Xolair® (Omalizumab) for Subcutaneous Use

Full Prescribing Information, Including Boxed WARNINGS
Medication Guide

What Is Xolair?

- It is a monoclonal antibody against IgE. It was approved by the U.S. Food and Drug Administration (FDA) in June 2003. Xolair represents a number of treatment firsts:
    - First biotechnology treatment targeting the antibody IgE approved by the FDA
    - First treatment specifically designed for moderate-to-severe persistent asthma mediated by IgE
    - First asthma maintenance therapy administered every two or four weeks
- Xolair® (omalizumab) for subcutaneous use is an injectable, prescription medicine for patients ages 12 and older. It is for patients with moderate to severe persistent allergic asthma caused by year-round allergens in the air. A skin or blood test is done to see if a person has allergic asthma. Xolair is for patients who are not controlled by asthma medicines called inhaled steroids. Xolair helps reduce the number of asthma attacks in people with allergic asthma who still have asthma symptoms even though they are taking inhaled steroids.

    - Xolair has not been proven to work in other allergic conditions.
    - Xolair is not a rescue medicine and should not be used to treat sudden asthma attacks.
    - Xolair should not be used in children under 12 years of age.

WARNINGS

Xolair should always be injected in a doctor's office.

A severe allergic reaction called anaphylaxis has happened in some patients after they received Xolair. Anaphylaxis is a life-threatening condition and can lead to death. Patients must seek emergency medical treatment right away if symptoms occur. **Signs and symptoms of anaphylaxis include:**

- wheezing, shortness of breath, cough, chest tightness, or trouble breathing
- low blood pressure, dizziness, fainting, rapid or weak heartbeat, anxiety, or feeling of "impending doom"
- flushing, itching, hives, or feeling warm
- swelling of the throat or tongue, throat tightness, hoarse voice, or trouble swallowing

Clinical Trial Results

- The companies' data submission to the FDA included two 52-week pivotal Phase III clinical trials with 1,071 asthma patients, 12-76 years of age, as well as data from several supportive safety and efficacy studies, including the 1,899-patient ALTO safety study. The pivotal trials were designed to study a reduction in asthma exacerbations. The co-primary endpoint of each study was the number of asthma exacerbations (asthma attacks) per patient during the stable-steroid phase and the steroid-reduction phase. Patients were randomized to receive subcutaneous Xolair or placebo every two or four weeks. Doses were determined based on patients' body weight and IgE level. Inhaled corticosteroid doses were kept stable over the initial 16 weeks of treatment (stable-steroid phase) and tapered during a further 12-week treatment period (steroid-reduction phase).

- In two pivotal clinical trials, Xolair significantly reduced exacerbations in many patients when added to inhaled corticosteroids and even as inhaled corticosteroid dose was lowered. In a third supportive study, the number of exacerbations in patients treated with Xolair was similar to placebo-treated patients. The absence of an observed treatment effect in study 3 may be related to differences in patient population, study sample size or other factors. Other clinical benefits seen included improved asthma symptom scores such as nocturnal awakenings and daytime asthma symptoms. The clinical relevance of the treatment-associated differences is unknown.
- Xolair should always be injected in a doctor's office. A severe allergic reaction called anaphylaxis has happened in some patients after they received Xolair.
- In clinical studies, the rate of cancer was higher in patients treated with Xolair than a placebo (0.5% vs 0.2%). Several different types of cancer were seen.

Important Safety Information

XOLAIR should always be injected in a doctor's office. Patients should read the Medication Guide before starting XOLAIR treatment and before each and every treatment.

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- wheezing, shortness of breath, cough, chest tightness, or trouble breathing
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Patients must not receive XOLAIR if they have ever had an allergic reaction to a XOLAIR injection. Patients should not use XOLAIR if they are allergic to any of its ingredients.

In clinical studies 0.5% of patients receiving XOLAIR developed cancer, compared to 0.2% of patients receiving placebo (an injection with no active medicine).

Joint inflammation or pain, rash, fever, and swollen lymph nodes have been seen in patients taking XOLAIR. Patients should talk to their doctor if they have experienced any of these signs and symptoms.

In patients ≥12 years of age, the most commonly observed side effects in asthma studies were joint pain (8%), pain (general) (7%), leg pain (4%), tiredness (fatigue) (3%), dizziness (3%), fracture (2%), arm pain (2%), itching (2%), inflammation of the skin (2%), and earache (2%).

In asthma studies, the most common side effects in patients, who either needed to stop XOLAIR or needed medical attention, were injection site reaction (45%), viral infections (23%), upper respiratory tract infection (20%), sinus infection (16%), headache (15%), and sore throat (11%). These side effects were seen at the same rates in XOLAIR-treated patients as in patients in the control group who received placebo.

XOLAIR is not a rescue medicine and should not be used to treat sudden asthma attacks.

Please visit www.xolair.com for the full Prescribing Information, including Boxed WARNINGS and Medication Guide for additional important safety information.

Mechanism of Action

- In patients with IgE-mediated asthma, Xolair specifically targets the antibody IgE, an underlying component of allergic asthma. Safety and efficacy have not been established in other allergic conditions. Xolair inhibits the binding of IgE to the high-affinity IgE receptor (FcåRI) on the surface of mast cells and basophils. Reduction in surface-bound IgE on FcåRI-bearing cells limits the degree of release of mediators of the allergic response. Treatment with Xolair also reduces the number of FcåRI receptors on basophils in atopic patients.

Administration

- Xolair is administered by a healthcare provider through subcutaneous (under the skin) injection once every two or four weeks. The therapeutic dose is determined by a patient's IgE level, which is measured by a simple blood test, and body weight. Based on the patient's IgE level and body weight, the doctor will administer one, two or three injections per dose. If more than one injection is needed, each will be given in a different place on the body.

Availability

- Xolair was approved by the Food and Drug Administration on June 20, 2003 and introduced to market in July 2003. Five specialty pharmacies serve as the primary
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- distributors of Xolair: Nova Factor, Caremark, Priority Health, Option Care and CuraScript. Working in conjunction with physicians prescribing Xolair, each specialty pharmacy provides comprehensive reimbursement services to patients; deliver Xolair and ancillary supplies; provide education, compliance programs, and support kits to patients; and provide nursing services and training.

Product Information Home

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