



[Cetirizine Hydrochloride Tablet USP 10 mg, Pack 500's HDPE container  
/ Batch No. PY925013 & PY925014]

[Retail or Pharmacy Level Recall]

[September 29, 2025]

[Notice # 478]

## **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](mailto: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 #:

Debit Memo # (If Applicable)

*\*DEA # is required in order to process your form*

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
16571-402-50	PY925013	2028-JAN			
16571-402-50	PY925014	2028-JAN			

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

**Cetirizine Hydrochloride Tablet USP 10 mg, Pack 500's HDPE container,  
Batch # PY925013 & PY925014, Exp date: 2028-JAN**

**Date: 09/29/2025**

<b>Marketing and Distribution Firm:</b> Rising Pharma Holdings. Inc, DBA Rising Pharmaceuticals 2 Tower Center Blvd, #1401 East Brunswick, NJ 08816	<b>Manufacturing &amp; Recalling Firm:</b> Unique Pharmaceutical Laboratories (A division of J.B. Chemicals & Pharmaceuticals Ltd.) Neelam Centre, B wing, 4th Floor Hind Cycle Road, Worli Mumbai 400030, India
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Product Name	NDC(s)	Lot(s)	Exp. date	Distribution Quantity	Distribution dates
Cetirizine Hydrochloride Tablet USP 10 mg	16571-402-50	PY925013	2028-JAN	7,608	July 25 <sup>th</sup> 2025 to August 22 <sup>nd</sup> 2025
Cetirizine Hydrochloride Tablet USP 10 mg	16571-402-50	PY925014	2028-JAN	5,832	August 1 <sup>st</sup> 2025 to August 14 <sup>th</sup> 2025

Dear Valued Wholesaler/Retailer,

Unique Pharmaceutical Laboratories (A division of J. B. Chemicals & Pharmaceuticals Ltd.) is initiating a voluntary recall for Cetirizine Hydrochloride Tablets USP 10 mg, Batch # PY925013 & PY925014 manufactured by Unique Pharmaceutical Laboratories located in 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 is based on a product quality complaint received from pharmacy, wherein a mix-up of the tablets was reported (tablets with two different imprints found in the same bottle).

Unique Pharmaceutical Laboratories have conducted a thorough investigation and comprehensive health hazard assessment, Unique confirmed that the tablets with two different imprints found in the same bottle are both identified as Cetirizine Hydrochloride Tablet USP 10 mg. Consequently, there is no anticipated risk to patient health or safety, and any potential long-term risk is deemed unlikely.

These batches were distributed between July 25<sup>th</sup> 2025 to August 22<sup>nd</sup> 2025 for the lot PY925013 and August 1<sup>st</sup> 2025 to August 14<sup>th</sup> 2025 for the lot PY925014 respectively. For ease of identification, a specimen of the product label is enclosed with this letter for your reference.



**DESCRIPTION:** White to off-white barrel shaped, biconvex, film coated tablets with "CTN" engraved on one face and "10" engraved on the other side of the tablet, free from cracks, mottling and chips on the tablet surface.

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, 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](mailto: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](mailto:recall@qualanex.com) or Office (800) 505-9291.

**This action applies only to Cetirizine Hydrochloride Tablet USP 10 mg, Batch # PY925013 and PY925014, Pack 500's HDPE container, NDC 16571-402-50.**

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](mailto: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: 2025.09.29  
09:50:42 -04'00'

Thanks and Regards,  
Sivaprasad Bachina  
Manager– Quality Assurance



**2 Tower Center Blvd, Suite 1401A**

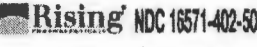
**East Brunswick, N.J. 08816**

**Email:** [sbachina@risingpharma.com](mailto:sbachina@risingpharma.com), [qa@risingpharma.com](mailto:qa@risingpharma.com)

**Phone:** [+1 315 742 0604](tel:+13157420604)

Product Bottle Label (NDC: 16571-402-50):

