In severe asthma:

THINK Allergy[1]
THINK IgE[2]
THINK Xolair[3]

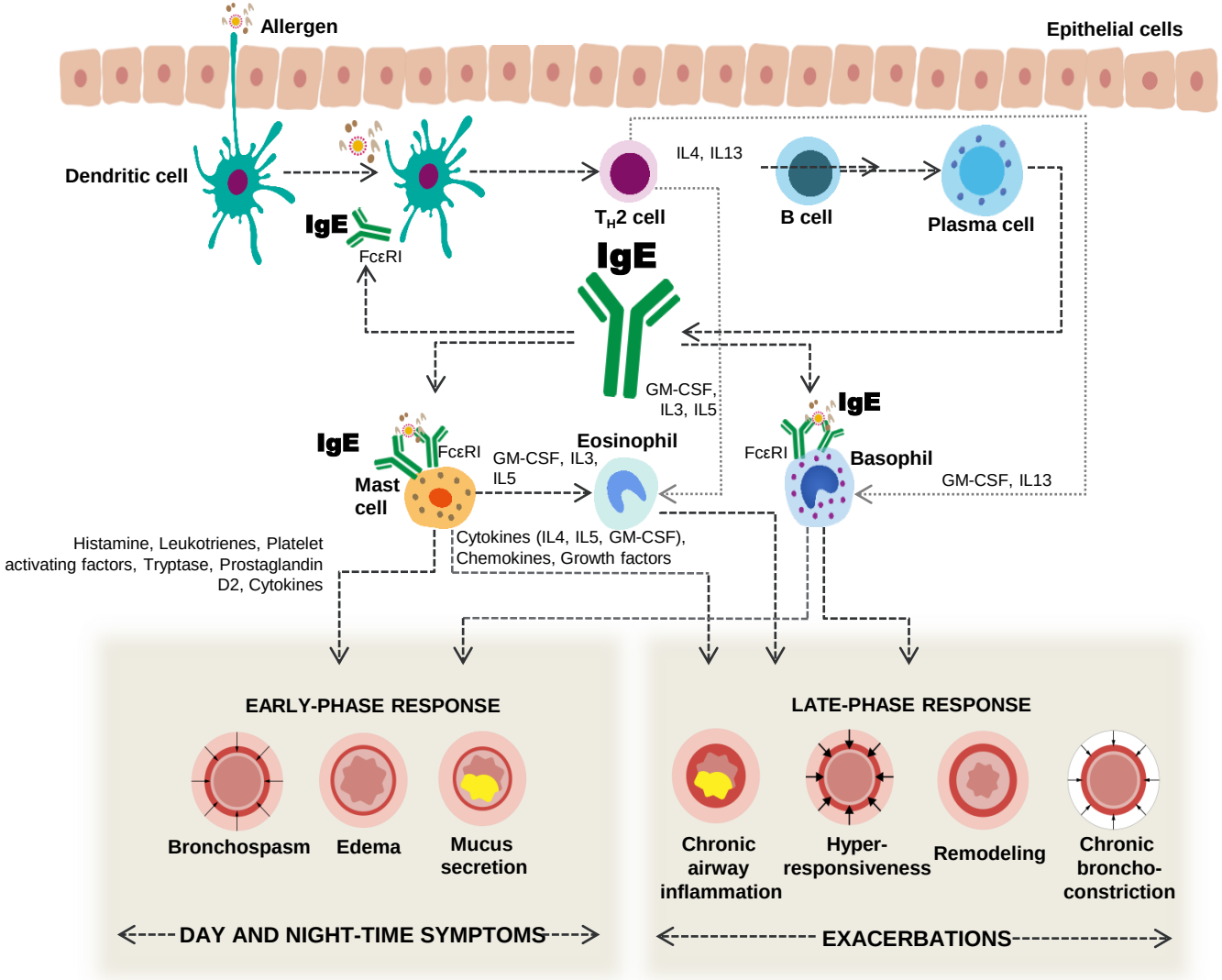
Xolair®
150mg omalizumab

1. Haselkorn T et al. J Asthma 2006; 43: 745-752
2. Rabe KF et al. Allergy 2011; 66: 1142-1151.
3. Humbert M et al. Allergy 2005; 60: 309-316.

