Omalizumab (Xolair®) for Food Allergy: What You Need to Know



This fact sheet provides the information you need to know so you can have an informed conversation with your healthcare provider about whether omalizumab (Xolair®) may be right for you.

Omalizumab is a medicine originally approved by the U.S. Food and Drug Administration (FDA) in 2003 for asthma, in 2014 for chronic hives, and in 2020 for chronic sinusitis with nasal polyps. In February 2024, it was also FDA-approved for the treatment of IgE-mediated food allergy.

How does omalizumab work?

Omalizumab is a type of biologic medicine called a monoclonal antibody. It targets, blocks and reduces immunoglobulin E (IgE) in your body. Since IgE is a key component of allergic reactions, it can reduce the ability of food allergens to cause severe allergic responses.

What Are the Benefits?

- Omalizumab makes it less likely that small accidental exposures to food allergens will cause severe symptoms.
- It's not a cure, but it adds another layer of safety for people at high risk of allergic reactions.
- It can help reduce reactions to many types of food allergens at the same time, not just one. In other words, it is not food specific.

How Is It Taken?

Omalizumab is given as a shot under the skin (a subcutaneous injection). You'll usually get it **once every 2 to 4 weeks**, with the first 3 doses given in the doctor's office or clinic in case of severe reaction (see Side Effects and Safety Considerations below). The dose and timing of the shot depends on your weight and your IgE level, which will be tested before you start treatment. With proper training, many patients can administer the medication at home following the first 3 doses.

What Are the Side Effects and Safety Considerations?

The most common side effects are redness, swelling, or pain where the shot is given. This is called an injection site reaction. Some people may get a fever, feel tired, experience dizziness, or get headaches.

Though rare, Xolair can cause **anaphylaxis** (pronounced a-nuh-fuh-LAK-suhs), which is a severe allergic reaction. People who take this drug should be aware of symptoms of anaphylaxis like swelling, hives, or difficulty breathing, and seek medical care right away if symptoms develop. For this reason, the first three doses are typically given in a medical office setting.



What Else Do You Need to Know?

- This drug is NOT a cure.
- You still need to avoid your allergens and carry epinephrine (such as an auto-injector or nasal spray) in case you have anaphylaxis.
- Patients and caregivers should be trained to recognize and to treat anaphylaxis using an epinephrine auto-injector or nasal spray if needed.
- Plan for the cost of omalizumab. Check with your insurance to see if it's covered and ask your
 doctor about financial assistance programs if needed. Learn more about financial assistance
 programs. You can find a list at Foodallergy.org/resources/medication-affordability-assistanceprograms
- It requires a commitment. You'll need to get regular shots, and the protection stops if you stop taking the drug. Regular follow-ups with an allergist to monitor treatment effectiveness and to address any concerns is also required.

How Is It Taken?

Omalizumab may be a good choice if:

- You have multiple allergies to foods that are difficult to avoid, and you want an extra level of protection against accidental exposure.
- You have a history of having lots of serious food allergy reactions to very small amounts of the food you are allergic to.

Questions to Ask Your Doctor

- Is omalizumab right for my specific allergy and situation?
- Will I need to continue to avoid my food allergens while on this treatment?
- Do I need to have regular laboratory blood tests performed while on this treatment?
- How long will it take to start working?
- How long will I need to stay on this treatment?
- How often will I need to see my doctor for follow-up clinic visits and monitoring?
- What side effects should I watch for?
- Are there any potential long-term risks with the use of this medication?
- Will I still need other medications for my food allergies?
- Will my insurance cover it?
- Are there other treatments I should consider?

Omalizumab offers a good option for some people with food allergy, but it's not right for everyone. Deciding to use omalizumab requires a thorough discussion with a board-certified allergist to weigh the benefits and risks of your situation. For more information, visit the Xolair website: https://www.xolair.com/food-allergies/resources/patient-resources.html

