XOLAIR®
Omalizumab

For Subcutaneous Use

DESCRIPTION

Xolair (Omalizumab) is a recombinant DNA-derived humanized IgG1κ monoclonal antibody that selectively binds to human immunoglobulin E (IgE). The antibody has a molecular weight of approximately 149 kilodaltons. Xolair is produced by a Chinese hamster ovary cell suspension culture in a nutrient medium containing the antibiotic gentamicin. Gentamicin is not detectable in the final product.

Xolair is a sterile, white, preservative-free, lyophilized powder contained in a single-use vial that is reconstituted with Sterile Water for Injection (SWFI), USP, and administered as a subcutaneous (SC) injection. A Xolair vial contains 202.5 mg of Omalizumab, 145.5 mg sucrose, 2.8 mg L-histidine hydrochloride monohydrate, 1.8 mg L-histidine, and 0.5 mg polysorbate 20, and is designed to deliver 150 mg of Omalizumab in 1.2 mL after reconstitution with 1.4 mL SWFI, USP.

CLINICAL PHARMACOLOGY

Mechanism of Action

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.

Pharmacokinetics

After SC administration, Omalizumab is absorbed with an average absolute bioavailability of 62%. Following a single SC dose in adult and adolescent patients with asthma, Omalizumab was absorbed slowly, reaching peak serum concentrations after an average of 7–8 days. The pharmacokinetics of Omalizumab are linear at doses greater than 0.5 mg/kg. Following multiple doses of Omalizumab, areas under the serum concentration-time curve from Day 0 to Day 14 at steady state were up to 6-fold of those after the first dose.

In vitro, Omalizumab forms complexes of limited size with IgE. Precipitating complexes and complexes larger than 1 million daltons in molecular weight are not observed *in vitro* or *in vivo*. Tissue distribution studies in cynomolgus monkeys showed no specific uptake of ^{125}I-

Omalizumab by any organ or tissue. The apparent volume of distribution in patients following SC administration was 78±32 mL/kg.

Clearance of Omalizumab involves IgG clearance processes as well as clearance via specific binding and complex formation with its target ligand, IgE. Liver elimination of IgG includes degradation in the liver reticuloendothelial system (RES) and endothelial cells. Intact IgG is also excreted in bile. In studies with mice and monkeys, Omalizumab:IgE complexes were eliminated by interactions with Fcγ receptors within the RES at rates that were generally faster than IgG clearance. In asthma patients Omalizumab serum elimination half-life averaged 26 days, with apparent clearance averaging 2.4±1.1 mL/kg/day. In addition, doubling body weight approximately doubled apparent clearance.

Pharmacodynamics

In clinical studies, serum free IgE levels were reduced in a dose dependent manner within 1 hour following the first dose and maintained between doses. Mean serum free IgE decrease was greater than 96% using recommended doses. Serum total IgE levels (i.e., bound and unbound) increased after the first dose due to the formation of Omalizumab:IgE complexes, which have a slower elimination rate compared with free IgE. At 16 weeks after the first dose, average serum total IgE levels were five-fold higher compared with pre-treatment when using standard assays. After discontinuation of Xolair dosing, the Xolair-induced increase in total IgE and decrease in free IgE were reversible, with no observed rebound in IgE levels after drug washout. Total IgE levels did not return to pre-treatment levels for up to one year after discontinuation of Xolair.

Special Populations

The population pharmacokinetics of Xolair were analyzed to evaluate the effects of demographic characteristics. Analyses of these limited data suggest that no dose adjustments are necessary for age (12–76 years), race, ethnicity, or gender.

CLINICAL STUDIES

The safety and efficacy of Xolair were evaluated in three randomized, double-blind, placebo-controlled, multicenter trials.

The trials enrolled patients 12 to 76 years old, with moderate to severe persistent (NHLBI criteria) asthma for at least one year, and a positive skin test reaction to a perennial aeroallergen. At screening, patients in Studies 1 and 2 had a forced expiratory volume in one second (FEV1) between 40% and 80% predicted, while in Study 3 there was no restriction on screening FEV1.

