



## **Xolair®: Your questions answered as of May 2024**

Xolair® (brand name for omalizumab) is the first approved medication for food allergy in the U.S., it is a biologic medicine designed to target and block immunoglobulin E (IgE), the antibody that triggers allergic reactions.

It's important to understand what Xolair delivers and who is best suited for it. Below is a list of Q/As answered by Dr. Sharon Chinthrajah, the senior investigator involved with OUtMATCH, the clinical trial which assessed Xolair and led to its approval in the U.S.

Watch our webinar: "[What's the big deal about Xolair: What is it and how does it reduce allergic reactions to foods?](#)" to hear directly from Dr. Chinthrajah on this topic.

### **1. What is Xolair approved for in the U.S. for food allergy?**

Xolair is indicated for IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions, including anaphylaxis, that may occur with accidental exposure to one or more foods. Patients who take Xolair must continue to avoid foods to which they are allergic.

### **2. How is Xolair administered?**

For IgE-mediated food allergy, Xolair is given through an injection every 2 or 4 weeks.

### **3. Do you have to stay on Xolair for life?**

Once someone stops taking Xolair, the IgE is no longer blocked.

### **4. What is the long-term safety profile of Xolair?**

Xolair is considered a safe medication, however, we do not have enough data in the 1-5 year old patient population and we need further study in this group for long-term use.

Short-term, mild side effects are more common with Xolair. These can vary depending on the condition you're treating with the medication, and examples include injection site reactions (redness, pain, swelling), headache, joint pain, and fatigue.

If you're concerned about long-term side effects with Xolair, speak to your doctor about it.

### **5. Specific to OUtMATCH, why was a history of anaphylaxis and uncontrolled asthma a part of the exclusion criteria? What does it mean for patients who experience those conditions?**

Individuals with a history of anaphylaxis or asthma were excluded from the OUtMATCH study for safety reasons. Unfortunately, those who have previously experienced anaphylaxis have a higher risk of having anaphylaxis in the future.

As part of the OUtMATCH study, all participants would undergo food challenges at baseline and other timepoints to assess the degree of the protection provided by omalizumab; so, individuals with a history

of anaphylaxis were excluded from the study due to the higher risk of them experiencing anaphylaxis during the study.

Outside of the OUtMATCH study, Xolair may be a great treatment option for patients with a history of food anaphylaxis as these patients are more sensitive to food allergens, so having this extra safety net is important. This is reinforced by the Xolair package insert noting “IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance (1.3)”.

Prior to the OUtMATCH study, Xolair was already FDA-approved for the treatment of moderate-to-severe asthma so it is possible that individuals with severe asthma may have already received omalizumab in the past. Furthermore, uncontrolled asthma is a risk factor for a severe allergic reaction to a food.

Any patient seeking therapy for their food allergies should work with their doctor to control all their allergic conditions. Omalizumab may be a therapy that could be helpful for food allergies and other allergic conditions and can be explored further with an allergist.

**6. Would Xolair be considered for patients who have both EoE and food allergy, where OIT is contraindicated?**

It has not been extensively studied for both conditions.

**7. Where can I find information about current clinical trials in Canada using Xolair?**

The BOOM study is currently recruiting for patients in Canada. This study is looking at the efficacy of using Xolair with oral immunotherapy (OIT). If you're interested in the BOOM trial, a study overview, along with the contacts and locations can be found on the [clinicaltrials.gov](https://clinicaltrials.gov) site.