
Help your patients with IgE-mediated food allergy prepare for the unexpected[1,2]

Models are for illustrative purposes only. Individual results may vary.

Image edited with AI.

IgE=immunoglobulin E.

# New phases of life bring excitement—and hidden risks.

## Consider XOLAIR to help reduce the risk of allergic reactions from accidental exposure.[1,2]

### 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.**

Xolair® Omalizumab

*FOR SUBCUTANEOUS USE 75 mg ▪ 150 mg ▪ 300 mg*

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

# ADOLESCENTS AND YOUNG ADULTS (AGED 13-22) MAY FACE ELEVATED RISKS FOR FOOD ALLERGY REACTIONS[3,4]

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

**Risks by Age Groups**

Risk Overview

## Do these situations pose a risk for your adolescent and young adult patients as they gain independence?

### Aged 13-14

- Kids sharing lunches at **field trips**
- Unfamiliar meals at **sleepaway camp**
- Desserts at **birthday parties**
- Expanded **school lunch** options

### Aged 15-17

- Catered dinner at **prom**
- Going to the **mall food court**
- **First date** at a new restaurant
- Late-night snacks at **sleepovers**

### Aged 18-22

- Diner stops on **road trips**
- **College cafeteria** meals
- New cuisine during **air travel**
- Concessions at **concerts/ live events**

Models are for illustrative purposes only. Individual results may vary. Images edited with AI.

**XOLAIR can reduce their risk of severe allergic reactions[1,2]**
Click here to learn more or visit xolairhcp.com/fa-resources

## IMPORTANT SAFETY INFORMATION (cont'd)

### 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.



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Risks by Age Groups

**Risk Overview**

## Risky behaviors exacerbate the chance of accidental exposure[3]

These behaviors include:

- Not always carrying prescribed epinephrine
- Consuming foods labeled "may contain" allergens
- Not asking about allergens when eating out at restaurants

In a survey study of 200 adolescents and young adults (aged 14-22) with food allergies, older age was associated with a **22% increase** in odds of engaging in risky behavior.

## Increased incidence of accidental exposure[4]

Adolescents and young adults (aged 15-19) with food allergies are likely to experience accidental exposure, leading to allergic reactions, including anaphylaxis.

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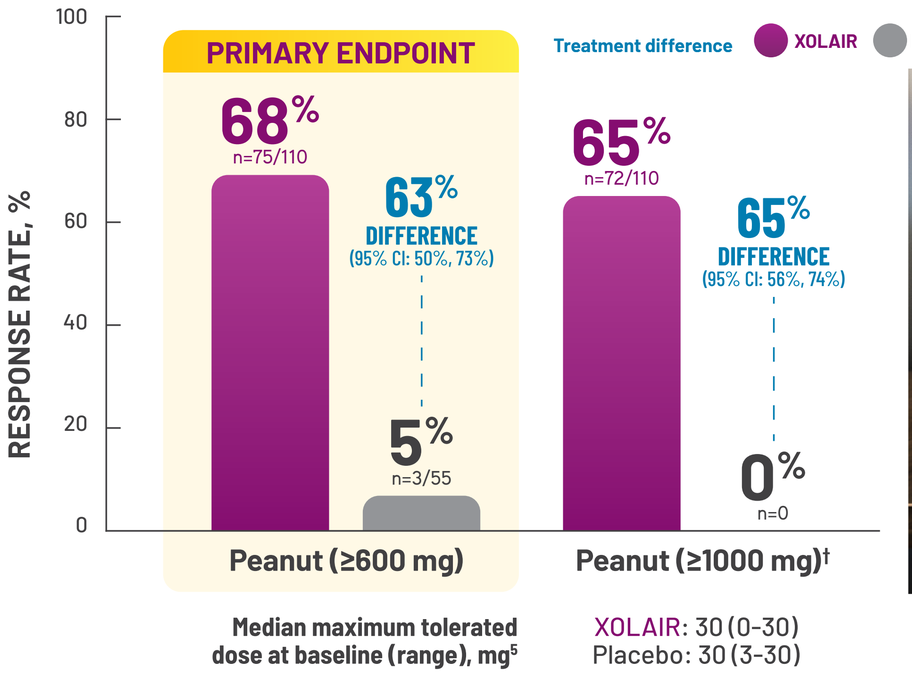
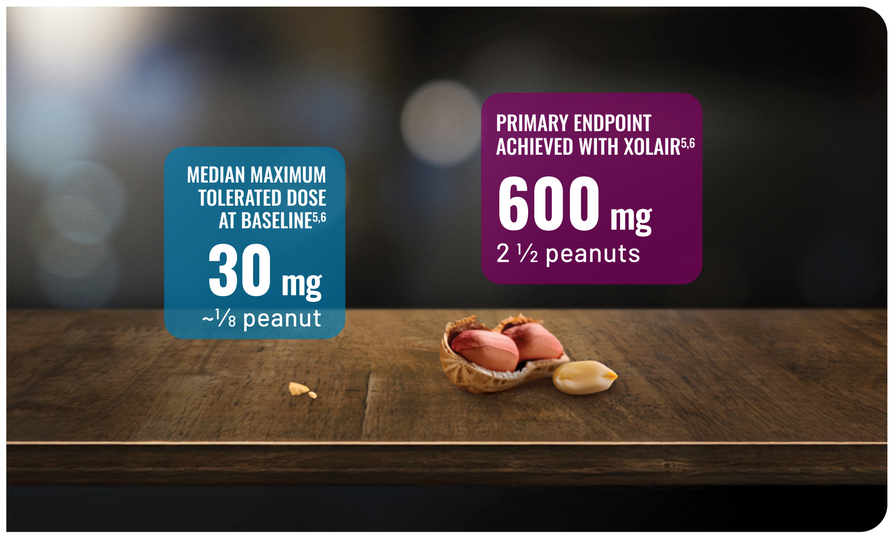
# XOLAIR HELPED PROTECT PATIENTS BY REDUCING MODERATE TO SEVERE ALLERGIC REACTIONS TO FOOD[1]

