HOW EXPOSED ARE TEENS TO FOOD ALLERGY TRIGGERS?

Even when patients practice food allergen avoidance, accidental exposures may be unavoidable.

RATTLED AT THE RESTAURANT

Public environments like restaurants are potential risk areas for accidental exposures—Joseph found that out the hard way

Joseph is 19 years old and allergic to dairy.

> *"When I got my meal, I knew a bite in that it had milk in it."*
>
> *—Joseph, food allergy sufferer*

- Joseph and his mother are very careful. He practices avoidance of food allergens and follows a strict diet
- This vigilance is particularly important during special occasions, like his sister's graduation party at a restaurant
- When he arrived, it was crowded and full of energy. Everyone was enjoying their food and bonding
- Joseph was on guard. He checked the menu for allergy-free foods, and the table for any visible signs of cross-contamination, but everything looked good
- He felt even better when he told the restaurant staff about his milk allergy and was reassured that they could accommodate his request

See Joseph's full story

Joseph is a real patient with allergies.
He received compensation to share his story.

JOSEPH'S EXPERIENCE IS NOT UNIQUE

No matter how careful patients are, accidents still happen

THE BIG PICTURE

Outside the home, restaurants are **the most common setting for allergic reactions**[1]

FACTS TO CONSIDER WHEN EATING OUT

Over half of accidental food exposures in restaurants occurred **despite staff being informed about specific food allergies**[1]

Nearly 30% of all allergic reactions happened **even when allergens were listed on the menu**[1]

1 in 2 restaurant workers surveyed **mistakenly believed** that patrons with food allergies could consume a small amount of allergen[2]

Cross-contamination in pots, plates, utensils, and other objects accounted for **1 in 3 allergic reactions** for patients with food allergies[3]

WHEN REACTIONS LEAD TO CRISIS

Risk of exposure to food allergens can be serious and recurring. Matthew had a severe reaction to peanuts that no patient or caregiver wants to experience again

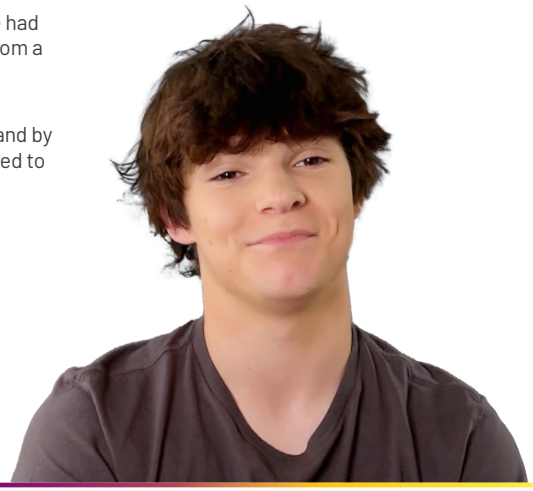
"I had no idea that it could be that severe. So that really changed the way we lived."

—Matthew's mother, caregiver of a food allergy sufferer

Matthew is allergic to peanuts, tree nuts, and shellfish.

- Matthew's severe reactions started young—he had his first anaphylactic reaction at 2 years old from a chocolate bar
- His mother didn't know it contained peanuts, and by the time she realized, his reaction had escalated to a severe level
- His reaction was so life-threatening that he needed 3 doses of epinephrine, even before the ambulance arrived

See Matthew's full story



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He received compensation to share his story.

SEVERE REACTIONS HAPPEN MILLIONS OF TIMES A YEAR

There are ~3.4 million food allergy–related ER visits annually in the US[4]

THE BIG PICTURE

Every 10 seconds a food allergy reaction **sends a patient to the ER[4]**

At least **2 in 5 children (40%)** have been **treated in the ER** for food allergy reactions[5]

SEVERE REACTIONS

53% of adults and 41% of children with food allergies **have experienced anaphylaxis[6]**

OFF TO COLLEGE WITH FOOD ALLERGIES

Transitional periods, such as moving homes or going away to college, greatly increase the risk for accidental exposures. Aalia just moved into her dorm for her first year in college, and her food allergies moved with her.

Aalia is 18 years old and allergic to egg, hazelnut, and cashew proteins.

