Xolair®
Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg

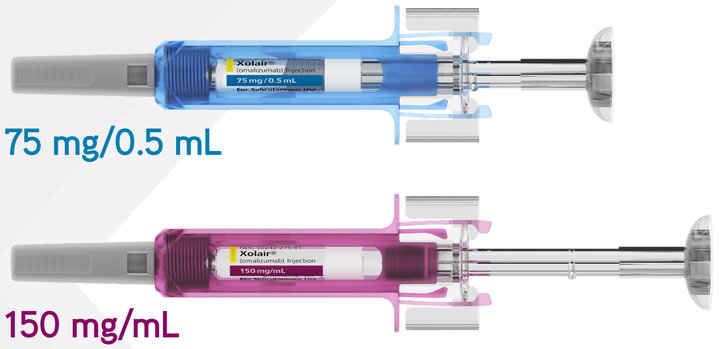
DOSING GUIDE

Available as a single-dose prefilled syringe and as a lyophilized powder in vial for reconstitution[1]

Both XOLAIR prefilled syringe and lyophilized powder should be **administered by a healthcare professional** by subcutaneous injection. The injection may take 5-10 seconds to administer. Do not administer more than one injection per site.

Prior to administration, be sure to review the full Prescribing Information including Medication Guide. Instruct patients to read the Medication Guide prior to treatment.

Single-dose prefilled syringe



75 mg/0.5 mL

150 mg/mL

150 mg vial of lyophilized powder for reconstitution

Products not shown to scale.

INDICATIONS

XOLAIR® (omalizumab) IS INDICATED FOR:

- Moderate to severe persistent asthma in patients 6 years of age and older who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. XOLAIR has been shown to decrease the incidence of asthma exacerbations in these patients.

  Limitations of Use: XOLAIR is not indicated for the relief of acute bronchospasm, status asthmaticus, or for treatment of other allergic conditions.
- Add-on maintenance treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.
- Chronic idiopathic urticaria in patients 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.

Limitations of Use: XOLAIR is not indicated for treatment of other forms of urticaria.

IMPORTANT SAFETY INFORMATION

WARNING: Anaphylaxis

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 as early as after the first dose of XOLAIR, but also has occurred beyond 1 year after beginning regularly administered treatment. Because of the risk of anaphylaxis, observe patients closely for an appropriate period of time after XOLAIR administration. Health care providers administering XOLAIR should be prepared to manage anaphylaxis that can be life-threatening. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should symptoms occur.

Please see pages 10-11 and accompanying full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

Adult and Adolescent Allergic Asthma: Aged ≥12 years	Pediatric Allergic Asthma: Aged 6 to <12 years	Chronic Idiopathic Urticaria: Aged ≥12 years	Nasal Polyps: Aged ≥18 years	Important Safety Information
pages 2-3	pages 4-5	pages 6-7	pages 8-9	pages 10-11

Administration[1]

Administer XOLAIR 75 mg to 375 mg by subcutaneous injection 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 by body weight (lb or kg)
- Adjust doses for significant changes in body weight during treatment
- Total IgE levels are elevated during treatment and remain elevated for up to one year after the discontinuation of treatment. Therefore, re-testing of IgE levels during XOLAIR treatment cannot be used as a guide for dose determination
- Periodically reassess the need for continued therapy based upon the patient's disease severity and level of asthma control

Dose	Single-Dose Prefilled Syringe			150 mg Vial (Lyophilized Powder for Reconstitution)		
	# of 75 mg syringes	# of 150 mg syringes	Total volume injected	# of vials	# of injections	Total volume injected
75 mg	1	0	0.5 mL	1	1	0.6 mL
150 mg	0	1	1 mL	1	1	1.2 mL
225 mg	1	1	1.5 mL	2	2	1.8 mL
300 mg	0	2	2 mL	2	2	2.4 mL
375 mg	1	2	2.5 mL	3	3	3.0 mL

IgE=immunoglobulin E.