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

## Response rate* for a single protein in pediatric patients[1]




| | |
|---|---|
| **Median maximum tolerated dose at baseline (range), mg[5]** | XOLAIR: 30 (0-30)<br>Placebo: 30 (3-30) |




These are hypothetical measurements and image is not to scale.

Additional secondary endpoint achieved with XOLAIR: 1000 mg of peanut protein = 4 ½ peanuts[6]

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).[1]

## IMPORTANT SAFETY INFORMATION (cont'd)

## WARNINGS AND PRECAUTIONS (cont'd)

**Anaphylaxis (cont'd)**

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.



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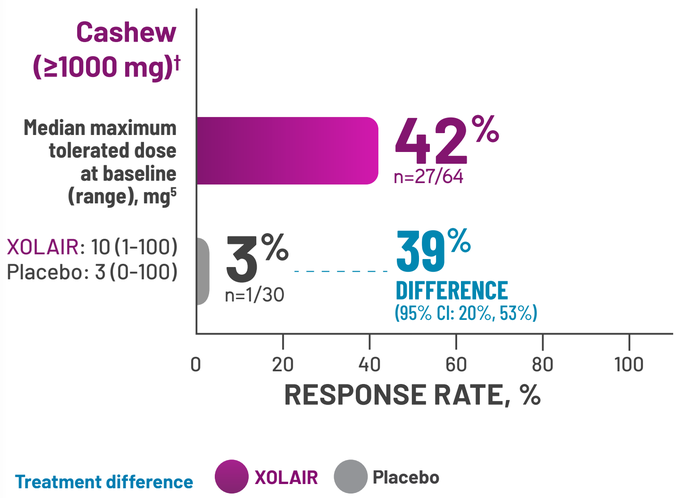
## Response rate* for a single protein in pediatric patients[1]

**Cashew**

Milk

Egg





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*Response was defined as consumption of a single dose of the specified amount of food without dose-limiting symptoms.[1]

†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.[1,2]

‡Serving size is based on egg white protein, not whole egg protein.[6]

CI=confidence interval; tbsp=tablespoon; tsp=teaspoon.

**Click here** to download a guided discussion tool to share with your patients with food allergies

## IMPORTANT SAFETY INFORMATION (cont'd)

## WARNINGS AND PRECAUTIONS (cont'd)

**Malignancy (cont'd)**

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.



