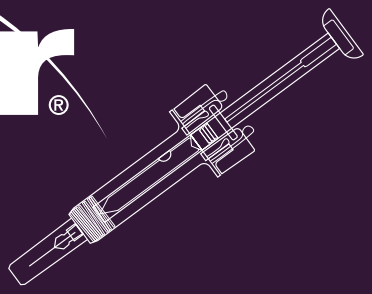
Pr Xolair®

Dosing



XOLAIR® (omalizumab) is indicated for:

- Adult and pediatric patients (6 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.
    - Adults and adolescents (12 years of age and older): XOLAIR® has been shown to significantly decrease the incidence of asthma exacerbations and improve control of asthma symptoms in these patients.
    - Children (6 to <12 years of age): XOLAIR®, used as add-on therapy, has been shown to significantly decrease asthma exacerbation rates in children who are inadequately controlled and have a documented history of exacerbation.
- Add-on maintenance treatment with intranasal corticosteroids in adult patients with severe chronic rhinosinusitis with nasal polyps (CRSwNP) inadequately controlled by intranasal corticosteroids alone.
- The treatment of adults and adolescents (12 years of age and above) with chronic idiopathic urticaria (CIU) who remain symptomatic despite H1 antihistamine treatment.

Pr Xolair® omalizumab

Recommended XOLAIR® dose and dosing a

Allergic asthma

Children (6 to <12 years of age)

	BODY WEIGHT (kg)									
Baseline IgE (IU/mL)*	20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
30-100	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	DO NOT DOSE	
>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	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								

*** 1 IU /mL = 2.4 ng/mL = 2.4 mcg/L**

Adapted from the XOLAIR® Product Monograph[1]

Adult and adolescents (12 years of age and older)

	BODY WEIGHT (kg)*								
Baseline IgE (IU/mL)*	>20-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
≥30-100	150	150	150	150	150	150	150	300	300
>100-200	150	150	300	300	300	300	300	225	300
>200-300	150	300	300	300	225	225	225	300	375
>300-400	300	300	225	225	225	300	300	DO NOT DOSE	
>400-500	300	225	225	300	300	375	375		
>500-600	300	225	300	300	375				
>600-700	225	225	300	375					

*** 1 IU /mL = 2.4 ng/mL = 2.4 mcg/L**

Adapted from the XOLAIR® Product Monograph[1]

The need for continued therapy should be periodically reassessed based upon the patient's disease severity and level of asthma control.

adjustment

CRSwNP

CRSwNP (Adults 18 years of age and older)

	BODY WEIGHT (kg)*							
Pretreatment serum IgE	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
30-100 IU/mL 72-240 ng/mL	75	150	150	150	150	150	300	300
>100-200 IU/mL >240-480 ng/mL	150	300	300	300	300	300	450	600
>200-300 IU/mL >480-720 ng/mL	225	300	300	450	450	450	600	375
>300-400 IU/mL >720-960 ng/mL	300	450	450	450	600	600	450	525
>400-500 IU/mL >960-1,200 ng/mL	450	450	600	600	375	375	525	600
>500-600 IU/mL >1,200-1,440 ng/mL	450	600	600	375	450	450	600	DO NOT DOSE
>600-700 IU/mL >1,440-1,680 ng/mL	450	600	375	450	450	525	DO NOT DOSE	DO NOT DOSE
>700-800 IU/mL >1,680-1,920 ng/mL	300	375	450	450	525	600	DO NOT DOSE	DO NOT DOSE
>800-900 IU/mL >1,920-2,160 ng/mL	300	375	450	525	600	DO NOT DOSE	DO NOT DOSE	DO NOT DOSE
>900-1,000 IU/mL >2,160-2,400 ng/mL	375	450	525	600	DO NOT DOSE	DO NOT DOSE	DO NOT DOSE	DO NOT DOSE
>1,000-1,100 IU/mL >2,400-2,640 ng/mL	375	450	600	DO NOT DOSE	DO NOT DOSE	DO NOT DOSE	DO NOT DOSE	DO NOT DOSE
>1,100-1,200 IU/mL >2,640-2,880 ng/mL	450	525	600	DO NOT DOSE	DO NOT DOSE	DO NOT DOSE	DO NOT DOSE	DO NOT DOSE
>1,200-1,300 IU/mL >2,880-3,120 ng/mL	450	525	DO NOT DOSE	DO NOT DOSE	DO NOT DOSE	DO NOT DOSE	DO NOT DOSE	DO NOT DOSE
>1,300-1,500 IU/mL >3,120-3,600 ng/mL	525	600	DO NOT DOSE	DO NOT DOSE	DO NOT DOSE	DO NOT DOSE	DO NOT DOSE	DO NOT DOSE