- Aalia has been acutely aware of her food allergies her whole life. But with so many new classmates, informing all of them about her allergies has been a challenge. She's also conscious of how strict her allergy management can be
- A month into college, she has done her best to avoid allergens, but the students' common area is a problem. Snacks and drinks are constantly being left behind
- Classmates often study together in the common area, but Aalia is more cautious in these areas because of her food allergies
- Aalia voiced her concerns to the resident advisor, who promised to keep the area as clean as possible—but students can be forgetful, and many don't understand how little exposure it takes to put Aalia at risk

Models are for illustrative purposes only. Aalia is a hypothetical patient with allergies. This hypothetical patient profile is based on patient experiences seen in clinical practice. This patient profile should not be used as a substitute for independent medical judgment.

See more patient stories

AALIA IS NOT ALONE

Over 1 in 10 college-aged students have food allergies[7]

THE BIG PICTURE

Up to 63% of students with food allergies reported having **an allergic reaction while attending college**[7]

Up to 88% of students reported that their dining halls have **no allergen labels**[7]

HOW BEHAVIOR INCREASES RISKS

Over half of students with food allergies don't always practice avoidance of foods they are allergic to[7]

As few as 7% of students carried their epinephrine autoinjector regularly, even when it was recommended[7]

No matter how attentive patients are, accidents still happen

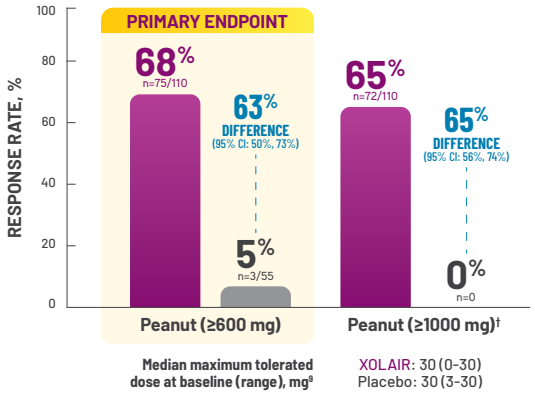
COULD PATIENTS BENEFIT FROM ANOTHER TREATMENT OPTION?

SEE HOW XOLAIR CAN HELP

XOLAIR is the first FDA-approved biologic treatment for the reduction of allergic reactions to one or more foods.[8]

XOLAIR significantly reduced allergic reactions, including anaphylaxis, after 16-20 weeks of treatment[8]

Response rate* for a single protein in pediatric patients[8]



XOLAIR provided a

6-FOLD INCREASE

in tolerance to peanut protein in

68%

OF PATIENTS

(vs 5% of patients taking placebo)[8]

600 mg of food protein ~ 2 ½ peanuts[10]

1000 mg of food protein ~ 4 ½ peanuts[10]

Treatment difference

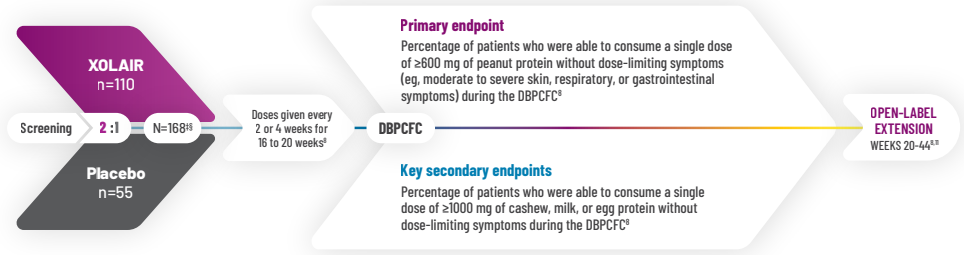
XOLAIR Placebo

Limitations: Median maximum tolerated doses at baseline provide context, and care should be taken with their interpretation. Prescribing should be done within the limits of the label.

