

Important Drug Safety Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC25-011-CG
May 29, 2025

FDA announced 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.

RECOMMENDATIONS

1. **Patients**
 - o 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.
 - o If you are planning on using cetirizine or levocetirizine long term, 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.
2. **Health Care Professionals**
 - o 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.
 - o Advise patients to contact you if they experience severe itching after stopping cetirizine or levocetirizine.
3. Expect patients to visit your pharmacy asking for information on this safety issue and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

Cetirizine or Levocetirizine: Drug Safety Communication - FDA Warns About Risk of Severe Itching After Discontinuation of Long-Term Use of Allergy Medicines

AUDIENCE: Consumer, Patient, Health Care Professional, Pharmacy, Dermatology

ISSUE: The 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.

BACKGROUND: 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.

RECOMMENDATIONS:

Patients

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.

If you are planning on using cetirizine or levocetirizine long term, 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.

Health Care Professionals

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 you if they experience severe itching after stopping cetirizine or levocetirizine.