



Oralair[®] (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens allergen extract) – Expanded indication

- On November 14, 2018, [Stallergenes Greer announced the FDA approval of Oralair \(Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue grass mixed pollens allergen extract\)](#), for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for any of the five grass species contained in this product in patients 5 to 65 years of age.
 - Previously, Oralair was approved for use in patients 10 to 65 years of age.
- The approval of Oralair's expanded indication was based on safety data from a 30-day open-label study in 307 children 5 through 9 years of age and a post-hoc analysis of the effectiveness data from a phase 3 study in children by age subgroups.
 - In the open-label safety study, the frequencies of adverse events (eg, local application site reactions) in children 5 through 9 years of age were comparable to those in adults and older children and adolescents.
 - The [post-hoc analyses](#), while not adequately powered to demonstrate uniformly statistically significant treatment effects in the younger age subgroup, showed that treatment effects were numerically similar in children 5 through 9 years of age when compared to children and adolescents 10 through 17 years of age.
- Oralair carries a boxed warning for serious allergic reactions.
- The recommended starting dose of Oralair in children and adolescents 5 through 17 years of age is 100 IR (index of reactivity) on day 1, 200 IR on day 2, and 300 IR on the following days.
 - Oralair should be administered sublingually only.
 - Treatment should be initiated 4 months before the expected onset of each grass pollen season and continued treatment throughout the season.
 - The first dose of Oralair should be administered under the supervision of a physician with experience in the diagnosis and treatment of severe allergic reactions. Patient should be observed for at least 30 minutes.



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