All patients had a FEV1 improvement of at least 12% following beta-agonist administration. All patients were symptomatic and were being treated with inhaled corticosteroids (ICS) and short acting beta-agonists. In Study 3, long-acting beta-agonists were allowed. Study 3 patients were receiving at least 1000 μg/day fluticasone propionate and a subset was also receiving oral corticosteroids. Patients receiving other concomitant controller medications were excluded, and initiation of additional controller medications while on study was prohibited. Patients currently smoking were excluded.

Each study was comprised of a run-in period to achieve a stable conversion to a common ICS (beclomethasone dipropionate, for Studies 1 and 2; fluticasone propionate for Study 3), followed by randomization to Xolair or placebo. In Study 3, patients were stratified by use of ICS-only or ICS with concomitant use of oral steroids. Patients received Xolair for 16 weeks with an unchanged corticosteroid dose unless an acute exacerbation necessitated an increase. Patients then entered an ICS reduction phase of 12 weeks (Studies 1 and 2) or 16 weeks (Study 3) during which ICS (or oral steroid in Study 3 subset) dose reduction was attempted in a step-wise manner.

Xolair dosing was based on body weight and baseline serum total IgE concentration. All patients were required to have a baseline IgE between 30 and 700 IU/mL and body weight not more than 150 kg. Patients were treated according to a dosing table to administer at least 0.016 mg/kg/IU (IgE/mL) of Xolair or a matching volume of placebo over each 4-week period. The maximum Xolair dose per 4 weeks was 750 mg; patients who had a weight-IgE combination that yielded a dose greater than 750 mg were excluded from the studies. Patients who were to receive more than 300 mg within the 4-week period were administered half the total dose every 2 weeks.

The distribution of the number of asthma exacerbations per patient in each group during a study was analyzed separately for the stable steroid and steroid-reduction periods. In all three studies an exacerbation was defined as a worsening of asthma that required treatment with systemic corticosteroids or a doubling of the baseline ICS dose.

In both Studies 1 and 2 the number of exacerbations per patient was reduced in patients treated with Xolair compared with placebo (Table 1). In Study 3 the number of exacerbations in patients treated with Xolair was similar to that in placebo-treated patients (Table 2). The absence of an observed treatment effect in Study 3 may be related to differences in the patient population compared with Studies 1 and 2, study sample size, or other factors. In all three studies most

exacerbations were managed in the out-patient setting and the majority were treated with 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 exacerbation, the distribution of exacerbation severity was similar between treatment groups.

Table 1
Frequency of Asthma Exacerbations per Patient by Phase in Studies 1 and 2

	Stable Steroid Phase (16 wks)			
	Study 1		Study 2	
Exacerbations per patient	Xolair N=268 (%)	Placebo N=257 (%)	Xolair N=274 (%)	Placebo N=272 (%)
0	85.8	76.7	87.6	69.9
1	11.9	16.7	11.3	25.0
≥2	2.2	6.6	1.1	5.1
p-Value	0.005		<0.001	
Mean number exacerbations/patient	0.2	0.3	0.1	0.4
	Steroid Reduction Phase (12 wks)			
Exacerbations per patient	Xolair N=268 (%)	Placebo N=257 (%)	Xolair N=274 (%)	Placebo N=272 (%)
0	78.7	67.7	83.9	70.2
1	19.0	28.4	14.2	26.1
≥2	2.2	3.9	1.8	3.7
p-Value	0.004		<0.001	
Mean number exacerbations/patient	0.2	0.4	0.2	0.3

Table 2
Percentage of Patients with Asthma Exacerbations by Subgroup and Phase in Study 3

	Stable Steroid Phase (16 wks)			
	Inhaled Only		Oral + Inhaled	
	Xolair N = 126	Placebo N = 120	Xolair N = 50	Placebo N = 45
% Patients with ≥ 1 exacerbations	15.9	15.0	32.0	22.2
Difference (95% CI)	0.9 (–9.7, 13.7)		9.8 (–10.5, 31.4)	
	Steroid Reduction Phase (16 wks)			
	Xolair N = 126	Placebo N = 120	Xolair N = 50	Placebo N = 45
% Patients with ≥ 1 exacerbations	22.2	26.7	42.0	42.2
Difference (95% CI)	–4.4 (–17.6, 7.4)		–0.2 (–22.4, 20.1)	

In all three of the studies, a reduction of asthma exacerbations was not observed in the Xolair-treated patients who had FEV1 > 80% at the time of randomization. Reductions in exacerbations were not seen in patients who required oral steroids as maintenance therapy.

