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**Xolair® (Omalizumab) for Subcutaneous Use**

**Who is Xolair For?**

Xolair® (omalizumab) for subcutaneous use is an injectable prescription medicine used to treat adults and children 12 years of age and older with:

* moderate to severe persistent allergic asthma who have had a skin or blood test that is positive for allergic asthma and whose asthma symptoms are not controlled by asthma medicines called inhaled corticosteroids.
* chronic idiopathic urticaria (CIU; chronic hives without a known cause) who continue to have hives that are not controlled by H1-antihistamine treatment.

Xolair is not used to treat other allergic conditions, other forms of urticaria (hives), acute bronchospasm (serious and sudden breathing problems) or status asthmaticus (acute, severe prolonged asthma attack that can be life-threatening). Xolair is not for use in children less than 12 years of age.

**Important Safety Information About Anaphylaxis**

**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.**

A severe allergic reaction called anaphylaxiscan happen when a patient receives Xolair. The reaction can occur after the first dose, or after many doses. It may also occur right after a Xolair injection or days later. Anaphylaxis is a life-threatening condition and can lead to death. Patients must go to the nearest emergency room right away if they have any of these symptoms of an allergic reaction:

* 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

**Mechanism of Action**

**Allergic Asthma**  
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 (FcεRI) on the surface of mast cells and basophils. Reduction in surface-bound IgE on FcεRI-bearing cells limits the degree of release of mediators of the allergic response. Treatment with Xolair also reduces the number of FcεRI receptors on basophils in atopic patients.

**Chronic Idiopathic Urticaria**  
Xolair binds to IgE and lowers free IgE levels. Subsequently, IgE receptors (FcεRI) on cells down-regulate. The mechanism by which these effects of Xolair result in an improvement of CIU symptoms is unknown.

**Clinical Trial Results**

**Allergic Asthma**

*Adult and Adolescent Patients 12 years of Age and Older*

* The efficacy and safety profile of Xolair for moderate to severe persistent allergic asthma was evaluated in three clinical studies. The trials included patients 12 to 76 years old, with moderate to severe persistent asthma for at least one year, and a positive skin test reaction to a perennial aeroallergen. In all trials, Xolair dosing was based on body weight and serum total IgE concentration before treatment began.
* In all three trials an asthma flare-up (exacerbation) was defined as a worsening of asthma that required treatment with medicines called systemic corticosteroids (ICS) or a doubling of the ICS dose that had been used prior to treatment with Xolair. Most asthma flare-ups were managed in the out-patient setting and the majority was treated with medicines called systemic steroids. Hospitalization rates were not significantly different between Xolair and placebo-treated patients; however, the overall hospitalization rate was small. Among those patients who experienced an asthma flare-up, the rate and severity of such attacks were similar between treatment groups.
* In both Asthma Studies 1 and 2 the number of asthma flare-ups per patient was reduced in patients treated with Xolair compared with placebo. In Asthma Study 3, the number of asthma flare-ups in patients treated with Xolair was similar to that in placebo treated patients.
* In all three of the studies, a reduction of asthma flare-ups was not observed in the Xolair-treated patients who had FEV1 > 80 percent, a measure of lung function, at the time when they were assigned to treatment groups via a process called randomization. Reductions in flare-ups were not seen in patients who required oral steroids as maintenance therapy, i.e., on an ongoing basis.
* The most commonly seen side effects occurring more frequently in patients receiving Xolair than in patients who received placebo (an injection with no active medicine) were joint pain, pain (general), leg pain, tiredness (fatigue), dizziness, fracture, arm pain, itching, inflammation of the skin, and earache.
* Injection site reactions of any severity occurred at a rate of 45 percent in Xolair-treated patients compared with 43 percent in placebo-treated patients. The types of injection site reactions included: bruising, redness, warmth, burning, stinging, itching, hive formation, pain, indurations, mass, and inflammation.

**Chronic Idiopathic Urticaria**

*Adult and Adolescent Patients 12 years of Age and Older*

* The efficacy and safety profile of Xolair for the treatment of CIU was evaluated in two clinical studies called ASTERIA I and ASTERIA II. In these studies, patients 12 to 75 years old received doses of Xolair at 150 mg, 300 mg or placebo. Xolair or placebo was given every four weeks for 24 weeks (ASTERIA I) and 12 weeks (ASTERIA II). In addition, patients continued to receive H1-antihistamine medicines they had been taking for CIU before starting treatment with Xolair.
* The efficacy of Xolair in patients 12 years and older who remained symptomatic despite taking H1-antihistamines was assessed using a scale known as the average (mean) weekly Itch Severity Score (ISS) at Week 12. The weekly ISS has potential scores ranging from 0 to 21.
* In ASTERIA I, Xolair 150 mg improved ISS from the starting measurement by 47 percent (-6.7) and Xolair 300 mg improved ISS from the starting measurement by 66 percent (-9.4) at Week 12, compared to a 25 percent (-3.6) score improvement for patients who received placebo.
* A larger proportion of patients (36 percent) treated with Xolair 300 mg reported no itch and no hives at Week 12, compared to patients treated with Xolair 150 mg (15 percent), and patients in the placebo group (9 percent). Similar results were observed for the ASTERIA II study.
* The most common side effects in patients treated with Xolair were nausea, headaches, swelling of the inside of the nose, throat or sinuses, cough, joint pain, and upper respiratory tract infection.
* Injection site reactions of any severity occurred during the studies in more Xolair-treated patients [11 patients (2.7 percent) at 300 mg, 1 patient (0.6 percent) at 150 mg] compared with 2 placebo-treated patients (0.8 percent). The types of injection site reactions included: swelling, redness, pain, bruising, itching, bleeding and hive formation. None of the events resulted in study discontinuation or treatment interruption.

