

FDA Drug Safety Communication

FDA requires warning about rare but severe itching after stopping long-term use of oral allergy medicines cetirizine or levocetirizine (Zyrtec, Xyzal, and other trade names)

Can occur with both prescription and over-the-counter forms of these medicines

05-16-2025 FDA Drug Safety Communication

What safety concern is FDA announcing?

The U.S. Food and Drug Administration (FDA) is warning that patients stopping the oral allergy medicines cetirizine (Zyrtec) or levocetirizine (Xyzal) after long-term use may experience rare but severe itching. These medicines are available in prescription and [over-the-counter \(OTC\) forms](#). The itching, also called 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. As a result, we are revising the prescription cetirizine and levocetirizine [prescribing information](#) to include a new warning about this risk. We will subsequently request that manufacturers add a warning about pruritus to the [Drug Facts Label](#) of the OTC versions.

What is FDA doing?

We are adding a warning about the risk of pruritus after stopping long-term use of prescription cetirizine or levocetirizine to the [prescribing information](#) to increase awareness about this rare but serious reaction. The updated prescribing information also states that pruritus symptoms may improve with restarting the medicines. We will also request that manufacturers add a warning about pruritus to the [Drug Facts Label](#) of OTC cetirizine and levocetirizine. In the meantime, we want to make the public aware of this risk. We will follow up when additional information becomes available.

What are cetirizine and levocetirizine, and how can they help me?

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. The medicines 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.

Cetirizine was approved for oral use by prescription in December 1995 under the trade name Zyrtec (no longer sold as a prescription medicine) and approved for OTC use in November 2007. Levocetirizine was approved for oral use by prescription in May 2007 under the trade name Xyzal and approved for OTC use in January 2017.

What should patients and parents/caregivers do?

Patients should contact your health care professional if you develop severe itching after stopping prescription or OTC cetirizine or levocetirizine. Patients should know that itching typically occurred within a few days of stopping these medicines after daily use for a few months to years. Individuals planning on long-term use of cetirizine or levocetirizine, especially for more than a few months, should discuss the benefits and risks with your health care professional, who can provide advice based on your personal needs.

What should health care professionals do?

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. Encourage patients to contact you if they experience severe itching after stopping cetirizine or levocetirizine. Effective treatments for pruritus have not been evaluated. However, symptoms resolved in most patients who restarted the medicine and in some who tapered off the medicine after restarting it.

What did FDA find?

We identified 209 cases worldwide (197 in the United States) of pruritus after stopping use of cetirizine (n=180), levocetirizine (n=27), or both (n=2) reported to FDA between April 25, 2017, and July 6, 2023. This number includes only reports submitted to FDA* so there may be additional cases of which we are unaware (see Data Summary). The majority of these medications are OTC; it is estimated that the total OTC purchases for these products in 2022 was more than 60 million packages. Pruritus after medicine discontinuation appears to be rare compared to how often the medicine is used (see Facts about Cetirizine and Levocetirizine). The underlying mechanism for this risk is unknown, but our evaluation supports a causal relationship between stopping cetirizine or levocetirizine and pruritus. 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. Most patients who experienced pruritus after medicine discontinuation reported using these medicines for more than 3 months; however, some experienced this reaction after less than 1 month of use. Restarting the medicine resolved pruritus in most individuals, and tapering off the medicine after restarting it resolved symptoms in some who tried this approach. Other than prolonged use, we have not identified any clear risk factors for pruritus after medicine discontinuation.

*The cases were reported to the [FDA Adverse Event Report System \(FAERS\) database](#).

What is my risk?

All medicines may have side effects even when used correctly as prescribed. People respond differently to medicines depending on their health, genetic factors, other medicines they are taking, and many other factors. As a result, we cannot determine the likelihood of someone experiencing pruritus after stopping cetirizine or levocetirizine. Talk to your health care professional(s) if you have questions or concerns about the risks of taking these medicines.

How do I report side effects from cetirizine and levocetirizine?

To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving cetirizine or levocetirizine or other medicines to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of this page.

How can I get new safety information on medicines I'm prescribing or taking?

You can sign up for [email alerts](#) about Drug Safety Communications on medicines or medical specialties of interest to you.

Facts about cetirizine and levocetirizine

- Cetirizine and levocetirizine are available as prescription and over-the-counter (OTC) medicines to treat seasonal allergies, called seasonal allergic rhinitis; year-round allergies, called perennial allergic rhinitis; and chronic hives, called chronic idiopathic urticaria.
- Cetirizine and levocetirizine are antihistamines that block a molecule called histamine that the body releases during allergic reactions.
- These medicines are available as tablets or solution taken by the mouth once daily.
- Common side effects of cetirizine and levocetirizine include fatigue, drowsiness, sore throat, cough, dry mouth, nosebleed, fever, diarrhea, and vomiting.
- In 2022, an estimated 26.8 million cetirizine and levocetirizine prescriptions were dispensed from U.S. outpatient pharmacies, 65 percent (n=17.5 million) were for the OTC version of the medicine and 35 percent (n=9.3 million) were for prescription products.¹ In addition, an estimated 62.7 million packages of OTC cetirizine and levocetirizine products were purchased by consumers (point-of-sale transactions) from U.S retail outlets.²