In Studies 1 and 2 measures of airflow (FEV1) and asthma symptoms were evaluated (Table 3). The clinical relevance of the treatment-associated differences is unknown.

Table 3
Asthma Symptoms and Pulmonary Function During Stable Steroid Phase of Study 1

	Xolair N=268[a]		Placebo N=257[a]	
Endpoint	Mean Baseline	Median Change (Baseline to Wk 16)	Mean Baseline	Median Change (Baseline to Wk 16)
Total asthma symptom score	4.3	–1.5[b]	4.2	–1.1[b]
Nocturnal asthma score	1.2	–0.4[b]	1.1	–0.2[b]
Daytime asthma score	2.3	–0.9[b]	2.3	–0.6[b]
FEV1 % predicted	68	3[b]	68	0[b]

Asthma symptom scale: total score from 0 (least) to 9 (most); nocturnal and daytime scores from 0 (least) to 4 (most symptoms).

[a] Number of patients available for analysis ranges 255–258 in the Xolair group and 238–239 in the placebo group.

[b] Comparison of Xolair versus placebo ($p<0.05$).

Results from the stable steroid phase of Study 2 and the steroid reduction phases of both Studies 1 and 2 were similar to those presented in Table 3.

INDICATIONS AND USAGE

Xolair (Omalizumab) is indicated for adults and adolescents (12 years of age and above) 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.

CONTRAINDICATIONS

Xolair should not be administered to patients who have experienced a severe hypersensitivity reaction to Xolair (see WARNINGS: Anaphylaxis).

WARNINGS

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 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 (see ADVERSE REACTIONS: Malignancy).

Anaphylaxis

Anaphylaxis has occurred within 2 hours of the first or subsequent administration of Xolair in 3 (<0.1%) patients without other identifiable allergic triggers. These events included urticaria and throat and/or tongue edema (see ADVERSE REACTIONS). Patients should be observed after injection of Xolair, and medications for the treatment of severe hypersensitivity reactions including anaphylaxis should be available. If a severe hypersensitivity reaction to Xolair occurs, therapy should be discontinued (see CONTRAINDICATIONS).

PRECAUTIONS

General

Xolair has not been shown to alleviate asthma exacerbations acutely and should not be used for the treatment of acute bronchospasm or status asthmaticus.

Corticosteroid Reduction

Systemic or inhaled corticosteroids should not be abruptly discontinued upon initiation of Xolair therapy. Decreases in corticosteroids should be performed under the direct supervision of a physician and may need to be performed gradually.

Information for Patients

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. Patients should be told that they may not see immediate improvement in their asthma after beginning Xolair therapy.

Parasitic (Helminth) Infection

In a one-year clinical trial conducted in Brazil in patients at high risk for geohelminthic infections (roundworm, hookworm, whipworm, threadworm), 53% (36/68) of omalizumab-treated patients experienced an infection, as diagnosed by standard stool examination, compared to 42% (29/69) of placebo controls. The point estimate of the odds ratio for infection was 1.96, with a 95% confidence interval (0.88, 4.36) indicating that in this study a patient who had an infection was anywhere from 0.88 to 4.36 times as likely to have received Omalizumab than a patient who did not have an infection. Response to appropriate anti-geohelminth treatment of

infection as measured by stool egg counts was not different between treatment groups. Patients at high risk of geohelminth infection should be monitored for such infections while on Xolair therapy. Insufficient data are available to determine the length of monitoring required for geohelminth infections after stopping Xolair treatment.

