NOVARTIS

Regulatory Affairs

XOLAIR®

(omalizumab)

75mg, 150 mg Powder and solvent for solution for injection

Basic Succinct Statement

Version 3.0

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This material is only meant for Healthcare Professionals

XOLAIR®

Important note: Before prescribing, please read full prescribing information.

Presentation: 75 mg and 150 mg Omalizumab. Powder and solvent for solution for injection.

One vial of XOLAIR® 75 mg delivers 75 mg of omalizumab. Reconstituted Xolair contains 125 mg/mL of omalizumab (75 mg in 0.6 mL).

One vial of XOLAIR 150 mg delivers 150 mg of omalizumab. Reconstituted Xolair contains 125 mg/mL of omalizumab (150 mg in 1.2 mL).

Omalizumab is a humanized monoclonal antibody manufactured from a mammalian cell line

Indications:

- Allergic Asthma: **Adults and adolescents (12 years of age and above):** Adults and adolescents (12 years of age and above) with moderate to severe persistent allergic asthma whose symptoms are inadequately controlled with inhaled corticosteroids (ICS). **Children (6 to < 12 years of age):** Add-on therapy to improve asthma control 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. Xolair has been shown to decrease the incidence of asthma exacerbations in these patients. Safety and efficacy have not been established in other allergic conditions.
- Chronic Spontaneous Urticaria (CSU): Add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment.

Dosage and administration:

- Allergic Asthma: 75 to 600 mg of Xolair in one to four injections s.c. every two to four weeks according to body weight and baseline serum total IgE level.
- Chronic Spontaneous Urticaria (CSU): 300 mg subcutaneous injection every 4 weeks. Some patients may achieve control of their symptoms with a dose of 150 mg subcutaneous injection every 4 weeks.

Contraindications: Hypersensitivity to omalizumab or to any of the excipients.

Warnings and precautions: ♦Not indicated for the treatment of acute asthma exacerbations, acute bronchospasm or status asthmaticus; ♦no abrupt discontinuation of corticosteroids; ♦caution in use with renal or hepatic impaired patients, patients with autoimmune diseases and immune complex-mediated conditions; ♦patients with high risk of parasitic infections; ♦occurrence of local or systemic allergic reactions, including anaphylaxis or serum sickness.

Pregnancy, lactation, females and males of reproductive potential

Pregnancy

A prospective pregnancy registry study showed the prevalence of major congenital anomalies was similar (8.1% vs 8.9%) between patients treated with Xolair and disease matched patients not treated with Xolair. Animal studies showed no evidence of fetal harm up to approximately 8 times the maximum recommended human dose (MRHD).

Lactation

Omalizumab is expected to be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Xolair and any potential adverse effects on the breastfed child from omalizumab or from the underlying maternal condition.

Adverse drug reactions:

Serious adverse drug reactions are:

♦**Rare (≥0.01 to <0.1%)**: Angioedema, anaphylactic reactions and other allergic conditions, laryngoedema.

♦**Uncommon (≥0.1 to <1%)**: allergic bronchospasm.

♦**Not known**: Eosinophilic Granulomatosis with Polyangiitis (i.e., Churg Strauss syndrome), idiopatic severe thrombocytopenia, serum sickness.

Additional adverse drug reactions are:

♦**Very common (≥10%)**: Pyrexia (very common in children). ♦**Common (≥1 to <10%)**: Headache (very common in children), injection site reactions including swelling, erythema, pruritus, and pain, abdominal pain upper (in children), nasopharyngitis, upper respiratory tract infection, urinary tract infections, sinusitis and sinus headache, arthralgia, myalgia, pain in extremity, musculoskeletal pain. ♦**Uncommon (≥0.1 to <1%)**: Dizziness, somnolence, paresthesia, syncope, postural hypotension, flushing, pharyngitis, coughing, nausea, diarrhea, dyspeptic signs and symptoms, urticaria, rash, pruritus, photosensitivity, weight increase, fatigue, swelling arms, influenza-like illness. ♦**Rare (≥0.01 to <0.1%)**: Parasitic infections, anti-therapeutic antibody development. ♦**Not known**: Alopecia, joint swelling.

Interactions: None known.