~50% of patients taking H1 antihistamines* don't find relief from chronic idiopathic urticaria symptoms.[1]

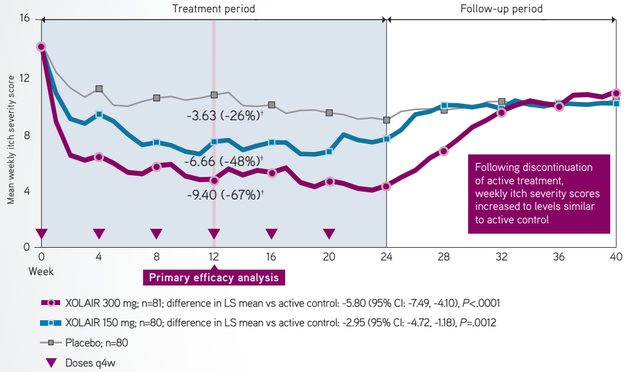
IS COMPLETE RELIEF POSSIBLE?

*At FDA-approved doses.
Model for illustrative purposes only.

Feeling is believing: XOLAIR delivered significant itch relief

Demonstrated reductions in mean weekly itch severity score throughout treatment[2-4]

Weekly itch severity score in Study 1



Study 1: Change From Baseline in Mean Weekly Itch Severity Score at Week 12 (N=241)*†

LS=least squares; q4w=every 4 weeks.

Study Designs

Itch severity: During Studies 1 and 2, the itch severity score was measured twice a day (AM and PM) on a scale of 0 (none) to 3 (severe). The daily itch severity score was the average of the morning and evening scores, and the weekly itch severity score (0-21) was the sum of the daily itch severity scores over 7 days.[3]

*All patients received their dose of study drug or placebo in addition to stable doses of their prerandomization H1 antihistamine.[3]

†The weekly itch severity score was calculated for each patient at each week. The mean change from baseline (the primary efficacy analysis) and the mean percentage change in weekly itch severity score were calculated for each treatment group for comparison vs active control at week 12 (the primary efficacy analysis time point).[5]

Primary efficacy analysis

300 mg n=81
67%
RELATIVE REDUCTION

150 mg n=80
48%
RELATIVE REDUCTION

Placebo n=80
26%
RELATIVE REDUCTION

INDICATION

XOLAIR® (omalizumab) IS INDICATED FOR adults and adolescents 12 years of age and older with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment.

Limitation 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.

Seeing is believing: XOLAIR delivered significant relief from hives

Demonstrated reductions in mean weekly hive count score from baseline at week 12[2,3]

Weekly hive count score in Study 1

XOLAIR 300 mg + H1 antihistamines

Baseline weekly hive count score: 17.1

Mean change, week 12: -11.35

Difference in LS mean vs active control -6.93 (95% CI:–9.10, –4.76), P<.0001

XOLAIR 150 mg + H1 antihistamines

Baseline weekly hive count score: 16.2

Mean change, week 12: -7.78

Difference in LS mean vs active control -3.44 (95% CI:–5.57, –1.32), P=.0017

Placebo + H1 antihistamines

Baseline weekly hive count score: 16.7

Mean change, week 12: –4.37

Images are for illustrative purposes only.

Study 1: Change From Baseline in Mean Weekly Hive Count Score at Week 12 (N=241)[‡1]

Hive count: During Studies 1 and 2, the hive count score was measured twice a day (AM and PM) on a scale of 0 (no hives) to 3 (>12 hives). The daily hive count score was the average of the morning and evening scores, and the weekly hive count score (0-21) was the sum of the daily hive count scores over 7 days.[3]

Study Designs

The safety and efficacy of XOLAIR for the treatment of CIU was assessed in 2 placebo-controlled, multiple-dose clinical studies of 24 weeks' duration (CIU Study 1; N=319) and 12 weeks' duration (CIU Study 2; N=322). Patients received XOLAIR 300 mg, 150 mg, 75 mg, or placebo in addition to their baseline level of H1 antihistamine therapy.[4] The 75-mg dose is not approved for use. Concomitant CIU treatments other than H1 antihistamines were not allowed during the study.[2,4]

‡Secondary efficacy endpoints across all studies were change from baseline in UAS7 at week 12, change from baseline in weekly hive count score at week 12, and the proportion of patients with UAS7=0 at week 12.[3]

UAS7=Urticaria Activity Score over 7 days.

IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

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

Please see pages 8-9 and accompanying full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 150 mg

The XOLAIR Effect: Study 2 confirms significant relief

Reductions in itch severity score[3*†]

300 mg n=79	150 mg n=82	Placebo n=79
71% RELATIVE REDUCTION	56% RELATIVE REDUCTION	36% RELATIVE REDUCTION

XOLAIR reduced mean weekly itch severity score at week 12 from baseline, which was the primary endpoint (XOLAIR 300 mg [n=79], -9.8 from 13.7; XOLAIR 150 mg [n=82], -8.1 from 14.2; placebo [n=79], -5.1 from 14.0).[5]

- The difference in LS mean vs active control was -4.8 for XOLAIR 300 mg (P<.001; 95% CI: -6.5, -3.1) and -3.0 for XOLAIR 150 mg (P<.01; 95% CI: -4.9, -1.2)[5]

Reductions in hive count score[3*‡]

300 mg n=79	150 mg n=82	Placebo n=79
74% REDUCTION	57% REDUCTION	31% REDUCTION

XOLAIR reduced mean weekly hive count score at week 12 from baseline, (XOLAIR 300 mg [n=79], 12.0 from 15.8; XOLAIR 150 mg [n=82], 9.8 from 17.1; placebo [n=79], 5.2 from 17.0).[5]

- The difference in LS mean vs active control was 7.1 for XOLAIR 300 mg (P<.001; 95% CI: 9.3, 4.9) and 4.5 for XOLAIR 150 mg (P<.001; 95% CI: 6.7, 2.4)[5]

*All patients received their dose of study drug or placebo in addition to stable doses of their prerandomization H1 antihistamine.[3]

†The weekly itch severity score was calculated for each patient at each week. The mean change from baseline (the primary efficacy analysis) and the mean percentage change in weekly itch severity score were calculated for each treatment group for comparison vs active control at week 12 (the primary efficacy analysis time point).[5]

‡Secondary efficacy endpoints across all studies were change from baseline in UAS7 at week 12, change from baseline in weekly hive count score at week 12, and the proportion of patients with UAS7=0 at week 12.[3]

Studied across a broad range of patients

In Studies 1 and 2 (N=641), patients

- Experienced symptoms after CIU diagnosis for an average of 6.9 and 6.5 years, respectively[3,5]
- Had already tried an average of 4.7 and 4.3 CIU medications, respectively, without adequate relief[4,5]
  ~50% of patients in Studies 1 and 2 received steroids prior to enrollment.[3,5]

Select Baseline Characteristics[4,5]

	Study 1			Study 2		
	XOLAIR 300 mg (n=81)	XOLAIR 150 mg (n=80)	Active Control (n=80)	XOLAIR 300 mg (n=79)	XOLAIR 150 mg (n=82)	Active Control (n=79)
Demographic information						
Male, n (%)	21 (25.9)	16 (20.0)	28 (35.0)	16 (20.3)	17 (20.7)	24 (30.4)
Female, n (%)	60 (74.1)	64 (80.0)	52 (65.0)	63 (79.7)	65 (79.3)	55 (69.6)
Mean (SD) age, years	42.4 (13.2)	41.1 (14.0)	40.4 (15.6)	44.3 (13.7)	43.0 (13.2)	43.1 (12.5)
Medical history						
Mean (SD) time since CIU diagnosis, years	6.2 (8.0)	7.6 (9.2)	7.0 (9.7)	6.1 (7.3)	7.2 (8.9)	7.2 (10.7)
Mean no. of previous CIU medications (SD)	4.5 (2.3)	4.5 (3.2)	5.0 (2.8)	4.3 (2.5)	4.5 (3.2)	4.4 (2.9)
Mean UAS7 score (SD)	31.3 (5.8)	30.3 (7.3)	31.1 (6.7)	29.5 (6.9)	31.4 (7.0)	31.0 (6.6)

Legend
XOLAIR 300 mg = XOLAIR + H1 antihistamine
XOLAIR 150 mg = XOLAIR + H1 antihistamine
Active control = Placebo + H1 antihistamine

SD=standard deviation.

