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 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, patients should be closely observed for an appropriate period of time after XOLAIR administration, and health care providers administering XOLAIR should be prepared to manage anaphylaxis that can be life-threatening. Patients should also be informed of the signs and symptoms of anaphylaxis and instructed to seek immediate medical care should symptoms occur (see WARNINGS, and PRECAUTIONS, Information for Patients).

Please see enclosed Full Prescribing Information, including Boxed WARNING and Medication Guide, and reverse side for additional important safety information.

Xolair®
Omalizumab
FOR SUBCUTANEOUS USE
Anti-IgE therapy that helps protect

A quick reference for easier XOLAIR dosing

XOLAIR is dosed every 2 or 4 weeks

Simply select the patient's pretreatment serum IgE level from the vertical column and select body weight from the horizontal row. The box at which they intersect provides appropriate dose (mg) and dosing schedule for XOLAIR.

Q4-week dosing table*

Pretreatment serum IgE (IU/mL)	Body weight: Pounds 66-132 / Kilograms 30-60	>132-154 / >60-70	>154-198 / >70-90	>198-330 / >90-150
≥30-100	150 mg	150 mg	150 mg	300 mg
>100-200	300 mg	300 mg	300 mg	
>200-300	300 mg	See table on right ►		

Q2-week dosing table*

Pretreatment serum IgE (IU/mL)	Body weight: Pounds 66-132 / Kilograms 30-60	>132-154 / >60-70	>154-198 / >70-90	>198-330 / >90-150
≥30-100	◄ See table on left			
>100-200				225 mg
>200-300		225 mg	225 mg	300 mg
>300-400	225 mg	225 mg	300 mg	
>400-500	300 mg	300 mg	375 mg	
>500-600	300 mg	375 mg		
>600-700	375 mg	DO NOT DOSE		

*Each XOLAIR vial delivers 150 mg of XOLAIR per 1.2 mL upon reconstitution with 1.4 mL of Sterile Water for Injection (SWFI), USP.
†Doses of more than 150 mg are divided among more than 1 injection site to limit injections to not more than 150 mg per site.
‡1.2 mL maximum delivered volume per vial.

XOLAIR volumes, vials, and injections

Refer to the table below to determine the number of vials and injections per dose and the total injection volume. Patients whose treatment serum IgE level or body weight is outside the limits of the dosing table should **NOT** be dosed.

Dose and SC injection specifications

Dose (mg)	Number of vials per dose	Number of injections†	Total volume injected (mL)‡
150 mg	1	1	1.2
225 mg	2	2	1.8
300 mg	2	2	2.4
375 mg	3	3	3.0

Total IgE levels are elevated during treatment and remain elevated for up to 1 year after the discontinuation of treatment. Retesting of IgE levels during XOLAIR treatment is unnecessary and cannot be used as a guide for dose determination. Dose determination after treatment interruptions lasting less than 1 year should be based on serum IgE levels obtained at the initial dose determination. Total serum IgE levels may be retested for dose determination if treatment with XOLAIR has been interrupted for 1 year or more. Doses should be adjusted for significant changes in body weight.

XOLAIR IS INDICATED FOR: Adults and adolescents (aged ≥12 years) with moderate-to-severe persistent asthma 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. Safety and efficacy have not been established in other allergic conditions.

IMPORTANT SAFETY INFORMATION

- XOLAIR should only be administered in a healthcare setting by healthcare providers prepared to manage anaphylaxis that can be life-threatening
- XOLAIR should not be administered to patients who have experienced a severe hypersensitivity reaction to XOLAIR (see Boxed WARNING). XOLAIR should be discontinued in patients who experience a severe hypersensitivity reaction
- 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 asthma and other allergic disorders
- Patients should be given and instructed to read the accompanying Medication Guide before starting treatment and before each subsequent treatment
- Patients receiving XOLAIR should be told not to decrease the dose of, or stop taking, any other asthma medications unless otherwise instructed by their physician
- The adverse reactions most commonly observed among patients treated with XOLAIR in clinical studies included injection site reaction (45%), viral infections (23%), upper respiratory tract infection (20%), sinusitis (16%), headache (15%), and pharyngitis (11%). These events were observed at similar rates in XOLAIR-treated patients and control patients
- Injection site reactions of any severity occurred at a rate of 45% in XOLAIR-treated patients compared with 43% in placebo-treated patients. The types of injection site reactions included: bruising, redness, warmth, burning, stinging, itching, hive formation, pain, indurations, mass, and inflammation. Severe injection site reactions occurred more frequently in XOLAIR-treated patients compared with patients in the placebo group (12% versus 9%). The majority of injection site reactions occurred within 1 hour post-injection, lasted less than 8 days, and generally decreased in frequency at subsequent dosing visits

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