Unique Pharmaceutical Laboratories Issues Voluntary Nationwide Recall of Cetirizine 5 mg Tablets

Date: 07/20/2026

At Prime Therapeutics, we want to help you receive the best possible care. Visit our drug recall site for details: https://www.primetherapeutics.com/drugrecalls.

About this recall:
Unique Pharmaceutical Laboratories (a division of J. B. Chemicals & Pharmaceuticals) has voluntarily recalled four lots of Cetirizine Hydrochloride (HCl) Tablets, USP, 5 mg (NDC 16571-0401-10) to the consumer level due to cross contamination with ranitidine. The issue was identified after red-colored dots and discoloration (due to multiple red dots) were detected on affected tablets by a pharmacy technician.

For lot recalls, the lot/batch information and expiration date for the recalled product can be viewed by clicking on the link to the FDA Recall Notification found on the following page.

Cetirizine is an over-the-counter (OTC) antihistamine used for temporarily relieving symptoms (runny nose, sneezining, itchy/watery eyes, etc.) due to hay fever or other upper respiratory allergies. The recalled product is packaged in 100-count bottles with the lot number displayed on the bottle label.

What this means to you:
For patients with a hypersensitivity to the ingredients in ranitidine, the potential exists that consuming cetirizine tablets contaminated with ranitidine could lead to serious adverse reactions including serious hypersensitivity reactions (such as anaphylaxis). This may result in low blood pressure, shortness of breath, difficulty swallowing, throat and facial swelling, itching, hives 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.

Consumers with inquiries regarding this recall can contact Rising Pharma Holdings at 1-844-874-7464 8:00 a.m. to 5:00 p.m. (EST), Monday to Friday or via email at pv@risingpharma.com or qa@risingpharma.com. Consumers should contact their healthcare professional 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.
  Regular Mail or Fax: Download form 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.

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/unique-pharmaceutical-laboratories-div-j-b-chemicals-pharmaceuticals-ltd-issues-voluntary-nationwide

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.