UK Prescribing Information

XSU20-C003 March 2020

Xolair® (omalizumab) 150mg solution for injection

Please refer to the Summary of Product Characteristics before prescribing

Indications: Chronic Spontaneous Urticaria:
Xolair is indicated as an 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.

Presentation: Pre-filled syringe of 1 ml omalizumab solution (150 mg).

Dosage and administration: Xolair treatment should be initiated by physicians experienced in the diagnosis and treatment of CSU. The recommended dose is 300 mg by subcutaneous injection every four weeks. Prescribers are advised to periodically reassess the need for continued therapy. Clinical trial experience of long-term treatment beyond 6 months in CSU is limited. Administration: Subcutaneous administration only. Doses of more than 150 mg should be divided across 2 or more injection sites. Patients with no known history of anaphylaxis may self-inject or be injected by a caregiver from the fourth dose onwards if appropriate. The patient or caregiver must be trained in the correct injection technique and the recognition of early signs and symptoms of serious allergic reactions. Patients or caregivers should be instructed to inject the full amount according to the instructions provided in the package leaflet.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Precautions: Not studied in patients with autoimmune diseases, immune-complex-mediated conditions, pre-existing renal or hepatic impairment. Caution should be exercised when administering Xolair in these patient populations. Xolair has not been studied and is not indicated for the treatment of hyperimmunoglobulin E syndrome, allergic bronchopulmonary aspergillosis or for the prevention of anaphylactic reactions, including those provoked by food allergy, atopic dermatitis, or allergic rhinitis. Immune system disorders: *Allergic reactions type I*: Type I local or systemic allergic reactions, including anaphylaxis and anaphylactic shock, may occur even after a long duration of treatment. The first 3 doses must be administered either by or under the supervision of a healthcare professional. 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. *Serum sickness:* Serum sickness and serum-sickness-like reactions (delayed type III reactions) have been seen in patients treated with humanized monoclonal antibodies including omalizumab. Patients should be advised to report suspected symptoms. Discontinuation of omalizumab should be considered in all severe cases with these immune system disorders. *Parasitic (helminth) infections:* Caution may be warranted in patients at high risk of helminth infection. If patients do not respond to recommended anti-helminth treatment discontinuation of Xolair should be considered. *Latex-sensitive individuals:* The removable needle cap of the pre-filled syringe contains a derivative of natural rubber thus there is a potential risk for hypersensitivity reactions.

Drug interactions: Based on the clearance of Xolair there is little potential for drug–drug interactions. Medicinal product or vaccine interaction studies have not been performed.

Pregnancy and breast-feeding: Use may be considered during pregnancy and breast-feeding if clinically needed.

Undesirable effects: *Common (≥1/100 to <1/10):* sinusitis, headache, arthralgia, injection site reaction, upper respiratory tract infection.
Rare (≥1/10,000 to <1/1,000): Parasitic infection, anaphylactic reaction (0.2% in post-marketing data), other serious allergic conditions, anti-omalizumab antibody development, Systemic lupus erythematosus. *Not known (cannot be estimated from the available data):* Idiopathic thrombocytopenia, including severe cases, serum sickness, may include fever and lymphadenopathy, allergic granulomatous vasculitis (i.e. Churg-Strauss syndrome). *Other*: Arterial thromboembolic events.
Prescribers should consult the Summary of Product Characteristics in relation to other adverse reactions.

Quantities and basic NHS price (excl. VAT): 150 mg pre-filled syringe, £256.15.

Marketing authorisation numbers: EU/1/05/319/008.

Legal category: POM.

Date of last revision of prescribing information: March 2020.

Full prescribing information is available from: Novartis Pharmaceuticals UK Ltd, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Telephone: (01276) 692255.

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 via uk.patientsafety@novartis.com or online through the patient safety information (PSI) tool at https://psi.novartis.com. If you have a question about the product, please contact Medical Information on 01276 698370 or by email at medinfo.uk@novartis.com