Please see pages 8-9 and accompanying full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

Xolair® Omalizumab FOR SUBCUTANEOUS USE 150 mg

The XOLAIR Effect: More than one-third of patients on XOLAIR 300 mg experienced complete relief[2,4,5]

Based on decreases in mean weekly itch severity and hive count scores

Percentage of patients achieving complete relief at week 12

In Study 2:	UP TO **44%** OF PATIENTS 300 mg	UP TO **22%** OF PATIENTS 150 mg	UP TO **5%** OF PATIENTS Active control
In Study 1:	UP TO **36%** OF PATIENTS 300 mg	UP TO **15%** OF PATIENTS 150 mg	UP TO **9%** OF PATIENTS Active control

Complete relief defined as: No itch and no hives, (UAS7=0) at week 12 (N=241).

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

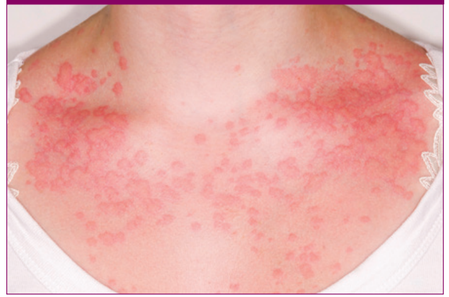
Anaphylaxis

Anaphylaxis has been reported to occur after administration of XOLAIR in premarketing clinical trials for a different indication 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.

The XOLAIR Effect: Complete relief is possible for your patients

Typical presentation of CIU flare before treatment



Actual 23-year-old female patient with CIU on her upper chest.

Potential complete relief (no itch and no hives) with XOLAIR at week 12*

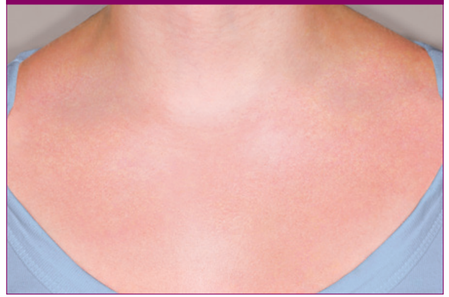


*Image for illustrative purposes only. Individual results may vary.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Anaphylaxis (continued)

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.

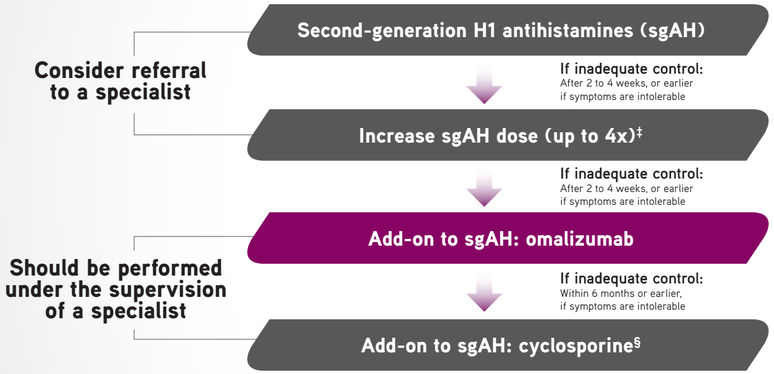
Please see pages 8-9 and accompanying full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

Xolair® Omalizumab FOR SUBCUTANEOUS USE 150 mg

When H1 antihistamines are not enough, start XOLAIR

For appropriate patients

Guidelines* recommend starting omalizumab as early as step 3 in the treatment algorithm[6†]



*Guidelines were developed by EAACI (European Academy of Allergy and Clinical Immunology), EDF (European Dermatology Forum), GA²LEN (Global Allergy and Asthma European Network), and WAO (World Allergy Organization).

