NOVARTIS

Xolair SAA - Dosing and administration - HCP

Prescribing information

Image

Image

Xolair® (omalizumab) dosing and administration

Indications in severe allergic asthma (SAA):[1]

Xolair is indicated in adults, adolescents and children (6 to <12 years of age).

Xolair treatment should only be considered for patients with convincing immunoglobulin E (IgE) mediated asthma.

Adults and adolescents (12 years of age and older)
Xolair is indicated as add-on therapy to improve asthma control in patients with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial

aeroallergen and who have reduced lung function (FEV_1 <80%) as well as frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist.

Children (6 to <12 years of age)
Xolair is indicated as add-on therapy to improve asthma control in patients with severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist.

Please refer to the Xolair Summary of Product Characteristics (SmPC) for the full therapeutic indications.[1]

Dosing and administration instructions for Xolair in SAA

Xolair treatment should be initiated by physicians experienced in the diagnosis and treatment of SAA.[1]

Appropriate dose and dosing frequency with Xolair is determined by baseline IgE (IU/ml), measured before the start of treatment, and body weight (kg). Patients whose baseline IgE and body weight are outside the limits of the dosing table should not be given Xolair.[1]

Prior to administration of the initial dose, patients should have their IgE level determined by any commercial serum total IgE assay for their dose assignment. Based on these measurements, 75 to 600 mg of Xolair in 1 to 4 injections may be needed for each administration. Allergic asthma patients with baseline IgE lower than 76 IU/ml were less likely to experience benefit. Prescribing physicians should ensure that adult and adolescent patients with IgE below 76 IU/ml and children (6 to <12 years of age) with IgE below 200 IU/ml have unequivocal *in vitro* reactivity (RAST) to a perennial allergen before starting therapy.[1]

Xolair is administered by subcutaneous injection every 2 or 4 weeks dependent on dose. Maximum recommended dose is 600 mg every two weeks.[1]

For full information on dosing, warnings and precautions, special populations and other important considerations, please refer to the SmPC.

	Body weight (kg)									
Baseline IgE (IU/ml)	**≥20–25**	**>25–30**	**>25–30**	**>40–50**	**>40–50**	**>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	450	600
>200–300	150	150	225	300	300	450	450	450	600	375
>300–400	225	225	300	450	450	450	600	600	450	525

>400–500	225	300	450	450	600	600	375	375	525	600
>500–600	300	300	450	600	600	375	450	450	600	
>600–700	300	225	450	600	375	450	450	525		
>700–800	225	225	300	375	450	450	525	600		
>800–900	225	225	300	375	450	525	600			
>900–1000	225	300	375	450	525	600				
>1000–1100	225	300	375	450	600	DO NOT ADMINISTER				
>1100–1200	300	300	450	525	600					
>1200–1300	300	375	450	525						
>1300–1500	300	375	525	600						

Administration every 4 weeks	Administration every 2 weeks

Adapted from Xolair® (omalizumab) Summary of Product Characteristics.[1]

Injection calculator[1]

Conversion from dose to number of pre-filled syringes/pens,* number of injections† and total injection volume for each administration.

	Number of syringes/pens*			**Number of injections**	**Total injection volume (ml)**
Dose (mg)	**75 mg**	**150 mg**	**300 mg***		
75	1	0	0	1	0.5
150	0	1	0	1	1.0
225	1	1	0	2	1.5
300	0	0	1	1	2.0
375	1	0	1	2	2.5
450	0	1	1	2	3.0
525	1	1	1	3	3.5
600	0	0	2	2	4.0

Adapted from Xolair® (omalizumab) Summary of Product Characteristics.[1]

***Xolair 300 mg pre-filled syringe and all dose strengths of Xolair pre-filled pen are not intended for use in patients <12 years of age.**

†This table represents the least number of injections for the patients; however, there are other syringe/pen dosing combinations possible to achieve the desired dose.

Please refer to the SmPC for further information.

There’s no place like home

Following more than 16 years and 1.3 million patient-years of treatment experience, globally.[2] and supported by evidence from randomised clinical trials and the real world,[3–6] patients with no known history of anaphylaxis may self-inject Xolair or be injected by a caregiver from the 4th dose onwards if a physician determines that this is appropriate.[1] The patient or the caregiver must have been trained in the correct injection technique and the recognition of the early signs and symptoms of serious allergic reactions.[1] Patients or caregivers should be instructed to inject the full amount of Xolair according to the instructions provided in the package leaflet.[1,7]

- Self administration helps give eligible patients the freedom to fit their treatment around their lives, reducing time spent travelling to and from the clinic and meaning less disruption to work or school

- It may also increase clinic capacity, due to a reduction in appointments for dosing, helping give you more time to see more patients

Image

Considerations for self-administration

Transport and storage:

Updated storage conditions

- Xolair should be stored in a refrigerator at between 2 and 8°C. It can be kept at room temperature at 25°C for a total of 48 hours[1]

- Alternative provisions may need to be made if patients are travelling long distances after collection of Xolair or considering holidays, e.g.

    - Collection from a hospital/pharmacy closer to home

- Use of provisions to ensure that medicine remains within 2–8°C during transportation
- Delivery via a hospital trust homecare company if available

Latex allergy:[1]

- The removable needle cap of the pre-filled syringe contains a derivative of natural rubber latex. No natural rubber latex has to date been detected in the removable needle cap; however, the Xolair pre-filled syringe has not been tested on latex-sensitive individuals so there is a potential risk for hypersensitivity reactions which cannot be completely ruled out

Pregnancy:[1]

A moderate amount of data on pregnant women (between 300–1,000 pregnancy outcomes) based on pregnancy registry and post-marketing spontaneous reports, indicates no malformative or foeto/neonatal toxicity.

If clinically needed, the use of Xolair may be considered during pregnancy.

Please refer to the SmPC for full information regarding the use of Xolair during pregnancy.

- There are limited data from the use of Xolair in pregnant women and it should not be used in pregnancy without consideration of the risks and benefits (see SmPC for further information)

Interaction with other medicinal products and other forms of interaction:[1]

Since IgE may be involved in the immunological response to some helminth infections, Xolair may indirectly reduce the efficacy of medicinal products for the treatment of helminthic or other parasitic infections.

Cytochrome P450 enzymes, efflux pumps and protein-binding mechanisms are not involved in the clearance of Xolair; thus, there is little potential for drug-drug interactions. Medicinal product or vaccine interaction studies have not been performed with Xolair.

Patients already using Xolair:[1]

- Existing Xolair patients who meet the eligibility criteria for self-administration can be

trained[1]

We have produced a range of resources to help you identify patients suitable for self-administration and train these patients on the injection procedure

Click here to visit the Resources page

FEV_1, forced expiratory volume in 1 second; IgE, immunoglobulin E; RAST, radioallergosorbent test; SAA, severe allergic asthma; SmPC, summary of product characteristics.

References

1. Xolair® (omalizumab) Summary of Product Characteristics.
2. Novartis Data on File. Periodic Safety Update Report (PSUR) 2019.
3. Brusselle G, et al. *Respir Med* 2009;103(11):1633–1642.
4. Kulus M, et al. *Curr Med Res Opin* 2010;26(6):1285–1293.
5. Humbert M, et al. *Allergy* 2005;60(3):309–316.
6. Barnes N, et al. *J Asthma* 2013;50(5):529–536.
7. Xolair® (omalizumab) Patient Information Leaflet.

Xolair® (omalizumab) efficacy

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Xolair® (omalizumab) quality of life

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Xolair® (omalizumab) safety profile

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report, or alternatively email medinfo.uk@novartis.com or call 01276 698370.
