DOSING GUIDE

Available as an autoinjector, prefilled syringe, and as a lyophilized powder in vial for reconstitution[1]

Administer XOLAIR by subcutaneous injection. XOLAIR is intended for use under the guidance of a healthcare provider. Initiate therapy in a healthcare setting and once therapy has been safely established, the healthcare provider may determine whether self-administration of XOLAIR Autoinjector or prefilled syringe by the patient or caregiver is appropriate, based on careful assessment of risk for anaphylaxis and mitigation strategies.

See the full Prescribing Information for selection criteria of patients for self-administration of XOLAIR Autoinjector or prefilled syringe.

Please refer to the full Prescribing Information for additional information on administration and dosing.

150-mg vial of lyophilized powder for reconstitution

75 mg/0.5 mL • 150 mg/1 mL • 300 mg/2 mL

XOLAIR prefilled syringe

75 mg/0.5 mL • 150 mg/1 mL • 300 mg/2 mL

XOLAIR Autoinjector

The XOLAIR 75-mg and 150-mg prefilled syringes will have an updated design with a colored plunger rod as shown above.

Products not shown actual size.

INDICATIONS

XOLAIR® (omalizumab) is indicated for:

- Adults and pediatric patients 6 years of age and older 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.

  Limitations of Use: XOLAIR is not indicated for the relief of acute bronchospasm or status asthmaticus.
- Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.
- The reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy.

  XOLAIR is to be used in conjunction with food allergen avoidance.

  Limitations of Use: XOLAIR is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.
- Chronic spontaneous urticaria (CSU) in adults and adolescents 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, initiate XOLAIR therapy in a healthcare setting and closely observe patients for an appropriate period of time after XOLAIR administration. Health care providers administering XOLAIR should be prepared to manage anaphylaxis which can be life-threatening. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should symptoms occur. Selection of patients for self-administration of XOLAIR should be based on criteria to mitigate risk from anaphylaxis.

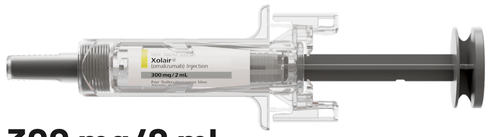
Please see pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information and Instructions for Use.

DISCOVER XOLAIR DOSAGE FORMS AND STRENGTHS

Effective April 11, 2025, the XOLAIR 75-mg and 150-mg prefilled syringes will have an updated design, including:

- Dose strength is indicated on the colored plunger rod
- A needle cap that does not contain any latex
- A smaller gauge needle

XOLAIR PREFILLED SYRINGE: COLORED PLUNGER ROD



300 mg/2 mL
NDC code: 50242-227-01

150 mg/1 mL
NDC code: 50242-215-03

75 mg/0.5 mL
NDC code: 50242-214-03

XOLAIR PREFILLED SYRINGE: COLORED NEEDLE-SHIELD

150 mg/1 mL
NDC code: 50242-215-01

75 mg/0.5 mL
NDC code: 50242-214-01

Products not shown actual size.
See the full Prescribing Information for selection criteria of patients for self-administration of XOLAIR Autoinjector and prefilled syringe.

Please see pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information and Instructions for Use.

MORE DOSAGE FORMS AND STRENGTHS

XOLAIR AUTOINJECTOR

300 mg/2 mL
NDC code: 50242-227-55

150 mg/1 mL
NDC code: 50242-215-55

75 mg/0.5 mL
NDC code: 50242-214-55

150-MG VIAL

NDC code: 50242-040-62

Products not shown actual size.
See the full Prescribing Information for selection criteria of patients for self-administration of XOLAIR Autoinjector and prefilled syringe.

XOLAIR is intended for use under the guidance of a healthcare provider. Initiate therapy in a healthcare setting, and once therapy has been safely established, the healthcare provider may determine whether self-administration of XOLAIR Autoinjector or prefilled syringe by the patient or caregiver is appropriate, based on careful assessment of risk for anaphylaxis and mitigation strategies.

Do **not** use XOLAIR for the emergency treatment of any allergic reactions, including anaphylaxis, hives, or sudden breathing problems.

Please see pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information and Instructions for Use.