†In addition, a short course of glucocorticosteroids may be considered in the case of a severe exacerbation. Other treatment options are available; see Table 9 of Zuberbier et al. 2018.[6]

‡A 4-times increase in the sgAH dose is not FDA approved.

§Cyclosporine A is off-label for urticaria.[6]

AAAAI=American Academy of Allergy, Asthma & Immunology; AAD=American Academy of Dermatology; ACAAI=American College of Allergy, Asthma and Immunology.

These evidence- and consensus-based guidelines were developed with the participation of 42 national and international societies, and are endorsed by **AAAAI, ACAAI, and AAD**[6]

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

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) for a different indication and other allergic disorders. The observed malignancies in XOLAIR-treated patients were of 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 (eg, elderly, current smokers) is not known.

Committed to helping patients get the treatment they need

XOLAIR has extensive coverage for CIU*

XOLAIR Access Solutions provides coverage support:

- Benefits investigations, resources for prior authorization and denials/appeals
- My Patient Solutions is our online patient management tool

Help your patients pay for XOLAIR through our co-pay program†:

Eligible commercially insured patients pay:

- $5 per XOLAIR **drug out-of-pocket cost**. The program covers the rest up to $10,000 for each 12-month period
- $5 per XOLAIR **administration out-of-pocket cost**. The program covers the rest up to $1,000 for each 12-month period

Help your patients receive treatment, regardless of coverage:

- For eligible patients with commercial or public health insurance, XOLAIR Access Solutions offers referrals to independent co-pay assistance foundations‡
- **Genentech Patient Foundation**§ gives eligible patients XOLAIR for free

- XOLAIR Sample Program
- XOLAIR Starter Program‖
- Support for You Adherence Program

*Information is current as of June 2019. Formularies are subject to change at the discretion of the payer. The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and health care provider. Genentech does not make any representation or guarantee concerning coverage or reimbursement for any service or item. No conclusions regarding comparative safety or efficacy can be drawn from this information.

†This XOLAIR Co-pay Program is valid ONLY for patients with commercial insurance who have a valid prescription for a Food and Drug Administration (FDA)-approved indication of XOLAIR. Patients using Medicare, Medicaid, or any other federal or state government program to pay for their medications are not eligible. Under the Program, the patient will pay a co-pay. After reaching the maximum Program benefit, the patient will be responsible for all out-of-pocket costs. All participants are responsible for reporting the receipt of all Program benefits as required by any insurer or by law. No party may seek reimbursement for all or any part of the benefit received through this Program. This Program is void where prohibited by law. Genentech, Inc. and Novartis Pharmaceuticals Corporation reserve the right to rescind, revoke, or amend the Program without notice at any time. Additional eligibility criteria apply. The XOLAIR Administration Co-pay Program is not valid for Massachusetts, Michigan, Minnesota, or Rhode Island residents, is void where prohibited by law and is subject to state specific restrictions. If you choose to enroll in both the XOLAIR Drug Co-pay Program and the XOLAIR Administration Co-pay Program, you must enroll into each program separately and meet all eligibility criteria. See full terms and conditions at XOLAIRcopay.com.

‡Genentech, Inc. and Novartis Pharmaceuticals Corporation do not influence or control the operations or eligibility criteria of any independent co-pay assistance foundation and cannot guarantee co-pay assistance after a referral from XOLAIR Access Solutions. The foundations to which we refer patients are not exhaustive or indicative of Genentech's or Novartis Pharmaceuticals Corporation's endorsement or financial support. There may be other foundations to support the patient's disease state.

§To be eligible for free XOLAIR from the Genentech Patient Foundation, insured patients must have exhausted all other forms of patient assistance (including the XOLAIR Co-pay Program and support from independent co-pay assistance foundations) and meet financial criteria. Uninsured patients must meet different financial criteria.

‖To be eligible for the XOLAIR Starter Program, patients must have insurance and must meet other criteria.