Tolerance is defined as the ability to consume a prespecified dose of food protein without dose-limiting symptoms (eg, moderate to severe skin, respiratory, or gastrointestinal symptoms).[8]

OUtMATCH: A phase 3 clinical study evaluating XOLAIR for IgE-mediated food allergy[8,11]

- The safety and efficacy of XOLAIR was evaluated in a multicenter, randomized, double-blind, placebo-controlled study in 168 patients (165 pediatric and 3 adult) who were allergic to peanut and at least 2 other foods, including milk, egg, wheat, cashew, hazelnut, or walnut[8]
- At baseline, participants experienced dose-limiting symptoms in response to a single dose of ≤100 mg of peanut protein and ≤300 mg of protein for each of the other 2 foods (milk, egg, wheat, cashew, hazelnut, or walnut) during the screening DBPCFC[8]
- Patients were randomized to receive XOLAIR or placebo, followed by a repeat of the 4 DBPCFCs (ie, challenges with peanut protein, 2 other qualifying foods, and a negative placebo)[8,9,11]



SAFETY PROFILE ESTABLISHED IN PEDIATRIC PATIENTS AGED ≥1 YEAR WITH IgE-MEDIATED FOOD ALLERGY[8]

Adverse reactions occurring in ≥3% of XOLAIR-treated pediatric patients and more frequently than in patients treated with placebo[8]

ADVERSE REACTION	XOLAIR n=110	Placebo n=55
Injection site reactions‖	15.5%	10.9%
Pyrexia	6.4%	3.6%

- Safety data were consistent with XOLAIR clinical trials in other indications, with no new adverse reactions observed[8]
- No patients experienced anaphylaxis due to XOLAIR[9]
- There were no discontinuations due to adverse reactions[8]

*Response was defined as consumption of a single dose of the specified amount of food without dose-limiting symptoms (eg, moderate to severe skin, respiratory, or gastrointestinal symptoms).[8]
†Consumption of a single dose of ≥1000 mg of peanut protein was an additional secondary endpoint. Secondary efficacy endpoints were the percentage of patients who were able to consume a single dose of ≥1000 mg of cashew, milk, egg, walnut, hazelnut, or wheat protein.[8,11]
‡Efficacy data based on pediatric population (n=165).[8]
§Study included 3 adult patients (≥18 years of age).[8]
‖Injection site reactions terms: injection site reaction, injection site urticaria, injection site discomfort, injection site erythema, injection site pain, injection site rash, and injection site swelling. All injection site reactions were mild to moderate severity and none resulted in study discontinuation.[8]
CI=confidence interval; DBPCFC=double-blind placebo-controlled food challenge; IgE=immunoglobulin E.

INDICATION

XOLAIR® (omalizumab) is indicated for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy.

XOLAIR is to be used in conjunction with food allergen avoidance.

Limitations of Use: XOLAIR is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

IMPORTANT SAFETY INFORMATION

WARNING: Anaphylaxis

Anaphylaxis presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of XOLAIR. Anaphylaxis has occurred as early as after the first dose of XOLAIR, but also has occurred beyond 1 year after beginning regularly administered treatment. Because of the risk of anaphylaxis, initiate XOLAIR therapy in a healthcare setting and closely observe patients for an appropriate period of time after XOLAIR administration. Health care providers administering XOLAIR should be prepared to manage anaphylaxis which can be life-threatening. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should symptoms occur. Selection of patients for self-administration of XOLAIR should be based on criteria to mitigate risk from anaphylaxis.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg • 300 mg

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CONTRAINDICATIONS

XOLAIR is contraindicated in patients with a severe hypersensitivity reaction to XOLAIR or to any ingredient of XOLAIR.

WARNINGS AND PRECAUTIONS

Anaphylaxis: Anaphylaxis has been reported to occur after administration of XOLAIR in premarketing clinical trials and in postmarketing spontaneous reports. In premarketing clinical trials in patients for a different indication, anaphylaxis was reported in 3 of 3507 (0.1%) patients. Anaphylaxis occurred with the first dose of XOLAIR in two patients and with the fourth dose in one patient. The time to onset of anaphylaxis was 90 minutes after administration in two patients and 2 hours after administration in one patient.

A case-control study in asthma patients showed that, among XOLAIR users, patients with a history of anaphylaxis to foods, medications, or other causes were at increased risk of anaphylaxis associated with XOLAIR, compared to those with no prior history of anaphylaxis.

In postmarketing spontaneous reports, the frequency of anaphylaxis attributed to XOLAIR use was estimated to be at least 0.2% of patients based on an estimated exposure of about 57,300 patients from June 2003 through December 2006. Approximately 60% to 70% of anaphylaxis cases have been reported to occur within the first three doses of XOLAIR, with additional cases occurring sporadically beyond the third dose.