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 (kg)
- Adjust doses for significant changes in body weight during treatment
- Total IgE levels are elevated during treatment and remain elevated for up to 1 year after the discontinuation of treatment. Therefore, retesting of IgE levels during XOLAIR treatment cannot be used as a guide for dose determination
  - Interruptions lasting less than 1 year: Dose based on serum IgE levels obtained at the initial dose determination
  - Interruptions lasting 1 year or more: Retest total serum IgE levels for dose determination based on table on page 5
- The appropriate duration of therapy for IgE-mediated food allergy has not been evaluated. Periodically reassess the need for continued therapy
- Persons with latex allergies should not handle XOLAIR prefilled syringe (colored needle-shield) because the needle cap of the XOLAIR 75 mg/0.5 mL and 150 mg/1 mL prefilled syringes (colored needle-shield) contains a derivative of natural rubber latex, which may cause allergic reactions in latex-sensitive individuals

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

*The XOLAIR Autoinjector (all doses) is not intended for use in pediatric patients under 12 years of age.

†This table represents the fewest number of injections for the patient; however, there are other syringe/autoinjector dosing combinations to achieve desired dose. For patients requiring more than 1 injection to complete a full dose, administer each injection at least 1 inch apart from other injection sites.

‡Doses of more than one 150-mg vial 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 after reconstitution.

IgE=immunoglobulin E.

Please see pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information and Instructions for Use.

DOSING: ADULT AND PEDIATRIC PATIENTS AGED ≥1 YEAR WITH IgE-MEDIATED FOOD ALLERGY[1]

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

Subcutaneous XOLAIR Dosing for Appropriate Adult and Pediatric IgE-Mediated Food Allergy Patients Aged ≥1 Year

Pretreatment Serum IgE (IU/mL)	Dosing Frequency	Body Weight (kg) ≥10-12	>12-15	>15-20	>20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
		Dose (mg)												
≥30-100	Every 4 weeks	75	75	75	75	75	75	150	150	150	150	150	300	300
>100-200		75	75	75	150	150	150	300	300	300	300	300	450	600
>200-300		75	75	150	150	150	225	300	300	450	450	450	600	375
>300-400		150	150	150	225	225	300	450	450	450	600	600	450	525
>400-500		150	150	225	225	300	450	450	600	600	375	375	525	600
>500-600		150	150	225	300	300	450	600	600	375	450	450	600	
>600-700	Every 2 weeks	150	150	225	300	225	450	600	375	450	450	525		
>700-800		150	150	150	225	225	300	375	450	450	525	600		
>800-900		150	150	150	225	225	300	375	450	525	600			
>900-1000		150	150	225	225	300	375	450	525	600				
>1000-1100		150	150	225	225	300	375	450	600					
>1100-1200		150	150	225	300	300	450	525	600					
>1200-1300		150	225	225	300	375	450	525						
>1300-1500		150	225	300	300	375	525	600						
>1500-1850			225	300	375	450	600							

Insufficient data to recommend a dose

Dosing Frequency

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

IgE=immunoglobulin E.

Please see pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information and Instructions for Use.

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg • 300 mg

ADMINISTRATION AND DOSING[1]

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

- Dosing of XOLAIR in chronic spontaneous urticaria patients is not dependent on serum IgE (free or total) level or body weight
- The appropriate duration of therapy for chronic spontaneous urticaria has not been evaluated. Periodically reassess the need for continued therapy
- The 300-mg dose may be administered as 1 subcutaneous injection of 300 mg/2 mL or as 2 subcutaneous injections of 150 mg/1 mL
- Persons with latex allergies should not handle XOLAIR prefilled syringe (colored needle-shield) because the needle cap of the XOLAIR 75 mg/0.5 mL and 150 mg/1 mL prefilled syringes (colored needle-shield) contains a derivative of natural rubber latex, which may cause allergic reactions in latex-sensitive individuals

PREFILLED SYRINGE OR AUTOINJECTOR*

Dose	# of 150-mg XOLAIR Autoinjectors or syringes	# of 300-mg XOLAIR Autoinjectors or syringes	Total volume injected
300 mg	0	1	2 mL
150 mg	1	0	1 mL

XOLAIR prefilled syringe

XOLAIR Autoinjector

The XOLAIR 75-mg and 150-mg prefilled syringes will have an updated design with a colored plunger rod as shown above.

Products not shown actual size.

*The XOLAIR Autoinjector (all doses) is not intended for use in pediatric patients under 12 years of age.
IgE=immunoglobulin E.

Please see pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information and Instructions for Use.