Please see pages 10-11 and accompanying full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

Dosing: Adults and Adolescents Aged ≥12 Years with Allergic Asthma[1]

Use the patient's pretreatment serum total IgE level (IU/mL) and body weight (lb or kg) to determine the dose. Values falling outside the table range provide insufficient data for recommending a dose. For adult patients with both asthma and nasal polyps, dosing determination should be based on the primary diagnosis for which XOLAIR is being prescribed.

Subcutaneous XOLAIR Dosing for Appropriate Allergic Asthma Patients Aged ≥12 Years

Pre-treatment Serum IgE (IU/mL)	Dosing Frequency	Body Weight (lb/kg)			
		66-132 lb (30-60 kg)	>132-154 lb (>60-70 kg)	>154-198 lb (>70-90 kg)	>198-330 lb (>90-150 kg)
		Dose (mg)			
≥30-100	Every 4 weeks	● 150	● 150	● 150	●● 300
>100-200		●● 300	●● 300	●● 300	●● 225
>200-300		●● 300	●● 225	●● 225	●● 300
>300-400	Every 2 weeks	●● 225	●● 225	●● 300	Insufficient data to recommend a dose
>400-500		●● 300	●● 300	●●● 375	
>500-600		●● 300	●●● 375		
>600-700		●●● 375			

Note: Doses of more than 150 mg are divided among more than one injection site to limit injections to not more than 150 mg per site.

Prefilled Syringe Dosage Strength

- ● 75 mg injection
- ● 150 mg injection

Dosing Frequency

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

Please see pages 10-11 and accompanying full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

Xolair® Omalizumab FOR SUBCUTANEOUS USE 75 mg • 150 mg

Administration[1]

Administer XOLAIR 75 mg to 375 mg by subcutaneous injection 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 by body weight (lb or kg)
- Adjust doses for significant changes in body weight during treatment
- Total IgE levels are elevated during treatment and remain elevated for up to one year after the discontinuation of treatment. Therefore, re-testing of IgE levels during XOLAIR treatment cannot be used as a guide for dose determination
- Periodically reassess the need for continued therapy based upon the patient's disease severity and level of asthma control

Dose	Single-Dose Prefilled Syringe			150 mg Vial (Lyophilized Powder for Reconstitution)		
	# of 75 mg syringes	# of 150 mg syringes	Total volume injected	# of vials	# of injections	Total volume injected
75 mg	1	0	0.5 mL	1	1	0.6 mL
150 mg	0	1	1 mL	1	1	1.2 mL
225 mg	1	1	1.5 mL	2	2	1.8 mL
300 mg	0	2	2 mL	2	2	2.4 mL
375 mg	1	2	2.5 mL	3	3	3.0 mL

Please see pages 10-11 and accompanying full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

Dosing: Pediatric Patients Aged 6 to <12 Years with Allergic Asthma[1]

Use the patient's pretreatment serum total IgE level (IU/mL) and body weight (lb or kg) to determine the dose. Values falling outside the table range provide insufficient data for recommending a dose.

Subcutaneous XOLAIR Dosing for Appropriate Allergic Asthma Patients Aged 6 to <12 Years

Pre-treatment Serum IgE (IU/mL)	Dosing Frequency	Body Weight (lb/kg)									
		44-55 lb (20-25 kg)	>55-66 lb (>25-30 kg)	>66-88 lb (>30-40 kg)	>88-110 lb (>40-50 kg)	>110-132 lb (>50-60 kg)	>132-154 lb (>60-70 kg)	>154-176 lb (>70-80 kg)	>176-198 lb (>80-90 kg)	>198-276 lb (>90-125 kg)	>276-330 lb (>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

Note: Doses of more than 150 mg are divided among more than one injection site to limit injections to not more than 150 mg per site.

