

Cetirizine or levocetirizine – Safety communication

- On May 16, 2025, the [Food and Drug Administration \(FDA\)](#) [warned](#) that patients stopping the oral allergy medicines cetirizine (eg, [Zyrtec[®]](#)) or levocetirizine (eg, [Xyzal[®]](#)) after long-term use may experience rare but severe itching.
 - These medicines are available in prescription and over-the-counter (OTC) forms.
- Pruritus 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.
- Cetirizine and levocetirizine are approved to treat seasonal allergic rhinitis in adults and children 2 years and older. They are also approved to treat perennial allergic rhinitis and chronic idiopathic urticaria in patients 6 months and older.
- There were 209 cases worldwide (197 in the U.S.) of pruritus after stopping use of cetirizine, levocetirizine, or both reported to the FDA between April 25, 2017, and July 6, 2023.
 - Many reports described widespread pruritus that required medical intervention after stopping these medicines, with a large number describing significant and persistent impact on quality of life and ability to function.
 - In nearly 92% (n = 97) of the 106 pruritus cases where patients reported time length of medicine usage, the length was more than 3 months, suggesting this timeframe may be a risk predictor. The number of pruritus cases increased with duration of use, suggesting that longer use may increase the risk of this reaction.
 - Restarting the medicine resolved pruritus in 71 out of 79 individuals (90%) and tapering off the medicine after restarting it resolved symptoms in 9 out of 24 (38%) of those who tried this approach.
- Patients should contact their health care professional if they experience severe itching after stopping OTC or prescription cetirizine or levocetirizine.
- Health care professionals should 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.
- The FDA is adding a warning about the risk of pruritus after stopping long-term use of prescription cetirizine or levocetirizine to the prescribing information for these medicines.
- The FDA will also request that manufacturers add a warning about pruritus after stopping use of cetirizine and levocetirizine to the drug facts label of the OTC versions.