NOVARTIS

Xolair SAA - Quality of life - HCP

Prescribing information

Image

Image

Xolair® (omalizumab) quality of life

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]

Quality of life scores

In the **INNOVATE** RCT, Xolair demonstrated:[2]

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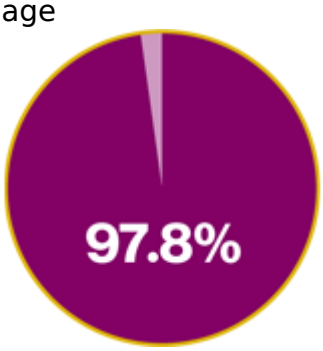

97.8% improvement in QoL vs placebo[2]

Mean AQLQ score at baseline for Xolair vs placebo was 3.9 (1.05) and 3.9 (1.12), respectively. LSM AQLQ overall score at Week 28 of 0.91 vs 0.46, respectively ($p<0.001$) (absolute difference: 0.45)

125% increase in AQLQ symptom domain score vs placebo[2]

LSM AQLQ symptom domain score at Week 28 of 0.90 vs 0.40, respectively ($p<0.001$) (absolute difference in overall AQLQ score: 0.50)

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Randomised, placebo-controlled, double-blind, multicentre study (N=419)[2]
QoL was assessed using the Juniper AQLQ at Weeks 0, 12 and 28 of the treatment phase

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Symptom-free days

In a post-hoc analysis of the **INNOVATE** RCT:[3]

Image

It was observed that Xolair responders experienced twice as many symptom-free days than those who received placebo (p<0.001)[3]

Xolair responders
(n=118)

45.8% of days without symptoms

Placebo
(n=210)

22.6% of days without symptoms

Image

Post-hoc analysis of INNOVATE (N=396)[3]
The percentage of symptom-free days (total symptom score of 0) were compared at the last observed interval (Weeks 26–28) between treatment groups using chi-square test

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Response within 16 weeks

In the **PERSIST** prospective, open-label, observational, multicentre study of Xolair in SAA:[4]

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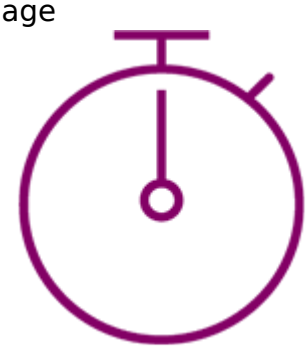

82% of ITT patients (n=163) experienced an increase in total AQLQ scores of ≥0.5 points at 16 weeks (p<0.001). AQLQ total mean score (SD) at baseline was 3.24 (1.21)[4]

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Observational, open-label, multicentre study (N=158)[4]
Subjective asthma-related QoL was assessed at baseline and at 16 and 52 weeks, using the Juniper AQLQ

A change of 0.5 on the 7-point AQLQ scale represents a clinically meaningful improvement in asthma-related QoL[4]

For information on Xolair's safety profile click below

View

INNOVATE study design[2]

A randomised, multicentre, placebo-controlled, double-blind, parallel-group study in 419 patients (aged 12–75 years) with severe persistent allergic asthma who were inadequately controlled despite treatment with a high-dose ICS plus LABA, and additional controller medication if required.

The primary efficacy variable analysis included a post-hoc adjustment for baseline exacerbation history. After adjustment for the primary ITT population, the clinically significant asthma exacerbation rate showed a statistically significant between-group difference (0.68 with Xolair vs 0.91 with placebo; p=0.042).

Primary endpoint:

- Rate of clinically significant asthma exacerbations (defined as a worsening of asthma

symptoms requiring treatment with systemic corticosteroids) during the 28-week double-blind treatment phase

Secondary endpoints included:

- Severe exacerbation rate (severe exacerbation defined as PEF or FEV_1 <60% of personal best, requiring treatment with systemic corticosteroids)
- Rate of hospitalisation, emergency room visits, and unscheduled doctor's visits for exacerbations
- Symptoms, morning PEF, rescue medication use and FEV_1
- Quality of life at Weeks 0, 12 and 28 of the treatment phase (assessed using AQLQ)
- Treatment effectiveness at treatment end

PERSIST study design[4]

Prospective, open-label, observational, multicentre 52-week study in 158 patients (aged ≥12 years) with severe persistent allergic asthma despite treatment with an ICS and a LABA.

Primary objectives:

- Describe the patients who, in the treating physician’s best clinical judgement, were being treated with Xolair

- Determine the 16- and 52-week effectiveness of Xolair as an add-on therapy by measuring the proportion of patients:

    - improving in 2005 GINA classification
    - with good/excellent GETE rating
    - achieving ≥0.5 point improvement in total AQLQ score
    - severe exacerbation-free (severe exacerbation defined as exacerbation during which the patient required a systemic corticosteroid, or emergency room visit or hospitalisation for the exacerbation)
    - improving in EQ-5D utility (52 weeks only)
- Describe the treatment patterns involving add-on Xolair treatment
- Describe the safety and tolerability of treatment with Xolair when used in a pragmatic trial

AQLQ, asthma quality of life questionnaire; EQ-5D, EuroQol 5-Dimensions; ICS, inhaled corticosteroid; IgE, immunoglobulin E; ITT, intent-to-treat; FEV_1, forced expiratory volume in 1 second; GETE, global evaluation of treatment effectiveness; GINA, Global Initiative for Asthma; LABA, long-acting beta2-agonist; LSM, least squares mean; PEF, peak expiratory flow; QoL, quality of life; RCT, randomised controlled trial; SAA, severe allergic asthma; SmPC, summary of product characteristics.

References

1. Xolair® (omalizumab) Summary of Product Characteristics.
2. Humbert M, et al. *Allergy* 2005;60(3):309–316.
3. Humbert M, et al. *Allergy* 2008;63(5):592–596.
4. Brusselle G, et al. *Respir Med* 2009;103(11):1633–1642.

Xolair® (omalizumab) efficacy

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See more details

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Xolair® (omalizumab) safety profile

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Xolair® (omalizumab) dosing and administration

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UK | May 2025 | FA-11359989-1

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