Prefilled Syringe Dosage Strength

- ● 75 mg injection
- ● 150 mg injection

Dosing Frequency

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

Xolair® Omalizumab FOR SUBCUTANEOUS USE 75 mg • 150 mg

Administration and Dosing[1]

Administer XOLAIR 150 mg or 300 mg by subcutaneous injection every 4 weeks

- Dosing of XOLAIR in chronic idiopathic urticaria patients is not dependent on serum IgE (free or total) level or body weight
- The appropriate duration of therapy for chronic idiopathic urticaria has not been evaluated. Periodically reassess the need for continued therapy

Single-Dose 150 mg/mL Prefilled Syringe

Dose	# of 150 mg syringes*	Total volume injected
300 mg	2	2 mL
150 mg	1	1 mL

150 mg/mL single-dose prefilled syringe.
Product not shown to scale.

*Doses of more than 150 mg are divided among more than one injection site to limit injections to not more than 150 mg per site.

Please see pages 10-11 and accompanying full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

Xolair® Omalizumab FOR SUBCUTANEOUS USE 150 mg

Administration and Dosing[1]

Administer XOLAIR 150 mg or 300 mg by subcutaneous injection every 4 weeks

- Dosing of XOLAIR in chronic idiopathic urticaria patients is not dependent on serum IgE (free or total) level or body weight
- The appropriate duration of therapy for chronic idiopathic urticaria has not been evaluated. Periodically reassess the need for continued therapy

150 mg Vial (Lyophilized Powder for Reconstitution)

Dose	# of 150 mg syringes*	Total volume injected†
300 mg	2	2.4 mL
150 mg	1	1.2 mL

Two 150 mg vials of lyophilized powder for reconstitution=300 mg. Products not shown to scale.

*Doses of more than 150 mg are divided among more than one injection site to limit injections to not more than 150 mg per site.
†1.2 mL maximum delivered volume per vial after reconstitution.

Please see pages 10-11 and accompanying full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

Xolair® Omalizumab FOR SUBCUTANEOUS USE 150 mg

Administration[1]

Administer XOLAIR 75 mg to 600 mg by subcutaneous injection 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 by body weight (lb or kg)
- Adjust doses for significant changes in body weight during treatment
- Total IgE levels are elevated during treatment and remain elevated for up to one year after the discontinuation of treatment. Therefore, re-testing of IgE levels during XOLAIR treatment cannot be used as a guide for dose determination
- Periodically reassess the need for continued therapy based upon the patient's disease severity and level of symptom control

Dose	Single-Dose Prefilled Syringe			150 mg Vial (Lyophilized Powder for Reconstitution)		
	# of 75 mg syringes	# of 150 mg syringes	Total volume injected	# of vials	# of injections	Total volume injected
75 mg	1	0	0.5 mL	1	1	0.6 mL
150 mg	0	1	1 mL	1	1	1.2 mL
225 mg	1	1	1.5 mL	2	2	1.8 mL
300 mg	0	2	2 mL	2	2	2.4 mL
375 mg	1	2	2.5 mL	3	3	3.0 mL
450 mg	0	3	3 mL	3	3	3.6 mL
525 mg	1	3	3.5 mL	4	4	4.2 mL
600 mg	0	4	4 mL	4	4	4.8 mL

Please see pages 10-11 and accompanying full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

Dosing: Adults Aged ≥18 Years with Nasal Polyps[1]

Use the patient's pretreatment serum total IgE level (IU/mL) and body weight (lb or kg) to determine the dose. Values falling outside the table range provide insufficient data for recommending a dose. For adult patients with both asthma and nasal polyps, dosing determination should be based on the primary diagnosis for which XOLAIR is being prescribed.

Subcutaneous XOLAIR Dosing for Appropriate Nasal Polyps Patients Aged ≥18 Years

Pre-treatment Serum IgE (IU/mL)	Dosing Frequency	Body Weight (lb/kg)							
		>66-88 lb (>30-40 kg)	>88-110 lb (>40-50 kg)	>110-132 lb (>50-60 kg)	>132-154 lb (>60-70 kg)	>154-176 lb (>70-80 kg)	>176-198 lb (>80-90 kg)	>198-276 lb (>90-125 kg)	>276-330 lb (>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					
>1200-1300		●●● 450	●●●● 525						
>1300-1500		●●●● 525	●●●● 600						

Insufficient data to recommend a dose

Note: Doses of more than 150 mg are divided among more than one injection site to limit injections to not more than 150 mg per site.