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg • 300 mg

ADMINISTRATION AND DOSING: ADULTS AND ADOLESCENTS AGED ≥12 YEARS WITH CSU[1]

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

- Dosing of XOLAIR in chronic spontaneous urticaria patients is not dependent on serum IgE (free or total) level or body weight
- The 300-mg dose may be administered as 1 subcutaneous injection of 300 mg/2 mL or as 2 subcutaneous injections of 150 mg/1 mL
- The appropriate duration of therapy for chronic spontaneous urticaria has not been evaluated. Periodically reassess the need for continued therapy

150-mg VIAL (Lyophilized Powder for Reconstitution)

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

Two 150-mg vials of lyophilized powder for reconstitution=300 mg.

Products not shown actual size.

*Doses of more than one 150-mg vial 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 after reconstitution.
IgE=immunoglobulin E.

Please see pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information and Instructions for Use.

Xolair® Omalizumab
FOR SUBCUTANEOUS USE 75 mg ▪ 150 mg ▪ 300 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 (kg)
- Adjust doses for significant changes in body weight during treatment
- Total IgE levels are elevated during treatment and remain elevated for up to 1 year after the discontinuation of treatment. Therefore, retesting of IgE levels during XOLAIR treatment cannot be used as a guide for dose determination
  - Interruptions lasting less than 1 year: Dose based on serum IgE levels obtained at the initial dose determination
  - Interruptions lasting 1 year or more: Retest total serum IgE levels for dose determination based on table on page 9
- Periodically reassess the need for continued therapy based upon the patient's disease severity and level of asthma control
- Persons with latex allergies should not handle XOLAIR prefilled syringe (colored needle-shield) because the needle cap of the XOLAIR 75 mg/0.5 mL and 150 mg/1 mL prefilled syringes (colored needle-shield) contains a derivative of natural rubber latex, which may cause allergic reactions in latex-sensitive individuals

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

*The XOLAIR Autoinjector (all doses) is not intended for use in pediatric patients under 12 years of age.

†This table represents the fewest number of injections for the patient; however, there are other syringe/autoinjector dosing combinations to achieve desired dose. For patients requiring more than 1 injection to complete a full dose, administer each injection at least 1 inch apart from other injection sites.

‡Doses of more than one 150-mg vial 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 after reconstitution.

IgE=immunoglobulin E.

Please see pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information and Instructions for Use.

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 (kg) to determine the dose. Values falling outside the table range provide insufficient data for recommending a dose. For adult patients with IgE-mediated food allergy, allergic asthma, and chronic rhinosinusitis with nasal polyps, dosing determination should be based on the primary diagnosis for which XOLAIR is being prescribed. Periodically reassess the need for continued therapy based upon the patient's disease severity and level of asthma control.

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

Pretreatment Serum IgE (IU/mL)	Dosing Frequency	Body Weight (kg)			
		30-60	>60-70	>70-90	>90-150
		Dose (mg)			
≥30-100	Every 4 weeks	150	150	150	300
>100-200	Every 4 weeks	300	300	300	225
>200-300	Every 4 weeks	300	225	225	300
>300-400	Every 2 weeks	225	225	300	
>400-500	Every 2 weeks	300	300	375	
>500-600	Every 2 weeks	300	375		
>600-700	Every 2 weeks	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

IgE=immunoglobulin E.

Please see pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information and Instructions for Use.

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 (kg)
- Adjust doses for significant changes in body weight during treatment
- Total IgE levels are elevated during treatment and remain elevated for up to 1 year after the discontinuation of treatment. Therefore, retesting of IgE levels during XOLAIR treatment cannot be used as a guide for dose determination
  - Interruptions lasting less than 1 year: Dose based on serum IgE levels obtained at the initial dose determination
  - Interruptions lasting 1 year or more: Retest total serum IgE levels for dose determination based on table on page 11
- Periodically reassess the need for continued therapy based upon the patient's disease severity and level of asthma control
- Persons with latex allergies should not handle XOLAIR prefilled syringe (colored needle-shield) because the needle cap of the XOLAIR 75 mg/0.5 mL and 150 mg/1 mL prefilled syringes (colored needle-shield) contains a derivative of natural rubber latex, which may cause allergic reactions in latex-sensitive individuals

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

*This table represents the fewest number of injections for the patient; however, there are other syringe dosing combinations to achieve desired dose. For patients requiring more than 1 injection to complete a full dose, administer each injection at least 1 inch apart from other injection sites.

†Doses of more than one 150-mg vial 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 after reconstitution.

IgE=immunoglobulin E.

Please see pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information and Instructions for Use.

