UK Prescribing Information
Xolair® (omalizumab) 75mg and 150mg solution for injection
Please refer to the Summary of Product Characteristics before prescribing

Indications: Allergic asthma
Xolair is indicated in adults, adolescents and children (6 to <12 years of age) with convincing IgE (immunoglobulin E) mediated asthma.
Adults and adolescents (12 years of age and above): 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):* 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. **Presentation:** Pre-filled syringe of either 0.5 ml omalizumab solution (75 mg) or 1 ml omalizumab solution (150 mg). **Dosage and administration:** Xolair treatment should be initiated by physicians experienced in the diagnosis and treatment of severe persistent asthma. The appropriate dose and dosing frequency is determined by baseline IgE (IU/ml), measured before the start of treatment, and body weight (kg). Children, adolescents and adults (6 years of age and older): 75-600 mg by subcutaneous injection every 2 or 4 weeks in 1-4 injections per administration. Adult and adolescent patients with IgE below 76 IU/ml and children (6 to < 12 years of age) with IgE below 200 IU/ml should have unequivocal *in vitro* reactivity to a perennial allergen before starting therapy. Patients whose baseline IgE levels or body weight are outside the limits of the dosing table in the Summary of Product Characteristics (SmPC) should not be given Xolair. Treatment effectiveness should be assessed by a physician at 16 weeks before further injections are given. Xolair is intended for long-term administration. Dose should be adjusted for significant changes in weight. 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 indicated for the treatment of acute asthma exacerbations, acute bronchospasm or status asthmaticus. 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 populations. Xolair has not been studied and is not indicated in 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. Abrupt discontinuation of systemic or inhaled corticosteroids after initiation of Xolair therapy is not recommended. 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. *Churg-Strauss and hypereosinophilic syndromes*: Patients with severe asthma may rarely present with systemic hypereosinophilic syndrome or allergic eosinophilic granulomatous vasculitis (Churg-Strauss syndrome). In rare cases, patients on anti-asthma therapy may present or develop systemic eosinophilia and vasculitis. In these patients, physicians should be alert to the development of marked eosinophilia, vasculitic rash, worsening pulmonary symptoms, paranasal sinus abnormalities, cardiac complications, and/or neuropathy. 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 latex 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. Limited data are available on the use of Xolair in combination with specific immunotherapy (hypo-sensitisation therapy). **Pregnancy and breast-feeding**: Use may be considered during pregnancy and breast-feeding if clinically needed. **Undesirable effects:** *Very Common (≥ 1/10)* pyrexia (children 6 to <12 years of age). *Common* (≥ 1/100 to < 1/10): abdominal pain upper (in children 6 to <12 years of age), headache (very common in children 6 to <12 years of age) and injection site reactions such as pain, erythema, pruritus, swelling. *Uncommon (≥1/1,000 to <1/100):* pharyngitis, syncope, paraesthesia, somnolence, dizziness, postural hypotension, flushing, allergic bronchospasm, coughing, dyspeptic signs and symptoms, diarrhoea, nausea, photosensitivity, urticaria, rash, pruritus, influenza-like illness, swelling arms, weight increase, fatigue. *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, laryngoedema, angioedema, 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), alopecia, arthralgia, myalgia, joint swelling. *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): 75mg pre-filled syringe, £128.07 and 150 mg pre-filled syringe, £256.15. **Marketing authorisation numbers:** EU/1/05/319/005 (75mg) and EU/1/05/319/008 (150mg). **Legal category:** POM.
Date of last revision of prescribing information: March 2020.
Novartis Pharmaceuticals UK Ltd, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Telephone: (01276) 692255.

XSA20-C008 March 2020

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