

XOLAIR CSU - home - HCP

[Prescribing information](#)

Image



Image



Xolair® (omalizumab)

Indications:¹

Xolair is indicated as add-on therapy for the treatment of chronic spontaneous urticaria (CSU) in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment.

The recommended dose of Xolair in patients with chronic spontaneous urticaria is 300 mg by subcutaneous injection every four weeks.¹

For the full therapeutic indication of Xolair and for further safety profile information, please refer to the Summary of Product Characteristics (SmPC), [here](#).

In patients with CSU, the most common adverse reactions that occurred during treatment with Xolair were sinusitis (4.9%), headache (6.1%), arthralgia (2.9%), injection site reaction (2.7%) and upper respiratory tract infections (5.7%). Please see the SmPC for the full safety profile information.

[Click here](#) for more information on the safety profile of Xolair.

Image



Efficacy and symptom control vs placebo*

82% of patients (n=252) had an MID in UAS7 (reduction from baseline of ≥ 11 points) **at 12 weeks vs 59% with placebo (n=83), $p < 0.0001$** (exploratory endpoint). Mean UAS7 at baseline was 31.2 for Xolair and 30.2 for placebo²

34% of patients (n=252) were itch and hive-free at 12 weeks vs 5% placebo (n=82, $p < 0.001$)^{†3}

Image



Reduction in DLQI score from baseline observed vs placebo as early as week 12[†]

73% reduction in DLQI from baseline at 12 weeks (n=216), vs 23% with placebo (n=64, $p < 0.001$, post-hoc analysis). Mean DLQI at baseline was 13.8 for Xolair and 13.0 for placebo (for the modified intent-to-treat population)^{†4}

Image



Think an established safety profile

>1.3 million patient-years of market experience across CSU and other indications^{5,6}

Xolair

- Is the only licensed BAD-recommended treatment option for CSU after first-line antihistamines⁷
 - BAD guidelines recommend Xolair as a second-line treatment option for CSU, in addition to a second-generation H1-antihistamine
 - Requires simple dosing of 300 mg every 4 weeks¹
 - Prescribers are advised to periodically reassess the need for continued therapy¹
 - Directly targets and binds to IgE,^{1,8,9} impeding the IgE allergic pathway, and rendering mast cells and basophils insensitive to activation through IgE/ FcεRI^{8,9}
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Watch our short video to improve your understanding of Xolair

Immunology

An analog clock face showing the time 11:08. The hour hand is slightly past 11, and the minute hand is pointing at 2. A red second hand is pointing at approximately 8.

Xolair (omalizumab) in Chronic Spontaneous Urticaria



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➡ **2:57**

*Data from the GLACIAL study – a global, multicentre, randomised, double-blind, placebo-controlled study investigating Xolair in CSU patients aged 12–75 years whose signs and symptoms persisted despite treatment with H1-AH at up to 4× the approved dose ± H2-AH ± LTRAs for >6 consecutive weeks (Novartis does not condone the off-label use of any medicine. Please refer to the individual product Summary of Product Characteristics before

prescribing). The primary objective of the study was to evaluate the overall safety of Xolair (n=252) compared with placebo (n=84). Efficacy was also evaluated at Week 12.²⁻⁴

[†]Secondary endpoint, UAS7=0.

[‡]Additional efficacy endpoint. Absolute reduction of -9.7 (vs 5.1 placebo) in mean DLQI (observed data, p<0.0001).^{3,4}

BAD, British Association of Dermatologists; CSU, chronic spontaneous urticaria; DLQI, dermatology life quality index; H1-AH, H1-antihistamine; H2-AH, H2-antihistamine; IgE, immunoglobulin E; LTRA, leukotriene receptor antagonist; MID, minimal important difference; SmPC, summary of product characteristics; UAS7, urticaria activity score (seven days).

References

1. Xolair® (omalizumab) Summary of Product Characteristics.
2. Novartis Data on File. XSU15-R002. Proportion of UAS7 MID responders at Week 12 - GLACIAL study.
3. Kaplan A, et al. *J Allergy Clin Immunol* 2013;132(1):101-109.
4. Casale TB, et al. *J Allergy Clin Immunol Pract* 2015;3(5):743-750.e1.
5. Novartis Data on File. Periodic Safety Update Report (PSUR) 2019.
6. Bousquet J, et al. *J Allergy Clin Immunol Pract* 2021;9(7):2702-2714.
7. Sabroe RA, et al. *Br J Dermatol* 2022;186(3):398-413.
8. Chang TW, et al. *J Allergy Clin Immunol* 2015;135(2):337-342.
9. Kaplan AP, et al. *Allergy* 2017;72(4):519-533.



Xolair® (omalizumab) efficacy

Xolair® (omalizumab) efficacy

See more details

Hide details



Xolair® (omalizumab) mode of action

Xolair® (omalizumab) mode of action

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Xolair® (omalizumab) safety profile

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