Prefilled Syringe Dosage Strength

- ● 75 mg injection
- ● 150 mg injection

Dosing Frequency

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

Please see pages 10-11 and accompanying full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

Xolair® Omalizumab FOR SUBCUTANEOUS USE 75 mg • 150 mg

IMPORTANT SAFETY INFORMATION

INDICATIONS

XOLAIR® (omalizumab) IS INDICATED FOR:

- Moderate to severe persistent asthma in patients 6 years of age and older who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. XOLAIR has been shown to decrease the incidence of asthma exacerbations in these patients.

  Limitations of Use: XOLAIR is not indicated for the relief of acute bronchospasm, status asthmaticus, or for treatment of other allergic conditions.

- Add-on maintenance treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.

- Chronic idiopathic urticaria in patients 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.

  Limitations of Use: XOLAIR is not indicated for treatment of other forms of urticaria.

IMPORTANT SAFETY INFORMATION

WARNING: Anaphylaxis

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 as early as after the first dose of XOLAIR, but also has occurred beyond 1 year after beginning regularly administered treatment. Because of the risk of anaphylaxis, observe patients closely for an appropriate period of time after XOLAIR administration. Health care providers administering XOLAIR should be prepared to manage anaphylaxis that can be life-threatening. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should symptoms occur.

CONTRAINDICATIONS

The use of XOLAIR is contraindicated in patients with a severe hypersensitivity reaction to XOLAIR or to any ingredient of XOLAIR.

WARNINGS AND PRECAUTIONS

Anaphylaxis

Anaphylaxis has been reported to occur after administration of XOLAIR in asthma premarketing clinical trials and in postmarketing spontaneous reports. The frequency of anaphylaxis attributed to XOLAIR use was estimated to be 0.1% and at least 0.2% (based on an estimated exposure of about 57,300 patients from June 2003 through December 2006), respectively.

A case-control study showed that among XOLAIR users, patients with a history of anaphylaxis to foods, medications, or other causes were at increased risk of anaphylaxis associated with XOLAIR, compared to those with no prior history of anaphylaxis.

Observe patients closely for an appropriate period of time after administration of XOLAIR, taking into account the time to onset of anaphylaxis seen in premarketing clinical trials and postmarketing spontaneous reports. Anaphylaxis occurred with the first dose of XOLAIR in 2 patients and with the fourth dose in 1 patient; the time to onset of anaphylaxis was 90 minutes after administration in 2 patients and 2 hours after administration in 1 patient. Discontinue XOLAIR in patients who experience a severe hypersensitivity reaction.

Malignancy

Malignant neoplasms were observed in 20 of 4127 (0.5%) XOLAIR-treated patients compared with 5 of 2236 (0.2%) control patients in clinical studies of adults and adolescents (≥12 years of age) with asthma and other allergic disorders. The observed malignancies in XOLAIR-treated patients were a variety of types, with breast, non-melanoma skin, prostate, melanoma, and parotid occurring more than once, and five other types occurring once each. The majority of patients were observed for less than 1 year. The impact of longer exposure to XOLAIR or use in patients at higher risk for malignancy (e.g., elderly, current smokers) is not known.

A subsequent 5-year observational study of 5007 XOLAIR-treated and 2829 non-XOLAIR-treated adolescent and adult patients with moderate to severe persistent asthma and a positive skin test reaction or in vitro reactivity to a perennial aeroallergen found that the incidence rates of primary malignancies (per 1000 patient years) were similar in both groups (12.3 vs 13.0, respectively). Study limitations which include the observational study design, the bias introduced by allowing enrollment of patients previously exposed to XOLAIR (88%), enrollment of patients (56%) while a history of cancer or a premalignant condition were study exclusion criteria, and the high study discontinuation rate (44%) preclude definitively ruling out a malignancy risk with XOLAIR.