PRE-XOL SAA 1-20 Sep 2020

Xolair- Mode for Action[1,2]

IgE Is Central To Allergic Airway Inflammation[2]



FcεRI= High-affinity IgE receptor 1; GM-CSF = granulocyte-macrophage colony-stimulating factor; IgE = immunoglobulin E; IL = Interleukin; T_H cell = T helper cell.

References: 1. Rabe KF et al. *Allergy* 2011;66:1142–1151. 2. Holgate ST. *Nat Med* 2012;18:673–683. 3. Olin JT & Wechsler ME. *BMJ* 2014;349:g5517. 4. Humbert M et al. Allergy 2005; 60: 309-316.

Xolair 150mg omalizumab

Xolair New Indication[1]

For patients 6 to 12 years of age

Allergic Asthma:

Xolair is indicated for patients **6 to 12** years of age with **severe** persistent asthma and for patients **12 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. Xolair has been shown to decrease the incidence of asthma exacerbations in these patients.

Limitations of use: Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus. Xolair is not indicated for the treatment of other allergic conditions.

1. Xolair Israeli Prescribing Information approved by the MoH Aug 2020

Xolair 150mg omalizumab

Table 6: Subcutaneous Xolair Doses Every 2 or 4 Weeks* for Pediatric Patients[1] (ages of 6 to <12 years) with Severe Asthma Who Begin Xolair Treatment

Pre-treatment Serum IgE (IU/mL)	Dosing Freq.	Body Weight									
		20-25 kg	>25-30 kg	>30-40 kg	>40-50 kg	>50-60 kg	>60-70 kg	>70-80 kg	>80-90 kg	>90-125 kg	>125-150 kg
		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	Insufficient Data to Recommend a 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	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								

1. Xolair Israeli Prescribing Information approved by the MoH Aug 2020

הכללה למתן XOLAIR בסל הבריאות[1]

<u>התרופה תינתן לטיפול בהתקיים סעיפים א-ד יחד עם סעיף ה' או סעיף ו':</u>

א. אסתמה קשה מתמדת שלמרות טיפול מרבי נכון ורציף לפי GINA שלב 4 , אינה מאוזנת ושיש בה מרכיב הפיך (שינוי של 12% או יותר בערכי FEV1 לאחר מתן מרחיבי סמפונות).

ב. חולה שאינו מעשן ושטופלו גורמים אחרים המחמירים אסתמה (אלרגנים, חשיפה תעסוקתית, תרופות).

ג. אסתמה אלרגית, באישור רופא מומחה למחלות אלרגיה או רופא מומחה למחלות ריאה בתנאי שהחולה עבר בירור אלרגי ונמצא חיובי לאלרגן רלוונטי.

ד. רמות IgE בין 30 ל - 1500 יחידות/מ"ל <u>(הרחבת מסגרת ההכללה בסל).</u>

ה. חולים שלמרות טיפול מיטבי על פי GINA שלב 4 עברו שני התקפי אסטמה או יותר שדרשו טיפול סיסטמי עם סטרואידים בשנים עשר החודשים האחרונים

ו. קיום התוויות נגד יחסיות למתן קורסים חוזרים של סטרואידים סיסטמיים בשל תופעות לוואי או מחלות נלוות (כגון אוסטיאופורוזיס).

