

MEDfacts

An Educational Health Series From National Jewish Health®



Anti-IgE Treatment

What is anti-IgE treatment?

Anti-IgE is a form of treatment for allergic conditions that has been approved for the treatment of moderate to severe asthma and chronic idiopathic urticarial (hives with an unknown cause). Anti-IgE interferes with the function of IgE. IgE is an antibody in the immune system.

How does anti-IgE work?

Allergens (such as pollen) are introduced to the body. Pre-made IgE against these allergens attaches to them and tells the rest of the immune cells to initiate an allergic reaction. This may bring on symptoms such as coughing, wheezing, nasal congestion, hives and swelling. Anti-IgE attaches to IgE in the blood and helps prevent the allergic reaction.

What anti-IgE medicine is available now?

Xolair® (omalizumab) is the anti-IgE medicine now available. Xolair is made to be similar to natural antibodies and is designed specifically to capture most of the IgE and block the allergic response. Xolair is approved by the FDA for use with patients over 6 years of age who:

- Have poorly controlled moderate to severe persistent asthma
- Have year-round allergies
- Are taking routine inhaled steroids.

Xolair has been shown to decrease asthma episodes in some of these patients.

Xolair has been approved for patients 12 years of age and older who:

- Have chronic idiopathic urticaria (CIU; chronic hives without a known cause) who continue to have hives that are not controlled by conventional treatment such as antihistamines or leukotriene modifying agents.

Xolair is given by a shot (injection) one to two times a month. The shots are given in the doctor's office.

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The dosage varies, depending on the person's weight and IgE blood level. Xolair is a long-term control medicine. This means it is given routinely to prevent asthma symptoms. It is **not** a quick relief medicine. Some patients improve quickly. Some patients show a gradual benefit. Xolair does not appear to work for all patients. Follow your health care provider's instructions for changing any of your asthma medicines.

Are there any side effects or adverse reactions to Xolair?

Common side effects of Xolair include a reaction at the injection site, viral infections, upper respiratory tract infection, sinusitis, headache and sore throat. These side effects were about as common in patients who received placebo injections.

Several rare, yet severe side effects were reported in the original studies. They include malignancy and anaphylaxis.

- In the initial studies, cancers (including breast, skin, prostate and salivary gland) were seen in 0.5 percent of patients treated with Xolair. The rate was 0.2 percent in patients treated with the placebo dose. A subsequent 5-year study of 5007 Xolair treated and 2829 non-Xolair treated adolescent and adult patients found similar rates of primary cancers (per 1000 patient years) in each group (12.3 compared to 13.0 respectively).
- In the initial studies, anaphylaxis was seen in less than 0.1 percent of the patients treated with Xolair. Since Xolair was approved in June 2003 additional reports of anaphylaxis have been reported to the FDA. Information was gathered from about 57,300 patients treated with Xolair (from June 2003-December 2006). The serious reactions occurred in at least 1 of every 1,000 patients. The reactions these patients had included combinations of symptoms of anaphylaxis. Symptoms of anaphylaxis include:
 - Increased trouble breathing, coughing, chest tightness or wheezing
 - Dizziness, fainting, rapid or weak heartbeat
 - Swelling in the mouth and throat or trouble swallowing
 - Flushing, itching, hives or a feeling of warmth
 - Vomiting, diarrhea or stomach cramping.

Although rare, an anaphylaxis reaction can be serious and life threatening. An anaphylactic reaction may occur with the first dose or after any dose of Xolair. The reaction may occur soon after the shot is given. It may also occur 24 hours or more after the shot is given.

Although anaphylaxis is rare several steps improve the patient's safety when receiving Xolair:

- The Xolair shots are given in the doctor's office.
- You will need to stay at the doctor's office for 2 hours after the initial three shots are given.
- After the initial three shots you will need to stay at the doctor's office for 1 hour after the shot is given.
- The doctor's office should be ready to treat an anaphylactic reaction.
- You will be instructed in the use of an epinephrine auto-injector. This is an easy-to-

give shot you can use if having an anaphylactic reaction after leaving the doctor's office.

- You should wear a medical alert bracelet.
- If you feel you are having an anaphylactic reaction, you need to get medical help right away.

Although anaphylaxis is very rare these steps can increase your safety when receiving anti-IgE treatment. Remember to talk with your doctor if you have any questions.

Note: This information is provided to you as an educational service of LUNG LINE® (1-800-222-LUNG). It is not meant to be a substitute for consulting with your own physician.

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