Acute Asthma Symptoms

XOLAIR has not been shown to alleviate asthma exacerbations acutely. Do not use XOLAIR to treat acute bronchospasm or status asthmaticus.

Corticosteroid Reduction

Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of XOLAIR therapy for asthma or nasal polyps. Decrease corticosteroids gradually under the direct supervision of a physician. In CIU patients, the use of XOLAIR in combination with corticosteroids has not been evaluated.

Eosinophilic Conditions

In rare cases, patients with asthma on therapy with XOLAIR may present with serious systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome. These events usually, but not always, have been associated with the reduction of oral corticosteroid therapy. Physicians should be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. A causal association between XOLAIR and these underlying conditions has not been established.

Please see page 11 and accompanying full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

Xolair® Omalizumab FOR SUBCUTANEOUS USE 75 mg • 150 mg

WARNINGS AND PRECAUTIONS (cont'd)

Fever, Arthralgia, and Rash
In post-approval use, some patients have experienced a constellation of signs and symptoms, including arthritis/arthralgia, rash, fever, and lymphadenopathy with an onset 1 to 5 days after the first or subsequent injections of XOLAIR. These signs and symptoms have recurred after additional doses in some patients. Physicians should stop XOLAIR if a patient develops this constellation of signs and symptoms.

Parasitic (Helminth) Infection
Monitor patients at high risk of geohelminth infection while on XOLAIR therapy. Insufficient data are available to determine the length of monitoring required for geohelminth infections after stopping XOLAIR treatment.

Laboratory Tests
Due to formation of XOLAIR:IgE complexes, serum total IgE levels increase following administration of XOLAIR and may remain elevated for up to 1 year following discontinuation of XOLAIR. Do not use serum total IgE levels obtained less than 1 year following discontinuation to reassess the dosing regimen for asthma or nasal polyps patients, because these levels may not reflect steady state free IgE levels.

ADVERSE REACTIONS

Indication-Specific Adverse Reactions

Asthma
In patients ≥12 years of age, the most common adverse reactions (≥1% more frequent in XOLAIR-treated patients) were: arthralgia (8%), pain (general) (7%), leg pain (4%), fatigue (3%), dizziness (3%), fracture (2%), arm pain (2%), pruritus (2%), dermatitis (2%), and earache (2%). In pediatric patients 6 to <12 years of age, the most commonly observed adverse reactions (≥3% more frequent in XOLAIR-treated pediatric patients) were: nasopharyngitis, headache, pyrexia, upper abdominal pain, pharyngitis streptococcal, otitis media, viral gastroenteritis, arthropod bite, and epistaxis.

Nasal Polyps
The most common adverse reactions (≥3% incidence in XOLAIR-treated patients and more frequent than placebo) included: headache (8.1%), injection site reaction (5.2%), arthralgia (3.0%), upper abdominal pain (3.0%), and dizziness (3.0%).

Chronic Idiopathic Urticaria
The most common adverse reactions (≥2% XOLAIR-treated patients and more frequent than in placebo) for XOLAIR 150 mg and 300 mg, respectively, included: headache (12%, 6%), nasopharyngitis (9%, 7%), arthralgia (3%, 3%), viral upper respiratory infection (2%, 1%), nausea (1%, 3%), sinusitis (1%, 5%), upper respiratory tract infection (1%, 3%), and cough (1%, 2%).

Injection Site Reactions

Asthma
In adults and adolescents with asthma, injection site reactions of any severity occurred at a rate of 45% in XOLAIR-treated patients compared with 43% in placebo-treated patients. Severe injection site reactions occurred more frequently in XOLAIR treated patients compared with patients in the placebo group (12% vs 9%, respectively). The types of injection site reactions in asthma studies included: bruising, redness, warmth, burning, stinging, itching, hive formation, pain, indurations, mass, and inflammation.

Nasal Polyps
Injection site reactions occurred at a rate of 5.2% in XOLAIR-treated patients compared with 1.5% in placebo-treated patients. Injection site reactions were mild to moderate severity and none resulted in study discontinuation.