1. חוזר המנהל הכללי מס' 4/11 מיום 23.1.2011 - הרחבת סל שירותי הבריאות לשנת 2011

Xolair®
Important note: Before prescribing, consult full prescribing information.
Presentation: 150 mg Omalizumab. Powder and solvent for solution for injection.
One vial of XOLAIR 150 mg delivers 150 mg of omalizumab in 1.2 ml after reconstitution with 1.4ml water for injection.
Xolair is a recombinant DNA-derived humanized IgG 1κ monoclonal antibody.
Indications:
•Allergic Asthma: Xolair is indicated for patients 6 to 12 years of age with severe persistent asthma and for patients 12 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. Xolair has been shown to decrease the incidence of asthma exacerbations in these patients.
Limitations of use:
Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus.
Xolair is not indicated for the treatment of other allergic conditions.
•Chronic spontaneous urticaria (CSU)
Xolair is indicated as add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment.
Dosage:
•**Allergic Asthma**: 75-600 mg of Xolair in one to four injections s.c. every two to four weeks according to body weight and baseline serum total IgE level.
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.
•**Chronic Spontaneous Urticaria**: 300 mg s.c. every 4 weeks. Prescribers are advised to periodically reassess the need for continued therapy.
Clinical trial experience of long-term treatment beyond 6 months in this indication is limited.
Contraindications: Hypersensitivity to the active substance or to any of the Xolair excipients.®
Warnings/Precautions: Xolair is not indicated for the treatment of acute asthma exacerbations, acute bronchospasm or status asthmatics. Abrupt discontinuation of systemic or inhaled corticosteroids after initiation of Xolair therapy is not recommended.
Decreases in corticosteroids should be performed under the direct supervision of a physician and may need to be performed gradually.
Caution in use with renal or hepatic impaired patients, patients with high risk of parasitic infections; patients with autoimmune diseases and immune complex-mediated conditions ; patients with high risk of parasitic infections; occurrence of local or systemic allergic reactions, including anaphylaxis or serum sickness;.
If clinically needed, the use of Xolair may be considered during pregnancy and breastfeeding.
Type I local or systemic allergic reactions, including anaphylaxis and anaphylactic shock, may occur when taking omalizumab, also with onset after a long duration of treatment. Most of these reactions occurred within 2 hours after the first and subsequent injections of Xolair but some started beyond 2 hours and even beyond 24 hours after the injection. The majority of anaphylactic reactions occurred within the first 3 doses of Xolair.
A history of anaphylaxis unrelated to omalizumab may be a risk factor for anaphylaxis following Xolair administration. Therefore medicinal products for the treatment of anaphylactic reactions should always be available for immediate use following administration of Xolair. If an anaphylactic or other serious allergic reaction occurs, administration of Xolair must be discontinued immediately and appropriate therapy initiated.
Patients should be informed that such reactions are possible and prompt medical attention
Should be sought if allergic reactions occur.

Interaction

Xolair may indirectly reduce the efficacy of medicinal products for the treatment of helminthic or other parasitic infections.
Adverse reactions:
•**Allergic Asthma:**
•Very common (≥1/10) : pyrexia (in children 6 to <12 years of age)
•Common (≥1/100 to <1/10): Headache and abdominal pain upper (very common in children 6 to <12 years of age), injection site reaction such as swelling, erythema, pain, pruritus.
•Uncommon (≥1/1,000 to <1/100): Pharyngitis, syncope, paraesthesia, somnolence, dizziness, postural hypotension, flushing, allergic bronchospasm, coughing, dyspeptic signs and symptoms, diarrhoea, nausea, photosensitivity, urticaria, rash, pruritus, Influenza-like illness, swelling arms, weight increase, fatigue.
•Rare (≥1/10,000 to<1/1,000): Parasitic infection, anaphylactic reaction, other serious allergic conditions, anti-omalizumab antibody development laryngoedema, angioedema, systemic lupus erythematosus (SLE).
•Not know: Idiopathic thrombocytopenia, including severe cases, serum sickness, may include fever and lymphadenopathy, Allergic granulomatous vasculitis (i.e. Churg-Strauss syndrome), alopecia, arthralgia, myalgia, joint swelling.
•**Chronic Spontaneous Urticaria**: Adverse reactions from the pooled CSU safety database (day 1 to week 24) at 300 mg Omalizumab
•Common – sinusitis, headache, arthralgia, injection site reaction, upper respiratory tract infection.
Packs: Each pack contains one single use vial of powder and one ampoule of water for injection.
XOL – NSS.09.2020 Based on IL PI – XOL API AUG 20 CL V1
Legal classification: Prescription only medicine

רופא/ה נכבד/ה, למידע נוסף יש לעיין בעלון לרופא כפי שאושר על ידי משרד הבריאות הישראלי

NOVARTIS

נוברטיס ישראל בע"מ, רח' תוצרת הארץ 6, תל אביב. טל. 03-9201111 , פקס. 03-9229244