Laboratory Tests

Serum total IgE levels increase following administration of Xolair due to formation of Xolair:IgE complexes (see CLINICAL PHARMACOLOGY, DOSAGE AND ADMINISTRATION). Elevated serum total IgE levels may persist for up to 1 year following discontinuation of Xolair. Serum total IgE levels obtained less than 1 year following discontinuation may not reflect steady state free IgE levels and should not be used to reassess the dosing regimen.

Drug Interactions

No formal drug interaction studies have been performed with Xolair. The concomitant use of Xolair and allergen immunotherapy has not been evaluated.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term studies have been performed in animals to evaluate the carcinogenic potential of Xolair.

No evidence of mutagenic activity was observed in Ames tests using six different strains of bacteria with and without metabolic activation at Omalizumab concentrations up to 5000 μg/mL.

The effects of Omalizumab on male and female fertility have been assessed in cynomolgus monkey studies. Administration of Omalizumab at doses up to and including 75 mg/kg/week did not elicit reproductive toxicity in male cynomolgus monkeys and did not inhibit reproductive capability, including implantation, in female cynomolgus monkeys. These doses provide a 2- to 16-fold safety factor based on total dose and 2- to 5-fold safety factor based on AUC over the range of adult clinical doses.

Pregnancy (Category B)

Reproduction studies in cynomolgus monkeys have been conducted with Omalizumab. Subcutaneous doses up to 75 mg/kg (12-fold the maximum clinical dose) of Omalizumab did not elicit maternal toxicity, embryotoxicity, or teratogenicity when administered throughout

organogenesis and did not elicit adverse effects on fetal or neonatal growth when administered throughout late gestation, delivery, and nursing.

IgG molecules are known to cross the placental barrier. There are no adequate and well-controlled studies of Xolair in pregnant women. Because animal reproduction studies are not always predictive of human response, Xolair should be used during pregnancy only if clearly needed.

Nursing Mothers

The excretion of Omalizumab in milk was evaluated in female cynomolgus monkeys receiving SC doses of 75 mg/kg/week. Neonatal plasma levels of Omalizumab after *in utero* exposure and 28 days of nursing were between 11% and 94% of the maternal plasma level. Milk levels of Omalizumab were 1.5% of maternal blood concentration. While Xolair presence in human milk has not been studied, IgG is excreted in human milk and therefore it is expected that Xolair will be present in human milk. The potential for Xolair absorption or harm to the infant are unknown; caution should be exercised when administering Xolair to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients below the age of 12 have not been established.

Geriatric Use

In clinical trials 134 patients 65 years of age or older were treated with Xolair. Although there were no apparent age-related differences observed in these studies, the number of patients aged 65 and over is not sufficient to determine whether they respond differently from younger patients.

ADVERSE REACTIONS

The most serious adverse reactions occurring in clinical studies with Xolair are malignancies and anaphylaxis (see WARNINGS). The observed incidence of malignancy among Xolair-treated patients (0.5%) was numerically higher than among patients in control groups (0.2%). Anaphylactic reactions were rare but temporally associated with Xolair administration.

The adverse reactions most commonly observed among patients treated with Xolair 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. These were also the most frequently

reported adverse reactions resulting in clinical intervention (e.g., discontinuation of Xolair, or the need for concomitant medication to treat an adverse reaction).

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of one drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in medical practice.

The data described above reflect Xolair exposure for 2076 adult and adolescent patients ages 12 and older, including 1687 patients exposed for six months and 555 exposed for one year or more, in either placebo-controlled or other controlled asthma studies. The mean age of patients receiving Xolair was 42 years, with 134 patients 65 years of age or older; 60% were women, and 85% Caucasian. Patients received Xolair 150 to 375 mg every 2 or 4 weeks or, for patients assigned to control groups, standard therapy with or without a placebo.

Table 4 shows adverse events that occurred ≥1% more frequently in patients receiving Xolair than in those receiving placebo in the placebo-controlled asthma studies. Adverse events were classified using preferred terms from the International Medical Nomenclature (IMN) dictionary. Injection site reactions were recorded separately from the reporting of other adverse events and are described following Table 4.

