related substances (By HPLC) test for unspecified impurities, LCMS has been carried out to find out the mass of unknown impurity peak and it was identified that the failure is attributed due to presence of traces of Ranitidine (Approximately< 0.5 %), a product also manufactured at Unique Pharmaceutical Laboratories (A Division of J. B. Chemicals &

Pharmaceuticals Ltd.). Based on the levels at which ranitidine was detected, no adverse impact on patient health and safety is anticipated as provided in HHE.

Further investigative activities are ongoing to confirm the root cause and to implement appropriate corrective measures.

This product was shipped to you between April 2026 to June 2026, and our records indicate that you purchased this product during the dates it was marketed.

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

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

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 or consumers, please notify the concerned wholesalers or retailers or consumer 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 (866) 306-5226.

This action applies only to Cetirizine Hydrochloride Tablets USP 5 mg, Batch No's. GY825029, GY825030, GY825031 and GY825032, 100 count, Exp date: 10/2028.

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 (866) 306-5226.

For adverse reactions or quality problems experienced with the use of this product, contact firm's website or to the FDA's Med Watch Adverse Event Reporting program either online, by regular mail or by fax: Complete and submit the report Online: www.fda.gov/medwatch/report.htm

Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800- 332-1088 to request a reporting form, then complete and return to the address on the pre- addressed form, or submit by fax to 1-800-FDA-0178

We regret any inconvenience and appreciate your immediate cooperation.

Thank you,

Sivaprasad Bachina

Digitally signed by Sivaprasad Bachina
Date: 2026.07.17 14:59:57 -04'00'

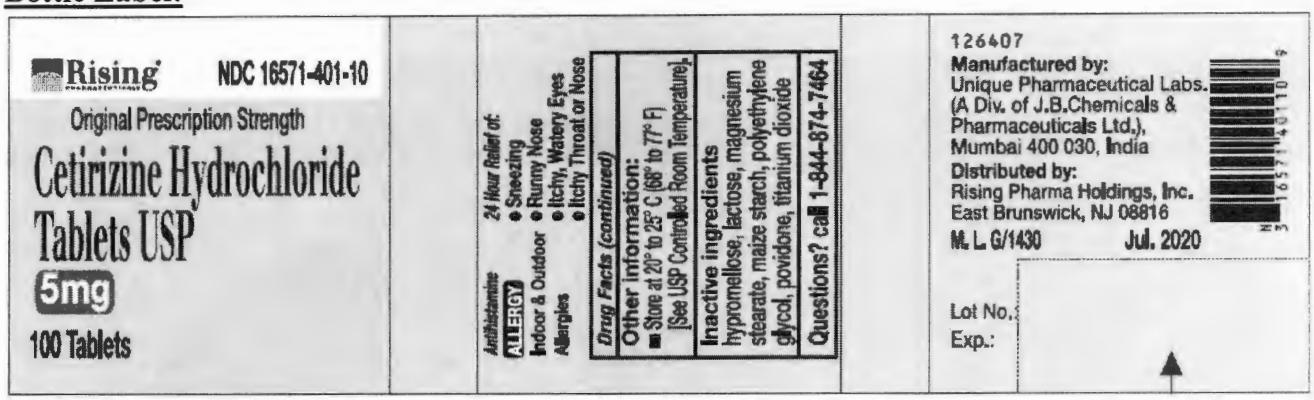
Thanks and Regards,

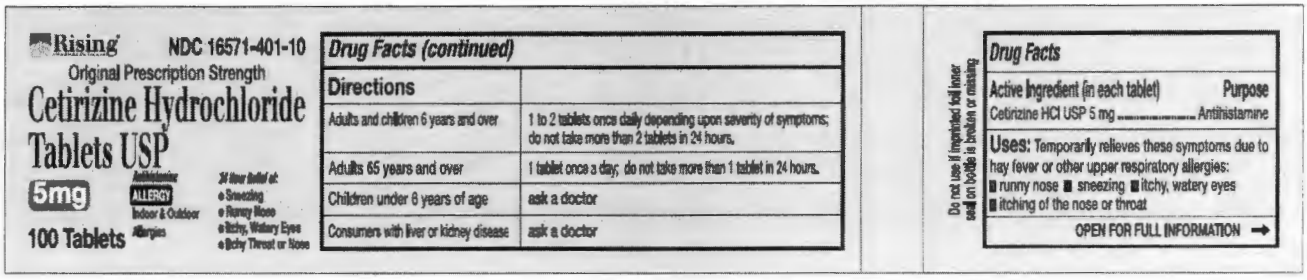
Sivaprasad Bachina
Manager– Quality Assurance

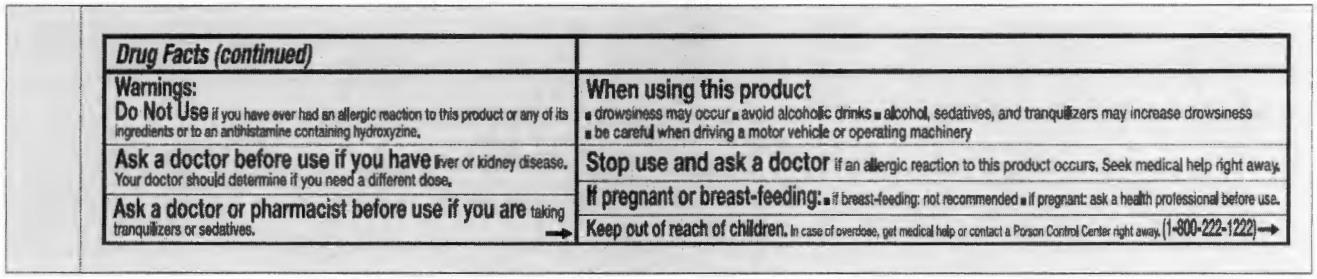
2 Tower Center Blvd, Suite 1401A
East Brunswick, N.J. 08816
Email: sbachina@risingpharma.com, qa@risingpharma.com
Phone: +1 315 742 0604

Description: White barrel shaped, biconvex, film coated tablets with "CTN" engraved on one face and "5" engraved on the other, free from cracks, mottling and chips on the tablet surface.

Bottle Label:







Rising® PHARMACEUTICALS

[Cetirizine Hydrochloride Tablets USP 5 mg, Batch # GY825029, #GY825030, #GY825031 and #GY825032, 100 count, Exp date: 10/2028

[Consumer Level Recall]

[July 17th, 2026]
[Notice # 507]

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**
Consumer/ Customer/Store Name:	
*DEA#.. Is Not applicable ***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/Retailer and address the product(s) in this recall were purchased from:

☐ ***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
16571-401-10	GY825029	10/2028			
16571-401-10	GY825030	10/2028			
16571-401-10	GY825031	10/2028			
16571-401-10	GY825032	10/2028			

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): _____