**Dosage and Administration**

**Allergic Asthma**

**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.**

* Xolair is administered by a healthcare provider (HCP) 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.

**Chronic Idiopathic Urticaria**

* Xolair is administered by an HCP in doses of 150 mg or 300 mg through subcutaneous injection every four weeks. Dosing of Xolair in CIU patients is not dependent on serum IgE (free or total) level or body weight. The appropriate duration of therapy for CIU has not been evaluated. Doctors should periodically reassess the need for continued therapy.

**Important Safety Information**

A severe allergic reaction called anaphylaxis can happen when a patient receives Xolair. The reaction can occur after the first dose, or after many doses. It may also occur right after a Xolair injection or days later. Anaphylaxis is a life-threatening condition and can lead to death. Patients must go to the nearest emergency room right away if they have any of these symptoms of an allergic reaction:

* 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

The patient’s healthcare provider will monitor the patient closely for symptoms of an allergic reaction while they are receiving Xolair and for a period of time after the patient’s injection. The patient’s healthcare provider should talk to the patient about getting medical treatment if they have symptoms of an allergic reaction after leaving the healthcare provider’s office or treatment center.

**Patients must not receive Xolair if they** are allergic to omalizumab or any of the ingredients in Xolair.

**Before receiving Xolair, patients must tell their healthcare provider about all of their medical conditions, including if they:**

* have any other allergies (such as food allergy or seasonal allergies)
* have sudden breathing problems (bronchospasm)
* have or have had low white blood cell count (patients should ask their doctor if they are not sure)
* have or have had a parasitic infection
* have or have had cancer
* are pregnant or plan to become pregnant. It is not known if Xolair may harm a patient’s unborn baby.
* if a patient becomes pregnant while taking Xolair, they should talk to their healthcare provider about registering with the Xolair Pregnancy Registry. Patients can get more information and register by calling (866) 4XOLAIR (866-496-5247) or visit http://www.xolairpregnancyregistry.com.
* are breastfeeding or plan to breastfeed. It is not known if Xolair passes into breast milk.

Patients must tell their healthcare provider about all the medicines they take, including prescription and over-the-counter medicines, vitamins, or herbal supplements.

**Receiving Xolair**

* Xolair should be given by a healthcare provider in a healthcare setting.
* Xolair is given in one or more injections under the skin (subcutaneous), one time every two or four weeks.
* The patient’s healthcare provider may do certain tests and change the patient’s Xolair dose as needed.
* Patients must not stop taking any of their other asthma or hive medicine unless their healthcare providers tell them to.
* Patients may not see improvement in their symptoms right away after Xolair treatment.

**Possible side effects of Xolair:**

**Xolair may cause serious side effects, including:**

* See “What is the most important information I should know about Xolair?” in the Xolair Medication Guide at http://www.xolair.com
* Cancer. People who receive treatment with Xolair may have a higher chance for getting certain types of cancer.
* Fever, muscle aches, and rash. Some people who take Xolair get these symptoms one to five days after receiving a Xolair injection. If a patient has any of these symptoms, they must tell their healthcare provider.
* Parasitic infection. Some people who are at a high risk for parasite (worm) infections, get a parasite infection after receiving Xolair. The patient’s healthcare provider can test the patient’s stool to check if they have a parasite infection.
* High blood levels of a certain antibody (Serum total IgE)

**The most common side effects of Xolair:**

* In people with allergic asthma: pain especially in the arms and legs, dizziness, feeling tired, skin rash, bone fractures, and pain or discomfort of the ears.
* In people with chronic idiopathic urticaria: nausea, headaches, swelling of the inside of the nose, throat or sinuses, cough, joint pain, and upper respiratory tract infection.

These are not all the possible side effects of Xolair. Patients should call their doctor for medical advice about side effects.

Report side effects to the FDA at (800) FDA-1088 or http://[www.fda.gov/medwatch](http://www.fda.gov/medwatch). Report side effects to Genentech at (888) 835-2555.

Please see full Prescribing Information, including Medication Guide for additional important safety information at http://www.xolair.com.

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