Table 4
Adverse Events ≥1% More Frequent in Xolair-Treated Patients

Adverse event	Xolair n=738 (%)	Placebo n=717 (%)
Body as a whole		
Pain	7	5
Fatigue	3	2
Musculoskeletal system		
Arthralgia	8	6
Fracture	2	1
Leg pain	4	2
Arm pain	2	1
Nervous system		
Dizziness	3	2
Skin and appendages		
Pruritus	2	1
Dermatitis	2	1
Special senses		
Earache	2	1

Age (among patients under age 65), race, and gender did not appear to affect the between group differences in the rates of adverse events.

Injection Site Reactions

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.

Immunogenicity

Low titers of antibodies to Xolair were detected in approximately 1/1723 (<0.1%) of patients treated with Xolair. The data reflect the percentage of patients whose test results were considered positive for antibodies to Xolair in an ELISA assay and are highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody positivity in the assay may be influenced by several factors including sample handling, timing of sample collection, concomitant medications, and underlying disease. Therefore, comparison of the incidence of antibodies to Xolair with the incidence of antibodies to other products may be misleading.

Allergic symptoms, including urticaria, dermatitis, and pruritus were observed in patients treated with Xolair. There were also 3 cases of anaphylaxis observed within 2 hours of Xolair administration in which there were no other identifiable allergic triggers (see WARNINGS: Anaphylaxis).

Postmarketing Experience

The following adverse reactions have been identified during postapproval use of Xolair. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Hematologic: severe thrombocytopenia

Skin: hair loss

OVERDOSAGE

The maximum tolerated dose of Xolair has not been determined. Single intravenous doses of up to 4000 mg have been administered to patients without evidence of dose-limiting toxicities. The highest cumulative dose administered to patients was 44,000 mg over a 20-week period, which was not associated with toxicities.

DOSAGE AND ADMINISTRATION

Xolair (Omalizumab) 150 to 375 mg is administered SC every 2 or 4 weeks. Because the solution is slightly viscous, the injection may take 5-10 seconds to administer. Doses (mg) and dosing frequency are determined by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). See the dose determination charts below (Table 5 and Table 6)

for appropriate dose assignment. 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.

Table 5
ADMINISTRATION EVERY 4 WEEKS
Xolair Doses (milligrams) Administered by Subcutaneous Injection Every 4 Weeks for Adults and Adolescents (12 Years of Age and Older) with Asthma

Pre-treatment Serum IgE (IU/mL)	Body Weight (kg)			
	30–60	> 60–70	> 70–90	> 90–150
≥ 30–100	150	150	150	300
> 100–200	300	300	300	
> 200–300	300			
> 300–400	**SEE TABLE 6**			
> 400–500				
> 500–600				

Table 6
ADMINISTRATION EVERY 2 WEEKS
Xolair Doses (milligrams) Administered by Subcutaneous Injection Every 2 Weeks for Adults and Adolescents (12 Years of Age and Older) with Asthma

<table>
<tr><td rowspan="2">Pre-treatment Serum IgE (IU/mL)</td><td colspan="4">Body Weight (kg)</td></tr>
<tr><td>30–60</td><td>> 60–70</td><td>> 70–90</td><td>> 90–150</td></tr>
<tr><td>≥ 30–100</td><td colspan="4" rowspan="2">SEE TABLE 5</td></tr>
<tr><td>> 100–200</td><td>225</td></tr>
<tr><td>> 200–300</td><td></td><td>225</td><td>225</td><td>300</td></tr>
<tr><td>> 300–400</td><td>225</td><td>225</td><td>300</td><td rowspan="4"></td></tr>
<tr><td>> 400–500</td><td>300</td><td>300</td><td>375</td></tr>
<tr><td>> 500–600</td><td>300</td><td>375</td><td colspan="2" rowspan="2">DO NOT DOSE</td></tr>
<tr><td>> 600–700</td><td>375</td></tr>
</table>

Dosing Adjustments

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. 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 re-tested for dose determination if treatment with Xolair has been interrupted for one year or more.

