HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use XOLAIR safely and effectively. See full prescribing information for XOLAIR.

XOLAIR® (omalizumab) injection, for subcutaneous use
XOLAIR® (omalizumab) for injection, for subcutaneous use
Initial U.S. Approval: 2003

WARNING: ANAPHYLAXIS

See full prescribing information for complete boxed warning.

Anaphylaxis, presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of XOLAIR. Anaphylaxis has occurred after the first dose of XOLAIR but also has occurred beyond 1 year after beginning treatment. Closely observe patients for an appropriate period of time after XOLAIR administration and be prepared to manage anaphylaxis that can be life-threatening. Inform patients of the signs and symptoms of anaphylaxis and have them seek immediate medical care should symptoms occur. (5.1)

----------RECENT MAJOR CHANGES----------

Indications and Usage (1.2)	11/2020
Dosage and Administration (2.1, 2.3, 2.5)	11/2020
Warnings and Precautions (5.4, 5.8)	11/2020

----------INDICATIONS AND USAGE----------

XOLAIR is an anti-IgE antibody indicated for:

- Moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids (1.1)
- Nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment (1.2)
- Chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment (1.3)

Limitations of Use:

- Not indicated for acute bronchospasm or status asthmaticus. (1.1, 5.3)
- Not indicated for other allergic conditions or other forms of urticaria. (1.1, 1.2)

----------DOSAGE AND ADMINISTRATION----------

For subcutaneous (SC) administration only. (2.2, 2.3, 2.4)
Divide doses of more than 150 mg among more than one injection site to limit injections to not more than 150 mg per site. (2.6, 2.7)

- Asthma: XOLAIR 75 to 375 mg SC every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). See the dose determination charts. (2.2)
- Nasal Polyps: XOLAIR 75 to 600 mg SC every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). See the dose determination charts. (2.3)
- Chronic Idiopathic Urticaria: XOLAIR 150 or 300 mg SC every 4 weeks. Dosing in CIU is not dependent on serum IgE level or body weight. (2.4)

----------DOSAGE FORMS AND STRENGTHS----------

- Injection: 75 mg/0.5 mL and 150 mg/mL solution in a single-dose prefilled syringe (3)
- For Injection: 150 mg lyophilized powder in a single-dose vial for reconstitution (3)

----------CONTRAINDICATIONS----------

Severe hypersensitivity reaction to XOLAIR or any ingredient of XOLAIR (4, 5.1)

----------WARNINGS AND PRECAUTIONS----------

- Anaphylaxis: Administer only in a healthcare setting prepared to manage anaphylaxis that can be life-threatening and observe patients for an appropriate period of time after administration. (5.1)
- Malignancy: Malignancies have been observed in clinical studies. (5.2)
- Acute Asthma Symptoms: Do not use for the treatment of acute bronchospasm or status asthmaticus. (5.3)
- Corticosteroid Reduction: Do not abruptly discontinue corticosteroids upon initiation of XOLAIR therapy. (5.4)
- Eosinophilic Conditions: Be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy, especially upon reduction of oral corticosteroids. (5.5)
- Fever, Arthralgia, and Rash: Stop XOLAIR if patients develop signs and symptoms similar to serum sickness. (5.6)

----------ADVERSE REACTIONS----------

- Asthma: The most common adverse reactions (≥ 1% of patients) in clinical studies with adult and adolescent patients ≥12 years of age were arthralgia, pain (general), leg pain, fatigue, dizziness, fracture, arm pain, pruritus, dermatitis, and earache. In clinical studies with pediatric patients 6 to <12 years of age, the most common adverse reactions were nasopharyngitis, headache, pyrexia, upper abdominal pain, pharyngitis streptococcal, otitis media, viral gastroenteritis, arthropod bites, and epistaxis. (6.1)
- Nasal Polyps: The most common adverse reactions (≥ 3% of patients) in clinical studies with adult patients included the following: headache, injection site reaction, arthralgia, upper abdominal pain, and dizziness. (6.1)
- Chronic Idiopathic Urticaria: The most common adverse reactions (≥2% of patients) included the following: nausea, nasopharyngitis, sinusitis, upper respiratory tract infection, viral upper respiratory tract infection, arthralgia, headache, and cough. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Genentech at 1-888-835-2555 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------

No formal drug interaction studies have been performed. (7)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 11/2020

FULL PRESCRIBING INFORMATION: CONTENTS*

Table 2. Subcutaneous XOLAIR Doses Every 2 or 4 Weeks* for Pediatric Patients with Asthma Who Begin XOLAIR Between the Ages of 6 to <12 Years

