



Xolair® (omalizumab) – Expanded Indication

- On July 6, 2016, the [FDA approved Genentech's Xolair \(omalizumab\)](#) for use in patients 6 years of age and older with moderate to severe asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.
 - Previously, Xolair was only approved for use in patients 12 years of age and older.
 - Xolair has been shown to decrease the incidence of asthma exacerbations in these patients.
 - Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus.
 - Xolair is not indicated for the treatment of other allergic conditions.
- Xolair is also indicated for the treatment of adults and adolescents 12 years of age and older with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment.
 - Xolair is not indicated for the treatment of other forms of urticaria.
- The expanded pediatric indication is based on two clinical studies of 926 children with moderate to severe persistent allergic asthma. Patients were randomized to Xolair or placebo with or without other controller asthma medications. The primary endpoint was the rate of asthma exacerbations.
 - In the first study, the Xolair group had a statistically significantly lower rate of asthma exacerbations vs. placebo (0.45 vs. 0.64) with an estimated rate ratio of 0.69 (95% CI: 0.53, 0.90) at 24 weeks. This effect was sustained at 52 weeks (0.78 vs. 1.36; rate ratio: 0.57; 95% CI: 0.45, 0.72).
 - In the second study, patients treated with Xolair had statistically significantly fewer asthma exacerbations vs. placebo during both the 16-week fixed steroid treatment period (0.18 vs. 0.32; rate ratio: 0.58; 95% CI: 0.35, 0.96) and the 28-week treatment period (0.38 vs. 0.76; rate ratio: 0.50; 95% CI: 0.36, 0.71).
- Xolair carries a boxed warning for anaphylaxis.
- Xolair dosing is weight based. Refer to the prescribing information for dosing recommendations.



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