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 (kg) to determine the dose. Values falling outside the table range provide insufficient data for recommending a dose. Periodically reassess the need for continued therapy based upon the patient's disease severity and level of asthma control.

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

Pretreatment Serum IgE (IU/mL)	Dosing Frequency	Body Weight (kg) 20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
		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

IgE=immunoglobulin E.

Please see pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information and Instructions for Use.

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 (kg)
- Adjust doses for significant changes in body weight during treatment
- Total IgE levels are elevated during treatment and remain elevated for up to 1 year after the discontinuation of treatment. Therefore, retesting of IgE levels during XOLAIR treatment cannot be used as a guide for dose determination
  - Interruptions lasting less than 1 year: Dose based on serum IgE levels obtained at the initial dose determination
  - Interruptions lasting 1 year or more: Retest total serum IgE levels for dose determination based on table on page 13
- Periodically reassess the need for continued therapy based upon the patient's disease severity and level of symptom control
- Persons with latex allergies should not handle XOLAIR prefilled syringe (colored needle-shield) because the needle cap of the XOLAIR 75 mg/0.5 mL and 150 mg/1 mL prefilled syringes (colored needle-shield) contains a derivative of natural rubber latex, which may cause allergic reactions in latex-sensitive individuals

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

*The XOLAIR Autoinjector (all doses) is not intended for use in pediatric patients under 12 years of age.

†This table represents the fewest number of injections for the patient; however, there are other syringe/autoinjector dosing combinations to achieve desired dose. For patients requiring more than 1 injection to complete a full dose, administer each injection at least 1 inch apart from other injection sites.

‡Doses of more than one 150-mg vial 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 after reconstitution.

IgE=immunoglobulin E.

Please see pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information and Instructions for Use.

DOSING: ADULTS AGED ≥18 YEARS WITH CHRONIC RHINOSINUSITIS WITH NASAL POLYPS[1]

Use the patient's pretreatment serum total IgE level (IU/mL) and body weight (kg) to determine the dose. Values falling outside the table range provide insufficient data for recommending a dose. For adult patients with IgE-mediated food allergy, allergic asthma, and chronic rhinosinusitis with nasal polyps, dosing determination should be based on the primary diagnosis for which XOLAIR is being prescribed. Periodically reassess the need for continued therapy based upon the patient's disease severity and level of symptom control.

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

Pretreatment Serum IgE (IU/mL)	Dosing Frequency	Body Weight (kg) >30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
		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				
>1100-1200		375	450	600					
>1100-1200		450	525	600					
>1200-1300		450	525						
>1300-1500		525	600						

Insufficient data to recommend a dose

Dosing Frequency

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

IgE=immunoglobulin E.

Please see pages 14-15 and full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information and Instructions for Use.

INDICATIONS

XOLAIR® (omalizumab) is indicated for:

- Adults and pediatric patients 6 years of age and older 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.

  Limitations of Use: XOLAIR is not indicated for the relief of acute bronchospasm or status asthmaticus.
- Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.
- The reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy.

  XOLAIR is to be used in conjunction with food allergen avoidance.

  Limitations of Use: XOLAIR is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.
- Chronic spontaneous urticaria (CSU) in adults and adolescents 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, initiate XOLAIR therapy in a healthcare setting and closely observe patients for an appropriate period of time after XOLAIR administration. Health care providers administering XOLAIR should be prepared to manage anaphylaxis which can be life-threatening. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should symptoms occur. Selection of patients for self-administration of XOLAIR should be based on criteria to mitigate risk from anaphylaxis.

CONTRAINDICATIONS

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 and in postmarketing spontaneous reports. In premarketing clinical trials in patients with asthma, anaphylaxis was reported in 3 of 3507 (0.1%) patients. Anaphylaxis occurred with the first dose of XOLAIR in two patients and with the fourth dose in one patient. The time to onset of anaphylaxis was 90 minutes after administration in two patients and 2 hours after administration in one patient.

A case-control study in asthma patients 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.

In postmarketing spontaneous reports, the frequency of anaphylaxis attributed to XOLAIR use was estimated to be at least 0.2% of patients based on an estimated exposure of about 57,300 patients from June 2003 through December 2006. Approximately 60% to 70% of anaphylaxis cases have been reported to occur within the first three doses of XOLAIR, with additional cases occurring sporadically beyond the third dose.

Initiate XOLAIR only in a healthcare setting equipped to manage anaphylaxis which can be life-threatening. 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. Inform patients of the signs and symptoms of anaphylaxis, and instruct them to seek immediate medical care should signs or symptoms occur.