Pre-treatment Serum IgE (IU/mL)	Dosing Freq.	Body Weight									
		20-25 kg	>25-30 kg	>30-40 kg	>40-50 kg	>50-60 kg	>60-70 kg	>70-80 kg	>80-90 kg	>90-125 kg	>125-150 kg
		Dose (mg)									
30-100	Every 4 weeks	75	75	75	150	150	150	150	150	300	300
>100-200		150	150	150	300	300	300	300	300	225	300
>200-300		150	150	225	300	300	225	225	225	300	375
>300-400		225	225	300	225	225	225	300	300		
>400-500		225	300	225	225	300	300	375	375		
>500-600		300	300	225	300	300	375				
>600-700		300	225	225	300	375					
>700-800	Every 2 weeks	225	225	300	375						
>800-900		225	225	300	375						
>900-1000		225	300	375							
>1000-1100		225	300	375							
>1100-1200		300	300								
>1200-1300		300	375								

Insufficient Data to Recommend a Dose

***Dosing frequency:**

- Subcutaneous doses to be administered every 4 weeks
- Subcutaneous doses to be administered every 2 weeks

Duration of Therapy

Periodically reassess the need for continued therapy based upon the patient's disease severity and level of asthma control.

2.3 Recommended Dosage for Nasal Polyps

Administer XOLAIR 75 mg to 600 mg by subcutaneous injection every 2 or 4 weeks based on serum total IgE level (IU/mL) measure before the start of treatment and by body weight (kg) *[see Dosage and Administration 2.2]*.

Table 3. Subcutaneous XOLAIR Doses Every 2 or 4 Weeks* for Adult Patients with Nasal Polyps

Pretreatment Serum IgE (IU/mL)	Dosing Freq.	Bodyweight							
		>30-40 kg	>40-50 kg	>50-60 kg	>60-70 kg	>70-80 kg	>80-90 kg	>90-125 kg	> 125-150 kg
		Dose (mg)							
30 - 100	Every 4 Weeks	75	150	150	150	150	150	300	300
>100 - 200		150	300	300	300	300	300	450	600
>200 - 300		225	300	300	450	450	450	600	375
>300 - 400		300	450	450	450	600	600	450	525
>400 - 500		450	450	600	600	375	375	525	600
>500 - 600		450	600	600	375	450	450	600	
>600 - 700		450	600	375	450	450	525		
>700 - 800	Every 2 Weeks	300	375	450	450	525	600		
>800 - 900		300	375	450	525	600			
>900 - 1000		375	450	525	600				
>1000 - 1100		375	450	600					
>1100 - 1200		450	525	600	Insufficient Data to Recommend a Dose				
>1200 - 1300		450	525						
>1300 - 1500		525	600						

***Dosing frequency:**

- Subcutaneous doses to be administered every 4 weeks
- Subcutaneous doses to be administered every 2 weeks

Duration of Therapy

Periodically reassess the need for continued therapy based upon the patient's disease severity and level of symptom control.

2.4 Recommended Dosage for Chronic Idiopathic Urticaria

Administer XOLAIR 150 mg or 300 mg by subcutaneous injection every 4 weeks. Dosing of XOLAIR in CIU patients is not dependent on serum IgE (free or total) level or body weight.

Duration of Therapy

The appropriate duration of therapy for CIU has not been evaluated. Periodically reassess the need for continued therapy.

2.5 Administration

XOLAIR is available as a prefilled syringe and as a lyophilized powder in vial for reconstitution. Both XOLAIR prefilled syringe and lyophilized powder should be administered by a healthcare professional. Administer XOLAIR by subcutaneous injection. The injection may take 5-10 seconds to administer. Do not administer more than one injection per site. (Table 4, Table 5).

Table 4. Number of Prefilled Syringes, Injections and Total Injection Volumes

XOLAIR Dose*	75 mg Syringes	150 mg Syringes	Total Volume Injected
75 mg	1	0	0.5 mL
150 mg	0	1	1 mL
225 mg	1	1	1.5 mL
300 mg	0	2	2 mL
375 mg	1	2	2.5 mL
450 mg	0	3	3 mL
525 mg	1	3	3.5 mL
600 mg	0	4	4 mL

* The 75 mg, 150 mg, 225 mg, 300 mg, and 375 mg XOLAIR doses are approved for use in asthma patients. All doses in the table are approved for use in nasal polyps patients. The 150 mg and 300 mg XOLAIR doses are also approved for use in CIU patients.

Table 5. Number of Vials, Injections and Total Injection Volumes

XOLAIR Dose*	Number of Vials	Number of Injections	Total Volume Injected
75 mg	1	1	0.6 mL
150 mg	1	1	1.2 mL
225 mg	2	2	1.8 mL
300 mg	2	2	2.4 mL
375 mg	3	3	3.0 mL
450 mg	3	3	3.6 mL
525 mg	4	4	4.2 mL
600mg	4	4	4.8 mL

* The 75 mg, 150 mg, 225 mg, 300 mg, and 375 mg XOLAIR doses are approved for use in asthma patients. All doses in the table are approved for use in nasal polyps patients. The 150 mg and 300 mg XOLAIR doses are also approved for use in CIU patients.

2.6 Preparation for Use and Injection of XOLAIR Prefilled Syringe