Additional Information for Patients and Caregivers

- FDA is warning that patients stopping allergy medicines cetirizine (Zyrtec) or levocetirizine (Xyzal) after long-term use may experience rare but severe itching. This itching, also called pruritus, has been reported in patients who had been using these medicines daily, typically for at least a few months and often years. Itching was not present before patients started the medicines.
- Pruritus can occur after stopping long-term use of prescription or over-the-counter (OTC) cetirizine or levocetirizine medicines.
- Itching developed within a few days of stopping these medicines after daily use for an extended period, typically a few months or more.
- Contact your health care professional if you experience severe itching after stopping cetirizine or levocetirizine.
- If you plan on long-term use of cetirizine or levocetirizine, especially for more than a few months, discuss the benefits and risks with your health care professional, who can provide advice based on your personal needs.
- 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.
- We will also request that manufacturers add a warning about pruritus after stopping use of these medicines to the [Drug Facts Label](#) of OTC cetirizine and levocetirizine. We will follow up when additional information becomes available.
- To help FDA track safety issues with medicines, report side effects from cetirizine or levocetirizine or other medicines to the FDA MedWatch program using the information in the “Contact FDA” box at the bottom of this page.
- You can sign up for [email alerts](#) about Drug Safety Communications on medicines and medical specialties of interest to you.

Additional Information for Health Care Professionals

- FDA is warning that patients discontinuing the antihistamine allergy medicines cetirizine or levocetirizine after long-term use may experience severe pruritus. This has been reported in patients using the medicines daily, typically for at least a few months and often years. Patients did not experience itching before starting the medicines.

- Pruritus developed within a few days after discontinuing long-term daily use of both prescription or over-the-counter (OTC) cetirizine or levocetirizine medicines.
- Encourage patients to contact you patients if they experience severe itching after stopping cetirizine or levocetirizine.
- Effective treatments for pruritus have not been evaluated. Symptoms resolved in most patients who restarted the medicine and in some patients who tapered off the medicine after restarting it.
- When prescribing or recommending these medicines, especially if planned for chronic use, discuss with patients the risk of pruritus after stopping cetirizine or levocetirizine. This risk should also be discussed with patients who indicate they are taking OTC cetirizine or levocetirizine.
- 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.
- We 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. We will follow up when additional information becomes available.
- To help FDA track safety issues with medicines, report side effects from cetirizine or levocetirizine or other medicines to the FDA MedWatch program using the information in the “Contact FDA” box at the bottom of this page.
- You can sign up for [email alerts](#) about Drug Safety Communications on medicines and medical specialties of interest to you.

Data Summary

Between April 25, 2017, and July 6, 2023, FDA identified 209 cases worldwide (197 domestic) of pruritus after stopping treatment with cetirizine (n=180), levocetirizine (n=27), or both (n=2), in the FDA Adverse Event Reporting System (FAERS) database. In all 209 cases, there was a temporal relationship between discontinuing the medicine and the onset of pruritus, and the median time to onset was 2 days, with a range of 1 to 5 days. Of these reported cases, 87 percent (n=182) were submitted by individuals using the medicines, including 6 self-identified health care professionals reporting their symptoms. In nearly 92 percent (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 median duration of medicine use before pruritus occurrence after stopping cetirizine or levocetirizine was 33 months, with a range of 1 week to 23 years. The number of pruritus cases increased with duration of use, suggesting that longer use may increase the risk of this reaction. Many reports described post-discontinuation pruritus over many areas of the body that significantly affected users’ quality of life and ability to function. Serious outcomes included disability (n=48), such as “debilitating itching to the point of being bed-ridden,” hospitalization (n=3), and thoughts of suicide or self-harm (n=2). In 92 of the 93 cases where patients reported one or more attempts at restarting then stopping the medicine, pruritus recurrence occurred. Restarting the medicine resolved pruritus in 71/79 individuals (90 percent) and tapering off the medicine after restarting it resolved symptoms in 9/24 (38 percent) of those who tried this approach.

References

1. IQVIA National Prescription Audit (NPA) database. Data year 2022. Data extracted August 2024. IQVIA home page available at <https://www.iqvia.com/insights/the-iqvia-institute/available-iqvia-data>.
2. IQVIA Consumer Health Insights and Private-Label Ingredient-Level Report. Data year 2022. Data extracted September 2023. IQVIA home page available at <https://www.iqvia.com/library/fact-sheets/iqvia-consumer-health-market-insights>.

Related Information

- [Know Which Medication Is Right for Your Seasonal Allergies](#)
- [Allergy Relief for Your Child](#)
- [The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective](#)
- [Think It Through: Managing the Benefits and Risks of Medicines](#)