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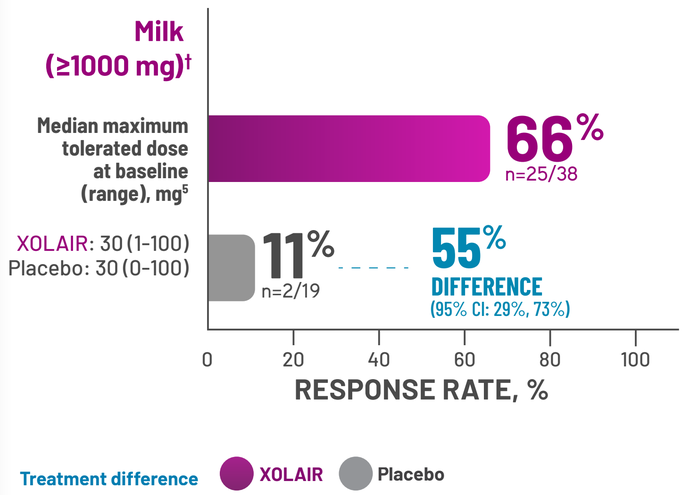



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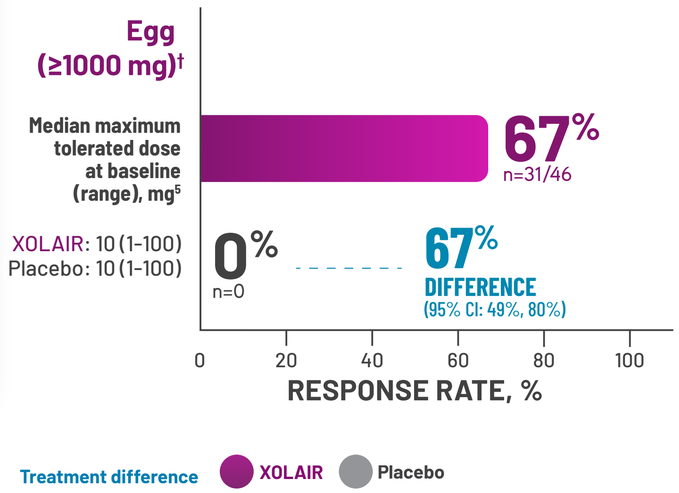



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# SAFETY PROFILE ESTABLISHED IN PEDIATRIC PATIENTS AGED ≥1 YEAR WITH IgE-MEDIATED FOOD ALLERGY[1]

Xolair® Omalizumab
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## Adverse reactions occurring in ≥3% of XOLAIR-treated pediatric patients and more frequently than in patients treated with placebo[1]

| 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[1]
- No patients experienced anaphylaxis due to XOLAIR[5]
- There were no discontinuations due to adverse reactions[1]

*Injection site reactions terms: injection site reaction, injection site urticaria, injection site discomfort, injection site erythema, injection site pain, and injection site rash. All injection site reactions were mild to moderate severity and none resulted in study discontinuation.[1]

IgE=immunoglobulin E.

## IMPORTANT SAFETY INFORMATION (cont'd)

## WARNINGS AND PRECAUTIONS (cont'd)

**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.



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## IMPORTANT SAFETY INFORMATION (cont'd)
## 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, and rash. 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 in Patients 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.

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**References: 1.** XOLAIR. Prescribing information. Genentech USA, Inc. and Novartis Pharmaceuticals Corporation. **2.** 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. **3.** Warren CM, Dyer AA, Otto AK, et al. Food allergy-related risk-taking and management behaviors among adolescents and young adults. *J Allergy Clin Immunol Pract*. 2017;5(2):381-390.e13. **4.** Dupuis R, Spergel JM, Brown-Whitehorn TF, et al. Incidence of food allergic reactions among adolescents engaged in food allergy management. *Ann Allergy Asthma Immunol*. 2025;134(6):719-723.e2. **5.** Data on file. Genentech USA, Inc. South San Francisco, CA. **6.** 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 Clin Immunol Pract*. 2023;11(2):572-580.e2.

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