Doses should be adjusted for significant changes in body weight. (See Table 5 and Table 6.)

Preparation for Administration

Xolair for SC administration should be prepared using SWFI, USP, ONLY.

Xolair is for single use only and contains no preservatives. The solution should be used for SC administration within 8 hours following reconstitution when stored in the vial at 2–8°C (36–46°F), or within 4 hours of reconstitution when stored at room temperature.

The lyophilized product takes 15–20 minutes to dissolve. The fully reconstituted product will appear clear or slightly opalescent and may have a few small bubbles or foam around the edge of the vial. The reconstituted product is somewhat viscous; in order to obtain the full 1.2 mL dose, ALL OF THE PRODUCT MUST BE WITHDRAWN from the vial before expelling any air or excess solution from the syringe.

STEP 1: Draw 1.4 mL of SWFI, USP into a 3-cc syringe equipped with a 1-inch, 18-gauge needle.

STEP 2: Place the vial upright on a flat surface and using standard aseptic technique, insert the needle and inject the SWFI, USP directly onto the product.

STEP 3: Keeping the vial upright, gently swirl the upright vial for approximately 1 minute to evenly wet the powder. Do not shake.

STEP 4: After completing STEP 3, gently swirl the vial for 5–10 seconds approximately every 5 minutes in order to dissolve any remaining solids. There should be no visible gel-like particles in the solution. Do not use if foreign particles are present.

> Note: Some vials may take longer than 20 minutes to dissolve completely. If this is the case, repeat STEP 4 until there are no visible gel-like particles in the solution. It is acceptable to have small bubbles or foam around the edge of the vial. Do not use if the contents of the vial do not dissolve completely by 40 minutes.

STEP 5: Invert the vial for 15 seconds in order to allow the solution to drain toward the stopper. Using a new 3-cc syringe equipped with a 1-inch, 18-gauge needle, insert the needle into the

inverted vial. Position the needle tip at the very bottom of the solution in the vial stopper when drawing the solution into the syringe. Before removing the needle from the vial, pull the plunger all the way back to the end of the syringe barrel in order to remove all of the solution from the inverted vial.

STEP 6: Replace the 18-gauge needle with a 25-gauge needle for subcutaneous injection.

STEP 7: Expel air, large bubbles, and any excess solution in order to obtain the required 1.2 mL dose. A thin layer of small bubbles may remain at the top of the solution in the syringe. Because the solution is slightly viscous, the injection may take 5–10 seconds to administer.

A vial delivers 1.2 mL (150 mg) of Xolair. For a 75 mg dose, draw up 0.6 mL into the syringe and discard the remaining product (see Table 7).

Table 7
Number of Injections and Total Injection Volumes for Asthma

Dose (mg)	Number of Injections	Total Volume Injected (mL)[a]
150	1	1.2
225	2	1.8
300	2	2.4
375	3	3.0

[a] 1.2 mL maximum delivered volume per vial.

Stability and Storage

Xolair should be shipped at controlled ambient temperature (≤30°C [≤86°F]). Xolair should be stored under refrigerated conditions 2–8°C (36–46°F). Do not use beyond the expiration date stamped on carton.

Xolair is for single-use only and contains no preservatives. The solution may be used for SC administration within 8 hours following reconstitution when stored in the vial at 2–8°C (36–46°F), or within 4 hours of reconstitution when stored at room temperature.

Reconstituted Xolair vials should be protected from direct sunlight.

HOW SUPPLIED

Xolair (Omalizumab) is supplied as a lyophilized, sterile powder in a single-use, 5-cc vial that is designed to deliver 150 mg of Xolair upon reconstitution with 1.4 mL SWFI, USP.

Each carton contains one single-use vial of Xolair® (Omalizumab) NDC 50242-040-62.

XOLAIR®
Omalizumab

For Subcutaneous Use

Manufactured by:

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7390203/XOL-4028

LX0113

(4821001)

FDA Approval Date: June 2003

Code Revision Date: March 2005

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