NOVARTIS

XOLAIR CSU - dosing and administration - HCP

Prescribing information

Image

Image

Xolair® (omalizumab) dosing and administration

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]

Please refer to the Xolair Summary of Product Characteristics (SmPC) for the full

therapeutic indication.[1]

Dosing and administration instructions for Xolair in CSU:[1]

- Recommended dose is 300 mg by subcutaneous injection every 4 weeks
- Xolair comes as either one 300 mg pre-filled pen or syringe or two 150 mg pre-filled pens or syringes

Treatment should be initiated by physicians experienced in the diagnosis and treatment of CSU. 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.

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

Retreatment guidance

Xolair is recommended as an option as add-on therapy for treating severe CSU in adults and young people aged 12 years and over only if:[2]

- the severity of the condition is assessed objectively, for example, using a weekly urticaria activity score of 28 or more
- the person’s condition has not responded to standard treatment with H1-antihistamines and leukotriene receptor antagonists
- Xolair is stopped at or before the fourth dose if the condition has not responded
- Xolair is stopped at the end of a course of treatment (6 doses) if the condition has responded, to establish whether the condition has gone into spontaneous remission, and is restarted only if the condition relapses
- Xolair is administered under the management of a secondary care specialist in dermatology, immunology or allergy

- the company provides Xolair with the discount agreed in the patient access scheme

- People whose treatment with omalizumab is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop

NICE states that treatment is only restarted if the condition comes back.[2] It is important to monitor patients post treatment to identify and restart those who are relapsing.

In the original model, before consultation 'relapse' was defined as moderate or severe urticaria (UAS7 of 16 or more) after a previous response.[2]

Considerations for self-administration[1]

Patients with no known history of anaphylaxis may self-inject Xolair or be injected by a caregiver from the fourth dose onwards if a physician determines that this is appropriate. 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.

Patients or caregivers should be instructed to inject the full amount of Xolair according to the instructions for use provided in the Patient Information Leaflet.

Storage

Store in the refrigerator between 2 and 8°C. Do not freeze. Can be left out for a total of 48 hours at 25°C.

Xolair should be stored in the original package to protect from light.

Blood tests

Routine blood tests are NOT required for Xolair patients.

Anaphylaxis

Type I local or systemic allergic reactions, including anaphylaxis and anaphylactic shock, may occur when taking Xolair, even after a long duration of treatment. However, 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. Therefore, the first 3 doses must be administered either by or under the supervision of a healthcare professional. A history of anaphylaxis unrelated to Xolair may be a risk factor for anaphylaxis following Xolair administration. Therefore for patients with a known history of anaphylaxis, Xolair must be administered by a healthcare professional, who should always have medicinal products for the treatment of anaphylactic reactions 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.

Antibodies to Xolair have been detected in a low number of patients in clinical trials. The clinical relevance of anti-Xolair antibodies is not well understood.

- If you are unsure about a patient’s current symptoms or any previous possible anaphylaxis, consult with a specialist healthcare professional before deciding if suitable for Xolair
- The rate of anaphylaxis in Xolair clinical trials was rare (≥1/10,000 to <1/1,000) and the post-marketing reporting rate for anaphylaxis is approximately 0.2%
- There is NO requirement to supply an adrenaline auto-injector to Xolair patients who are self-injecting

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

Administration by a caregiver

If a patient is unwilling or unable to inject themselves it is possible for a caregiver such as a partner, relative or friend to administer their injections for them providing:

- They are comfortable doing so
- They receive training as outlined in the summary of product characteristics and any local protocols you have in place

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CSU, chronic spontaneous urticaria; IgE, immunoglobulin E; NHS, National Health Service; NICE, National Institute for Health and Care Excellence; SmPC, summary of product

characteristics; UAS7, urticaria activity score at seven days.

References

1. Xolair® (omalizumab) Summary of Product Characteristics.

2. National Institute for Health and Care Excellence. Omalizumab for previously treated chronic spontaneous urticaria (TA339). Available at: https://www.nice.org.uk/guidance/ta339/resources/omalizumab-for-previously-treated-chronic-spontaneous-urticaria-pdf-82602555773893 [Accessed March 2025].

Xolair® (omalizumab) mode of action

Xolair® (omalizumab) mode of action

See more details

Hide details

Xolair® (omalizumab) efficacy

Xolair® (omalizumab) efficacy

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Xolair® (omalizumab) safety profile

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UK | March 2025 | FA-11360057

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.
