COMMUNICATION

COM-2025-030

20 MAY 2025

URGENT PLEASE REVIEW

Safety Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug safety information.

U.S. Food & Drug Administration Publication Date:

05/16/2025

Drug Indication:

For the treatment of seasonal allergies, perennial allergic rhinitis, and chronic hives (chronic idiopathic urticaria).

Safety Topic:

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)

FDA Requires Warning About Rare but Severe Itching After Stopping Long-Term Use of Oral Allergy Medicines

It is for this reason that we are notifying you that on 05/16/2025 the U.S. Food and Drug Administration (FDA) published a safety communication for the following product(s): cetirizine (Zyrtec®) or levocetirizine (Xyzal®).

Reason for Communication:

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 patients experiencing widespread, severe itching that required medical intervention. As a result, the FDA is revising the prescription cetirizine and levocetirizine prescribing information to include a new warning about this risk. Subsequently, the FDA will request that manufacturers add a warning about pruritus to the Drug Facts Label of the OTC versions.

Pharmacy Required Action:

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients should contact their health care professional if they develop severe itching after stopping cetirizine or levocetirizine.

Assess whether the potential benefits of continuing the drug outweigh the potential risks highlighted in this safety communication.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- ext. 219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

PharmPix Drug Safety Communication Number COM-2025-030 May 2025

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REFERENCES:

1. U.S. Food and Drug Administration (2025). *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).* https://www.fda.gov/drugs/drug-safety-and-availability/fda-requires-warning-about-rare-severe-itching-after-stopping-long-term-use-oral-allergy-medicines

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