Chronic Idiopathic Urticaria
Injection site reactions of any severity occurred in more XOLAIR-treated patients (11 patients [2.7%] at 300 mg, 1 patient [0.6%] at 150 mg) compared with 2 placebo-treated patients (0.8%). The types of injection site reactions included: swelling, erythema, pain, bruising, itching, bleeding, and urticaria.

Cardiovascular and Cerebrovascular Events from Clinical Studies in Patients with Asthma
A 5-year observational study was conducted in 5007 XOLAIR-treated and 2829 non-XOLAIR-treated patients ≥12 years of age with moderate to severe persistent asthma and a positive skin test reaction to a perennial aeroallergen to evaluate the long term safety of XOLAIR, including the risk of malignancy. Similar percentages of patients in both cohorts were current (5%) or former smokers (29%). Patients had a mean age of 45 years and were followed for a mean of 3.7 years. More XOLAIR-treated patients were diagnosed with severe asthma (50%) compared to the non-XOLAIR-treated patients (23%). A higher incidence rate (per 1000 patient-years) of overall cardiovascular and cerebrovascular serious adverse events (SAEs) was observed in XOLAIR-treated patients (13.4) compared to non-XOLAIR-treated patients (8.1). Increases in rates were observed for transient ischemic attack (0.7 vs 0.1), myocardial infarction (2.1 vs 0.8), pulmonary hypertension (0.5 vs 0), pulmonary embolism/venous thrombosis (3.2 vs 1.5), and unstable angina (2.2 vs 1.4), while the rates observed for ischemic stroke and cardiovascular death were similar among both study cohorts. The results suggest a potential increased risk of serious cardiovascular and cerebrovascular events in patients treated with XOLAIR, however the observational study design, the inclusion of patients previously exposed to XOLAIR (88% for a mean of 8 months), baseline imbalances in cardiovascular risk factors between the treatment groups, an inability to adjust for unmeasured risk factors, and the high study discontinuation rate (44%) limit the ability to quantify the magnitude of the risk.

Pregnancy
Data with XOLAIR use in pregnant women are insufficient to inform on drug associated risk.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555 or Novartis Pharmaceuticals Corporation at (888) 669-6682.

Reference: 1. XOLAIR [prescribing information]. Genentech USA, Inc. and Novartis Pharmaceuticals Corporation; 2020.

Please see page 10 and accompanying full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

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ACCESS THE XOLAIR DOSING TOOLS ONLINE

Our online tools can be used to determine the recommended XOLAIR dosing for **allergic asthma** or **nasal polyps**. Enter your patient's body weight and serum IgE (and age for allergic asthma), and the tools will calculate the appropriate XOLAIR dose and frequency based on the XOLAIR Prescribing Information.

Recommended dosing for **chronic idiopathic urticaria** is also provided at this address.

Dosing tools are intended for US healthcare professionals only.

For desktop access, go to:
xolair-dosing.com

Scan the QR code with your phone camera to open the XOLAIR dosing tools with ease.

INDICATIONS

XOLAIR® (omalizumab) IS INDICATED FOR:

- Moderate to severe persistent asthma in patients 6 years of age and older who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. XOLAIR has been shown to decrease the incidence of asthma exacerbations in these patients.

  Limitations of Use: XOLAIR is not indicated for the relief of acute bronchospasm, status asthmaticus, or for treatment of other allergic conditions.
- Add-on maintenance treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.
- Chronic idiopathic urticaria in patients 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.

  Limitations of Use: XOLAIR is not indicated for treatment of other forms of urticaria.

IMPORTANT SAFETY INFORMATION

WARNING: Anaphylaxis

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 as early as after the first dose of XOLAIR, but also has occurred beyond 1 year after beginning regularly administered treatment. Because of the risk of anaphylaxis, observe patients closely for an appropriate period of time after XOLAIR administration. Health care providers administering XOLAIR should be prepared to manage anaphylaxis that can be life-threatening. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should symptoms occur.

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M-US-00008265(v1.0) 12/20

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