

Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC26-016-CG

July 27, 2026

FDA announced that Panoli, Gujarat, Unique Pharmaceutical Laboratories (A Div. of J. B. Chemicals & Pharmaceuticals Ltd.) is voluntarily recalling four lots of Cetirizine Hydrochloride Tablets USP 5 mg to the consumer level due to cross contamination with Ranitidine.

RECOMMENDATIONS

1. Unique Pharmaceuticals has notified its distributor Rising Pharma Holdings Inc. (2 Tower Center Blvd., Suite 1401A, East Brunswick, NJ 08816) who has notified its distributors and direct customers by email and is arranging for the return of all recalled products.
2. Consumers with general or medical inquiries regarding this recall can contact Rising Pharma Holdings Inc. at: Phone number: 1-844-874-7464 8:00 a.m. to 5:00 p.m. (EST), (Monday-Friday) or e-mail address: pv@risingpharma.com or qa@risingpharma.com.
3. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
4. Review your inventory to identify existence of recalled products.
5. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

Cordially,

MC-Rx Pharmacy Services Department

Unique Pharmaceutical Laboratories (A Div. of J. B. Chemicals & Pharmaceuticals Ltd.) Issues Voluntary Nationwide Recall of Cetirizine Hydrochloride Tablets USP 5 mg Due to Potential Cross Contamination with Ranitidine

SUMMARY

Company Announcement Date:	July 18, 2026
FDA Publish Date:	July 20, 2026
Product Type:	Drugs
Reason for Announcement:	Potential cross contamination with Ranitidine
Company Name:	Unique Pharmaceutical Laboratories
Brand Name:	Rising Pharma Holdings Inc.
Product Description:	Cetirizine Hydrochloride Tablets USP 5 mg

Company Announcement

FOR IMMEDIATE RELEASE – July 18th, 2026 – Panoli, Gujarat, Unique Pharmaceutical Laboratories (A Div. of J. B. Chemicals & Pharmaceuticals Ltd.) is voluntarily recalling four lots of Cetirizine Hydrochloride Tablets USP 5 mg to the consumer level due to cross contamination with Ranitidine.

Risk Statement: For consumers with a hypersensitivity to the ingredients in ranitidine, there is a reasonable probability that ingestion of Cetirizine tablets contaminated with ranitidine could result in serious adverse events including severe hypersensitivity reactions and anaphylaxis that manifests as hypotension, dyspnea, difficulty swallowing, throat and facial edema, generalized pruritic, urticaria, and loss of consciousness, which are all life-threatening. To date, Unique Pharmaceuticals has not received any reports of adverse events related to this recall.

The product is used as an Antihistamine and is packaged in HDPE Bottle pack of 100 tablets (NDC: 16571-401-10).

Product complaint received that a pharmacy technician identifies the discrepancy while counting the tablets at the time of dispensing. A product complaint reported about Appearance of red dot on Tablets of Cetirizine Hydrochloride Tablets USP 5 mg and some tablets are discolored (Appeared as discolored due to multiple red colored dots on tablets).

The product subject to this recall is listed below and packaged in HDPE bottles. The product can be identified by reviewing the product name, manufacturer details and lot number displayed on the bottle. Product was distributed Nationwide to several wholesalers/retailers.

NDC	Manufacturer	Distributed By	Product Description	Lot Numbers	Expiration Date
16571-401-10	Unique Pharmaceutical Laboratories (A Div. of J. B. Chemicals & Pharmaceuticals Ltd.)	Rising Pharma Holdings Inc.	Cetirizine Hydrochloride Tablets USP 5 mg, Pack 100's HDPE container	GY825029	10/2028
16571-401-10	Unique Pharmaceutical Laboratories (A Div. of J. B. Chemicals & Pharmaceuticals Ltd.)	Rising Pharma Holdings Inc.	Cetirizine Hydrochloride Tablets USP 5 mg, Pack 100's HDPE container	GY825030	10/2028
16571-401-10	Unique Pharmaceutical Laboratories (A Div. of J. B. Chemicals & Pharmaceuticals Ltd.)	Rising Pharma Holdings Inc.	Cetirizine Hydrochloride Tablets USP 5 mg, Pack 100's HDPE container	GY825031	10/2028
16571-401-10	Unique Pharmaceutical Laboratories (A Div. of J. B. Chemicals & Pharmaceuticals Ltd.)	Rising Pharma Holdings Inc.	Cetirizine Hydrochloride Tablets USP 5 mg, Pack 100's HDPE container	GY825032	10/2028

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Consumers with general or medical inquiries regarding this recall can contact Rising Pharma Holdings Inc. at: **Phone number:** 1-844-874-7464 8:00 a.m. to 5:00 p.m. (EST), (Monday-Friday) or **e-mail address:** pv@risingpharma.com or qa@risingpharma.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm¹
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm² 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**