Initiate XOLAIR only in a healthcare setting equipped to manage anaphylaxis which can be life-threatening. Observe patients closely for an appropriate period of time after administration of XOLAIR, taking into account the time to onset of anaphylaxis seen in premarketing clinical trials and postmarketing spontaneous reports. Inform patients of the signs and symptoms of anaphylaxis, and instruct them to seek immediate medical care should signs or symptoms occur.

Once XOLAIR therapy has been established, administration of XOLAIR prefilled syringe or autoinjector outside of a healthcare setting by a patient or a caregiver may be appropriate for selected patients. Patient selection, determined by the healthcare provider in consultation with the patient, should take into account the pattern of anaphylaxis events seen in premarketing clinical trials and postmarketing spontaneous reports, as well as individual patient risk factors (e.g. prior history of anaphylaxis), ability to recognize signs and symptoms of anaphylaxis, and ability to perform subcutaneous injections with XOLAIR prefilled syringe or autoinjector with proper technique according to the prescribed dosing regimen and Instructions for Use.

Discontinue XOLAIR in patients who experience a severe hypersensitivity reaction.

Malignancy: Malignant neoplasms were observed in 20 of 4127 (0.5%) XOLAIR-treated patients compared with 5 of 2236 (0.2%) control patients in clinical studies of adults and adolescents (≥12 years of age) for a different indication and other allergic disorders. The observed malignancies in XOLAIR-treated patients were a variety of types, with breast, non-melanoma skin, prostate, melanoma, and parotid occurring more than once, and five other types occurring once each. The majority of patients were observed for less than 1 year. The impact of longer exposure to XOLAIR or use in patients at higher risk for malignancy (e.g., elderly, current smokers) is not known.

A subsequent 5-year observational study of 5007 XOLAIR-treated and 2829 non-XOLAIR-treated adolescent and adult patients for a different indication found that the incidence rates of primary malignancies (per 1000 patient years) were similar in both groups (12.3 vs 13.0, respectively). Study limitations which include the observational study design, the bias introduced by allowing enrollment of patients previously exposed to XOLAIR (88%), enrollment of patients (56%) while a history of cancer or a premalignant condition were study exclusion criteria, and the high study discontinuation rate (44%) preclude definitively ruling out a malignancy risk with XOLAIR.

Fever, Arthralgia, and Rash: In post-approval use, some patients have experienced a constellation of signs and symptoms, including arthritis/arthralgia, rash, fever, and lymphadenopathy with an onset 1 to 5 days after the first or subsequent injections of XOLAIR. These signs and symptoms have recurred after additional doses in some patients. Physicians should stop XOLAIR if a patient develops this constellation of signs and symptoms.

Parasitic (Helminth) Infection: Monitor patients at high risk of geohelminth infection while on XOLAIR therapy. Insufficient data are available to determine the length of monitoring required for geohelminth infections after stopping XOLAIR treatment.

Laboratory Tests: Due to formation of XOLAIR:IgE complexes, serum total IgE levels increase following administration of XOLAIR and may remain elevated for up to 1 year following discontinuation of XOLAIR. Do not use serum total IgE levels obtained less than 1 year following discontinuation to reassess the dosing regimen for IgE-mediated food allergy patients, because these levels may not reflect steady state free IgE levels.

Potential Medication Error Related to Emergency Treatment of Anaphylaxis
XOLAIR should not be used for the emergency treatment of allergic reactions, including anaphylaxis. In studies to simulate use, some patients and caregivers did not understand that XOLAIR is not intended for the emergency treatment of allergic reactions, including anaphylaxis. The safety and effectiveness of XOLAIR for emergency treatment of allergic reactions, including anaphylaxis, have not been established. Instruct patients that XOLAIR is for maintenance use to reduce allergic reactions, including anaphylaxis, while avoiding food allergens.

ADVERSE REACTIONS

IgE-Mediated Food Allergy: The most common adverse reactions (≥3% incidence in XOLAIR-treated patients) included: injection site reaction (15.5%) and pyrexia (6.4%). Safety data obtained from adults (n=3) in this trial was limited.

Injection Site Reactions: Injection site reactions occurred at a rate of 15.5% in XOLAIR-treated patients compared with 10.9% in placebo-treated patients. The types of injection site reactions included: urticaria, discomfort, erythema, pain, rash, and swelling. All injection site reactions were mild to moderate severity and none resulted in study discontinuation.