 <b>NDC 16571-402-50</b>  Original Prescription Strength <b>Cetirizine Hydrochloride</b> <b>Tablets USP</b>  <b>10mg</b>  6 yrs & older  <b>500 Tablets</b>	<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <b>Antihistamine</b>  <b>ALLERGY</b>            Indoor &amp; Outdoor Allergies         </div> <div style="width: 45%;"> <b>24 Hour Relief of:</b> <ul style="list-style-type: none"> <li>• Sneezing</li> <li>• Runny Nose</li> <li>• Itchy, Watery Eyes</li> <li>• Itchy Throat or Nose</li> </ul> </div> </div> <div style="border: 1px solid black; padding: 2px; margin-top: 5px;"> <b>Drug Facts (continued)</b>  <b>Other information:</b>            ■ Store at 20° to 25° C (68° to 77° F) [See USP Controlled Room Temperature].  <b>Inactive ingredients:</b>            hypromellose, lactose, magnesium stearate, maize starch, polyethylene glycol, povidone, titanium dioxide         </div> <p style="margin-top: 5px;"><b>Questions? call 1-844-874-7464</b></p>	<div style="text-align: right;">             126405 3 16571 40250 2         </div> <p><b>Manufactured by:</b>          Unique Pharmaceutical Labs.          (A Div. of J.B. Chemicals &amp; Pharmaceuticals Ltd.),          Mumbai 400 030, India</p> <p><b>Distributed by:</b>          Rising Pharma Holdings, Inc.          East Brunswick, NJ 08816</p> <p><b>M. L. G/1430 JUL 2020</b></p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <b>Lot No.</b>  <b>Exp.:</b> </div>
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 <b>NDC 16571-402-50</b>  Original Prescription Strength <b>Cetirizine Hydrochloride</b> <b>Tablets USP</b>  <b>10mg</b> <div style="display: flex; align-items: center;"> <div style="font-size: 0.8em; margin-right: 5px;"> <b>Antihistamine</b>  <b>ALLERGY</b>            Indoor &amp; Outdoor Allergies         </div> <div> <b>24 Hour Relief of:</b> <ul style="list-style-type: none"> <li>• Sneezing</li> <li>• Runny Nose</li> <li>• Itchy, Watery Eyes</li> <li>• Itchy Throat or Nose</li> </ul> </div> </div> <p>6 yrs &amp; older   <b>500 Tablets</b></p>	<div style="border: 1px solid black; padding: 5px;"> <b>Drug Facts (continued)</b> </div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 30%;">Directions</th> <th></th> </tr> <tr> <td>Adults and children 6 years and over</td> <td>one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms</td> </tr> <tr> <td>Adults 65 years and over</td> <td>ask a doctor</td> </tr> <tr> <td>Children under 6 years of age</td> <td>ask a doctor</td> </tr> <tr> <td>Consumers with liver or kidney disease</td> <td>ask a doctor</td> </tr> </table>	Directions		Adults and children 6 years and over	one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms	Adults 65 years and over	ask a doctor	Children under 6 years of age	ask a doctor	Consumers with liver or kidney disease	ask a doctor	<div style="border: 1px solid black; padding: 5px;"> <b>Drug Facts</b> </div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 60%;">Active Ingredient (in each tablet)</th> <th>Purpose</th> </tr> <tr> <td>Cetirizine HCl USP 10 mg</td> <td>Antihistamine</td> </tr> </table> <p><b>Uses:</b> Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:    ■ runny nose ■ sneezing ■ itchy, watery eyes    ■ itching of the nose or throat</p> <p style="text-align: right;"><b>OPEN FOR FULL INFORMATION →</b></p>	Active Ingredient (in each tablet)	Purpose	Cetirizine HCl USP 10 mg	Antihistamine
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Cetirizine HCl USP 10 mg	Antihistamine															

<b>Drug Facts (continued)</b>	<div style="border: 1px solid black; padding: 5px;"> <b>Warnings:</b>  <b>Do Not Use</b> if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.   <b>Ask a doctor before use</b> if you have liver or kidney disease. Your doctor should determine if you need a different dose.   <b>Ask a doctor or pharmacist before use</b> if you are taking tranquilizers or sedatives.         </div>
<div style="border: 1px solid black; padding: 5px;"> <b>When using this product</b> ■ drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery   <b>Stop use and ask a doctor</b> if an allergic reaction to this product occurs. Seek medical help right away.   <b>If pregnant or breast-feeding:</b> ■ if breast-feeding: not recommended ■ if pregnant: ask a health professional before use.   <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)         </div>	<div style="border: 1px solid black; padding: 5px;"> <b>Do not use if imprinted foil inner seal on bottle is broken or missing</b> </div>