Please see pages 8-9 and accompanying full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

Xolair® Omalizumab FOR SUBCUTANEOUS USE 150 mg

INDICATION

XOLAIR® (omalizumab) IS INDICATED FOR adults and adolescents 12 years of age and older with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment.

Limitation 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 premarketing clinical trials for a different indication 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) for a different indication and other allergic disorders. The observed malignancies in XOLAIR-treated patients were of 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 (eg, 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 for a different indication 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.

Corticosteroid Reduction

In CIU patients, the use of XOLAIR in combination with corticosteroids has not been evaluated.

Fever, Arthralgia, and Rash

In postapproval 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.

IMPORTANT SAFETY INFORMATION (continued)

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.

ADVERSE REACTIONS

In patients ≥12 years of age, the most commonly observed adverse reactions (≥2% XOLAIR-treated patients and more frequent than in placebo) from 3 placebo-controlled CIU studies (Day 1 to Week 12) for XOLAIR 150 mg and 300 mg, respectively, were: 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

In adults and adolescents, injection site reactions of any severity occurred during the trials 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. None of the events resulted in study discontinuation or treatment interruption.

Cardiovascular and Cerebrovascular Events from Clinical Studies for a Different Indication

A 5-year observational study was conducted in 5007 XOLAIR-treated and 2829 non-XOLAIR-treated patients ≥12 years of age for a different indication 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 a severe form of the condition studied (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

The 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.

References: 1. Maurer M, Weller K, Bindslev-Jensen C, et al. Unmet clinical needs in chronic spontaneous urticaria. A GA²LEN task force report [published online November 17, 2010]. *Allergy*. 2011;66(3):317-330. doi:10.1111/j.1398-9995.2010.02496.x. **2.** XOLAIR [prescribing information]. Genentech USA, Inc. and Novartis Pharmaceuticals Corporation; 2019. **3.** Data on file. Genentech USA, Inc. South San Francisco, CA. **4.** Saini SS, Bindslev-Jensen C, Maurer M, et al. Efficacy and safety of omalizumab in patients with chronic idiopathic/spontaneous urticaria who remain symptomatic on H1 antihistamines: a randomized, placebo-controlled study [published correction appears in *J Invest Dermatol*. 2015;135(3):925. doi:10.1038/jid.2014.512]. *J Invest Dermatol*. 2015;135(1):67-75. doi:10.1038/jid.2014.306. **5.** Maurer M, Rosén K, Hsieh H-J, et al. Omalizumab for the treatment of chronic idiopathic or spontaneous urticaria [published correction appears in *N Engl J Med*. 2013;368(24)(suppl):2340-2341]. *N Engl J Med*. 2013;368(10):924-935. doi:10.1056/NEJMoa1215372. **6.** Zuberbier T, Aberer W, Asero R, et al. The EAACI/GA²LEN/EDF/WAO guideline for the definition, classification, diagnosis and management of urticaria. *Allergy*. 2018;73(7):1393-1414. doi:10.1111/all.13397.

Please see accompanying full Prescribing Information, including Boxed WARNING and Medication Guide.

Xolair® Omalizumab FOR SUBCUTANEOUS USE 150 mg

Complete relief may be possible for your CIU patients

XOLAIR reduced weekly itch severity score and decreased weekly hive count score[2-4]

Up to 44% of patients taking XOLAIR 300 mg achieved complete relief[5]

- Up to 22% of patients taking XOLAIR 150 mg achieved complete relief, along with up to 9% in the placebo group[2,4,5]

When H1 antihistamines are not enough, guidelines recommend XOLAIR[6*]

Committed to helping patients get the treatment they need

*Guidelines were developed by EAACI (European Academy of Allergy and Clinical Immunology), EDF (European Dermatology Forum), GA²LEN (Global Allergy and Asthma European Network).

Model for illustrative purposes only.

INDICATION

XOLAIR® (omalizumab) IS INDICATED FOR adults and adolescents 12 years of age and older with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment.

Limitation 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 8-9 and accompanying full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information.

Genentech
A Member of the Roche Group

NOVARTIS

Xolair® Omalizumab FOR SUBCUTANEOUS USE 150 mg