Injection Site Reactions in Healthy Adults: In an open label trial in healthy adults, in which the 300 mg/2 mL autoinjector was compared to the 300 mg/2 mL prefilled syringe, injection site reactions (e.g., induration, pain, erythema, hemorrhage, swelling, discomfort, bruising, hypoesthesia, edema, pruritus) were observed in 24% (16/66) of subjects treated with the autoinjector compared with 14% (9/64) of subjects treated with the prefilled syringe.

Cardiovascular and Cerebrovascular Events from Clinical Studies for a Different Indication: A 5-year observational study was conducted in 5007 XOLAIR-treated and 2829 non-XOLAIR-treated patients ≥12 years of age for a different indication to evaluate the long-term safety of XOLAIR, including the risk of malignancy. The results suggest a potential increased risk of serious cardiovascular and cerebrovascular events in patients treated with XOLAIR, however the observational study design, the inclusion of patients previously exposed to XOLAIR (88% for a mean of 8 months), baseline imbalances in cardiovascular risk factors between the treatment groups, an inability to adjust for unmeasured risk factors, and the high study discontinuation rate (44%) limit the ability to quantify the magnitude of the risk.

Pregnancy: Data with XOLAIR use in pregnant women are insufficient to inform on drug associated risk.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch.
You may also report side effects to Genentech at (888) 835-2555 or Novartis Pharmaceuticals Corporation at (888) 669-6682.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

References: 1. Oriel RC, Waqar O, Sharma HP, Casale TB, Wang J. Characteristics of food allergic reactions in United States restaurants. *J Allergy Clin Immunol Pract*. 2021;9(4):1675-1682. **2.** Bjelac J, Abrams EM, Iglesia EGA. Food allergies on vacation—there and back again. *Ann Allergy Asthma Immunol*. 2023;130(4):438-443. **3.** Fierstein JL, Brown D, Gupta R, Bilaver L. Understanding food-related allergic reactions through a US national patient registry. *J Allergy Clin Immunol Pract*. 2021;9(1):206-215.e1. **4.** Facts and statistics. Food Allergy Research & Education. Accessed September 12, 2026. https://www.foodallergy.org/resources/facts-and-statistics **5.** Food allergies in schools. Centers for Disease Control and Prevention. Published July 9, 2024. Accessed September 12, 2026. https://www.cdc.gov/school-health-conditions/food-allergies/index.html **6.** Warren C, Gupta R, Seetasith A, et al. The clinical burden of food allergies: insights from the Food Allergy Research & Education (FARE) patient registry. *World Allergy Organ J*. 2024;17:100889. **7.** Wu AC, Wang AL. Preventing anaphylaxis in college students with food allergies. *J Allergy Clin Immunol Pract*. 2023;11(4):1047-1048. **8.** XOLAIR. Prescribing information. Genentech USA, Inc. and Novartis Pharmaceuticals Corporation. **9.** Data on file. Genentech USA, Inc. South San Francisco, CA. **10.** Groetch M, Mudd K, Woch M, et al. Retail food equivalents for post-oral immunotherapy dosing in the Omalizumab as Monotherapy and as Adjunct Therapy to Multi-Allergen Oral Immunotherapy in Food-Allergic Children and Adults (OUtMATCH) clinical trial. *J Allergy Immunol Pract*. 2023;11(2):572-580.e2. **11.** Wood RA, Togias A, Sicherer SH, et al. Omalizumab for the treatment of multiple food allergies. *N Engl J Med*. 2024;390(10):889-899.

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg • 300 mg

FOR YOUR PATIENTS WITH IgE-MEDIATED FOOD ALLERGY[8]

ACCIDENTS HAPPEN—CONSIDER XOLAIR

FIRST FDA-APPROVED BIOLOGIC TREATMENT[8]

For the reduction of allergic reactions to 1 or more foods

PROVEN REACTION REDUCTIONS[8]

68% of patients receiving XOLAIR tolerated a single dose of ≥600 mg of peanut protein without dose-limiting symptoms (eg, moderate to severe skin, respiratory, or gastrointestinal symptoms) vs 5% receiving placebo

Learn more about XOLAIR

ESTABLISHED SAFETY PROFILE[8]

The most common adverse reactions (occurring in ≥3% of XOLAIR-treated pediatric patients aged 1 year and older) were injection site reactions and pyrexia

IgE=immunoglobulin E.

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