

# FDA expands use of asthma med Xolair to treat food allergies

February 19 2024, by Ernie Mundell

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People threatened by accidental exposure to foods they're allergic to may

have a new weapon of defense: On Feb. 16, the U.S. Food and Drug Administration expanded the use of the asthma drug Xolair to help prevent anaphylactic reactions.

Xolair (omalizumab) is an injected drug and is not meant as a substitute for EpiPens or other anaphylaxis rescue remedies, the agency stressed.

Instead, "Xolair is intended for repeated use to reduce the risk of [allergic reactions](#)" if and when they occur, the FDA explained in a [news release](#).

Made by Genentech, Xolair is the first medication approved to help reduce allergic reactions to multiple types of foods, the agency noted.

Xolair was first approved in 2003 for the treatment of moderate to severe allergic asthma. It's also been approved to treat a skin rash called urticaria, as well as [chronic rhinosinusitis](#) with [nasal polyps](#) in certain patients.

The medication is a monoclonal antibody that works by binding to and blocking the function of immunoglobulin E (IgE), the antibody that helps trigger an allergic reaction.

"This newly approved use for Xolair will provide a treatment option to reduce the risk of harmful allergic reactions among certain patients with IgE-mediated food allergies," Dr. Kelly Stone said in the news release. She's associate director of the Division of Pulmonology, Allergy and Critical Care in the FDA's Center for Drug Evaluation and Research.

"While it will not eliminate food allergies or allow patients to consume food allergens freely, its repeated use will help reduce the health impact if accidental exposure occurs," she noted.

The expansion of Xolair to include folks allergic to foods opens up a

much bigger market for the drug.

"According to the Centers for Disease Control and Prevention, almost 6% of people in the United States in 2021 had a food allergy and exposure to the particular food[s] to which they are allergic can lead to potentially life-threatening allergic reactions," the FDA said.

While a drug called Palforzia can help prevent anaphylaxis in people with [peanut allergy](#), Xolair is now the only such treatment covering multiple types of food allergies.

Xolair's safety and effectiveness were tested in a trial of 168 babies, children and adults. Participants were allergic to peanut and at least two other foods, including milk, egg, wheat, cashew, hazelnut or walnut, the FDA said.

After getting Xolair or a placebo for up to five months, "of those who received Xolair, 68% [75 of 110 subjects] were able to eat the single dose of peanut protein without moderate to severe allergic symptoms [e.g., whole body hives, persistent coughing, vomiting], compared to 6% [3 of 55 subjects] who received placebo," the FDA said.

The study did not find any lessening of overall peanut allergy in people who got Xolair, however, so "continuation of strict allergen avoidance is still necessary, despite treatment with Xolair," the agency stressed.

Similar results were found among people allergic to cashew, milk or egg.

In a minority of patients, anaphylaxis can occur after taking Xolair, so the FDA is including a boxed warning with the drug.

"Patients should not receive Xolair if they have a history of known severe hypersensitivity to Xolair or any of its components," the agency

said.

**More information:** Find out more about anaphylaxis and its treatment at the [Mayo Clinic](#).

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Citation: FDA expands use of asthma med Xolair to treat food allergies (2024, February 19)  
retrieved 9 May 2024 from  
<https://medicalxpress.com/news/2024-02-fda-asthma-med-xolair-food.html>

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