Once XOLAIR therapy has been established, administration of XOLAIR prefilled syringe or autoinjector outside of a healthcare setting by a patient or a caregiver may be appropriate for selected patients. Patient selection, determined by the healthcare provider in consultation with the patient, should take into account the pattern of anaphylaxis events seen in premarketing clinical trials and postmarketing spontaneous reports, as well as individual patient risk factors (e.g. prior history of anaphylaxis), ability to recognize signs and symptoms of anaphylaxis, and ability to perform subcutaneous injections with XOLAIR prefilled syringe or autoinjector with proper technique according to the prescribed dosing regimen and Instructions for Use.

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 and Deteriorating Disease: XOLAIR has not been shown to alleviate asthma exacerbations acutely. Do not use XOLAIR to treat acute bronchospasm or status asthmaticus. Patients should seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment with XOLAIR.

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

Xolair® Omalizumab
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WARNINGS AND PRECAUTIONS (CONT'D)

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.

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, CRSwNP, or IgE-mediated food allergy patients, because these levels may not reflect steady state free IgE levels.

Potential Medication Error Related to Emergency Treatment of Anaphylaxis: XOLAIR should not be used for the emergency treatment of allergic reactions, including anaphylaxis. In studies to simulate use, some patients and caregivers did not understand that XOLAIR is not intended for the emergency treatment of allergic reactions, including anaphylaxis. The safety and effectiveness of XOLAIR for emergency treatment of allergic reactions, including anaphylaxis, have not been established. Instruct patients that XOLAIR is for maintenance use to reduce allergic reactions, including anaphylaxis, while avoiding food allergens.

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.

Chronic Rhinosinusitis with Nasal Polyps: The most common adverse reactions (≥3% in XOLAIR-treated patients) included: headache (8.1%), injection site reactions (5.2%), arthralgia (3.0%), upper abdominal pain (3.0%), and dizziness (3.0%).

IgE-Mediated Food Allergy: The most common adverse reactions (≥3% in XOLAIR-treated pediatric patients 1 year of age and older) included: injection site reactions (15.5%) and pyrexia (6.4%). Safety data obtained from adults (n=3) in this trial was limited.

Chronic Spontaneous Urticaria: The most common adverse reactions (≥2% in XOLAIR-treated patients) 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.

Chronic Rhinosinusitis with 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.

IgE-Mediated Food Allergy: Injection site reactions occurred at a rate of 15.5% in XOLAIR-treated patients compared with 10.9% in placebo-treated patients. The types of injection site reactions included: urticaria, discomfort, erythema, pain, and rash. All injection site reactions were mild to moderate severity and none resulted in study discontinuation.

Chronic Spontaneous 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. None of the events resulted in study discontinuation or treatment interruption.

Injection Site Reactions in Healthy Adults: In an open label trial in healthy adults, in which the 300 mg/2 mL autoinjector was compared to the 300 mg/2 mL prefilled syringe, injection site reactions (e.g., induration, pain, erythema, hemorrhage, swelling, discomfort, bruising, hypoesthesia, edema, pruritus) were observed in 24% (16/66) of subjects treated with the autoinjector compared with 14% (9/64) of subjects treated with the prefilled syringe.

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 to evaluate the long term safety of XOLAIR, including the risk of malignancy. 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.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information and Instructions for Use.

Reference: 1. XOLAIR. Prescribing information. Genentech USA, Inc. and Novartis Pharmaceuticals Corporation.

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INDICATIONS

XOLAIR® (omalizumab) is indicated for:

- Adults and pediatric patients 6 years of age and older 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.

  Limitations of Use: XOLAIR is not indicated for the relief of acute bronchospasm or status asthmaticus.
- Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.
- The reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy.

  XOLAIR is to be used in conjunction with food allergen avoidance.

  Limitations of Use: XOLAIR is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.
- Chronic spontaneous urticaria (CSU) in adults and adolescents 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, initiate XOLAIR therapy in a healthcare setting and closely observe patients for an appropriate period of time after XOLAIR administration. Health care providers administering XOLAIR should be prepared to manage anaphylaxis which can be life-threatening. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should symptoms occur. Selection of patients for self-administration of XOLAIR should be based on criteria to mitigate risk from anaphylaxis.

Please see pages 14-15 full Prescribing Information, including Boxed WARNING and Medication Guide, for additional Important Safety Information and Instructions for Use.

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