

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

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

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.

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.html
- 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

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

PRODUCT LABEL:

NDC 16571-401-10

Original Prescription Strength

Cetirizine Hydrochloride Tablets USP 5mg

100 Tablets

24 Hour Relief of:

- Sneezing
- Runny Nose
- Indoor & Outdoor Allergies
- Itchy, Watery Eyes
- Itchy Throat or Nose

Other Information:

- Store at 20° to 25° C (68° to 77° F)
- See USP Controlled Room Temperature.

Inactive ingredients: hypromellose, lactose, magnesium stearate, maize starch, polyethylene glycol, povidone, titanium dioxide

Questions? call 1-844-874-7464

129575

Manufactured by: Unique Pharmaceutical Labs. (A Div. of J.B.Chemicals & Pharmaceuticals Ltd.), Mumbai 400 030, India

Distributed by: Rising Pharma Holdings, Inc. East Brunswick, NJ 08816

M. L. G/25/2188 Jul. 2020

Lot No.:
Exp.:

THE PRODUCT CAN BE IDENTIFIED AS BELOW:



CETIRIZINE HYDROCHLORIDE TABLETS USP 5 MG