Administration every 4 weeks Administration every 2 weeks Do not dose

Adapted from the XOLAIR® Product Monograph[1]

The need for continued therapy should be periodically reassessed based upon the patient's disease severity and level of asthma control.

Dosing adjustments for asthma and CRSwNP patients

- 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.

CIU (12 years of age and older)

150 or 300 mg administered every 4 weeks

- The efficacy of XOLAIR® in CIU patients is dose-dependent
- Dosing is not dependent on serum IgE (free or total) level or body weight

Prescribers are advised to periodically reassess the need for continued therapy. Clinical trial experience in long term treatment (>6 months) of CIU is limited.

Please see the XOLAIR® Product Monograph for complete dosing information.

XOLAIR®: Extensive experience worldwide combined across all indications[2]

3 indications: asthma (2004), CRSwNP (2021), and CIU (2014)[1]*

19 years of clinical experience globally[2]

17 years of clinical experience in Canada[2]

1.5 million patient years worldwide[2]

>10,000 Canadian patients on XOLAIR®[2]

Clinical use:
The safety and efficacy of XOLAIR® have not been established in other conditions.
There is limited experience with XOLAIR® in patients over 65 years of age.

Most serious warnings and precautions:
Anaphylaxis: Anaphylaxis, presenting as angioedema of the throat or tongue, bronchospasm, hypotension, syncope, and/or urticaria has been reported to occur after administration of XOLAIR® in premarketing clinical trials and in postmarketing spontaneous reports. Anaphylaxis has occurred as early as after the first dose of XOLAIR®, but also has occurred beyond 1 year after beginning regularly administered treatment. Some of these events have been life-threatening. Initiate XOLAIR® therapy in a healthcare setting, closely observe patients for an appropriate period of time after XOLAIR® administration, and be prepared to manage anaphylaxis which can be life-threatening. Patients should also be informed of the signs and symptoms of anaphylaxis and instructed to seek immediate medical care should symptoms occur. The selection of patients for self-administration of XOLAIR® should be based on criteria to mitigate the risk from anaphylaxis.

Other relevant warnings and precautions:
- Not for the treatment of acute bronchospasm or status asthmaticus
- Cardiovascular and cerebrovascular disorders
- Corticosteroid reductions
- Immune system disorders: Churg-Strauss syndrome and hypereosinophilic syndrome; serum sickness; immunogenicity
- Information for patients on anaphylaxis; driving or using machines
- Information for asthma patients: do not decrease or stop taking any other asthma medication unless instructed by physician
- Caution in other IgE-associated disorders
- Patients at high risk of parasitic (helminth) infections
- Pre-filled syringe, latex-sensitive individuals
- Patients with renal or hepatic impairment
- Pregnant women
- Information for nursing women
- Fertility
- Pediatrics (<6 years of age for asthma indication; <18 years of age for chronic rhinosinusitis with nasal polyps (CRSwNP); <12 years of age for CIU indication)
- Geriatrics (>65 years of age)
- Monitoring and laboratory tests: elevated serum total IgE

For more information:
Consult the Product Monograph at http://www.novartis.ca/XolairMonograph for important information relating to adverse drug reactions, drug interactions, and dosage and administration information which have not been discussed in this piece. The Product Monograph also available by calling 1-800-363-8883.

References: 1. XOLAIR® Product Monograph. Novartis Pharmaceuticals Canada Inc. September 8, 2021. **2.** Novartis Data on File. Attestation letter. November, 2021.

* Years when each indication was introduced in Canada.

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REVIEWED BY PAAB

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