



## SAFETY ALERT

DRAP SAFETY ALERT NO. 66

### Safety Alert of Risk of severe itching after discontinuation of long-term use of Cetirizine and Levocetirizine.

Date: 9<sup>th</sup> of February, 2026

#### Target Audience.

- Provincial Health Departments/Provincial PV Centres;
- Manufacturers and importers of Cetirizine and Levocetirizine;
- Healthcare Professionals; and
- Patients.

#### Background.

The US Food and Drug Administration (FDA) in May, 2025 warned about the risk of severe itching after discontinuation of long-term use of allergy medicines (Cetirizine and Levocetirizine). FDA warned that patients stopping the oral allergy medicines cetirizine (Zyrtec®) or levocetirizine (Xyzal®) after long-term use may experience rare but severe itching, also called pruritus. The itching has been reported in patients who used these medicines daily, typically for at least a few months and often for years. Patients did not experience itching before starting the medicines. Reported cases were rare but sometimes serious, with patients experiencing widespread, severe itching that required medical intervention.

#### Action in Pakistan.

The case was discussed in the 6<sup>th</sup> meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) held on 31<sup>st</sup> of December, 2025 which decided as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022 that the National Pharmacovigilance Centre to issue a safety alert to inform healthcare professionals and patients, warning them of the risk of severe pruritus following discontinuation of long-term use of allergy medicines, namely cetirizine and levocetirizine, in line with the decision of the US FDA.

#### Therapeutic Good Affected.

**Name:** Cetirizine and levocetirizine are antihistamines and are approved to treat seasonal allergies, available in prescription and over-the-counter forms. Cetirizine and levocetirizine are antihistamines that block a molecule called histamine that the body releases during allergic reactions. Both medicines are approved to treat seasonal allergies, called seasonal allergic rhinitis, in adults and children 2 years and older. These are also approved to treat year-round allergies, called perennial allergic rhinitis, and chronic hives, called chronic idiopathic urticaria, in patients 6 months and older.





## Advice for Healthcare Professionals.

Healthcare professionals are advised to discuss the risk of pruritus after stopping cetirizine or levocetirizine with patients when prescribing or recommending these medicines, especially if planned for chronic use, and with those who indicate they are using OTC versions. Advise patients to contact healthcare professionals if they experience severe itching after stopping cetirizine or levocetirizine.

## Advice for patients.

Patients are advised to contact their healthcare professionals if they develop severe itching after stopping cetirizine or levocetirizine. Itching typically occurred within a few days of stopping these medicines after daily use for a few months to years. If patients are planning on using cetirizine or levocetirizine on a long-term basis, especially for more than a few months, they should discuss the benefits and risks with their healthcare professional, who can provide advice based on their personal needs.

## Guidelines for reporting Adverse Drug Reactions (ADRs).

Healthcare professionals and patients are requested to report any adverse drug reaction/ event with the Cetirizine and Levocetirizine and/or any other medicines to the National Pharmacovigilance Centre (NPC), Drug Regulatory Authority of Pakistan (DRAP), through the [Med Vigilance E-Reporting System \(E-forms\)](#) available on the DRAP website. Similarly, adverse events and adverse drug reactions can also be reported through the VigiMobile App by scanning the following QR code, which can also be downloaded (add to home screen) in the mobile:



## References.

- [Minutes of the 6<sup>th</sup> meeting of the Pharmacovigilance Risk Assessment Expert Committee \(PRAEC\), DRAP.](#)
- [US-FDA: Cetirizine or Levocetirizine: Drug Safety Communication - FDA Warns About Risk of Severe Itching After Discontinuation of Long-Term Use of Allergy Medicines.](#)

