

## Ragwitek® (short ragweed pollen allergen extract) – Expanded indication

- On April 19, 2021, [ALK-Abelló announced](#) the [FDA approval](#) of [Ragwitek \(short ragweed pollen allergen extract\)](#), for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen. Ragwitek is approved for use in persons 5 through 65 years of age.
  - Ragwitek was previously approved for this indication in adults only.
  - Ragwitek is not indicated for the immediate relief of allergic symptoms.
- The approval of Ragwitek for the expanded indication was based on a double-blind, placebo-controlled study in 1,022 children and adolescents 5 through 17 years of age with ragweed pollen-induced allergic rhinitis, with or without conjunctivitis. Patients received Ragwitek or placebo 12 to 20 weeks prior to the start of the ragweed pollen season and throughout the ragweed pollen season. Efficacy was established by self-reporting of rhinoconjunctivitis daily symptom scores (DSS) and daily medication scores (DMS). The sums of the DSS and DMS were combined into the Total Combined Score (TCS) which was averaged over the peak ragweed pollen season. The average TCS over the entire ragweed season was also assessed.
  - When compared to placebo, Ragwitek’s treatment difference for TCS over the peak ragweed pollen was -2.73 (difference relative to placebo: -38%; 95% CI: -46.0, -29.7).
  - When compared to placebo, Ragwitek’s treatment difference for TCS over the entire ragweed season was -1.86 (difference relative to placebo: -32%; 95% CI: -40.7, -23.3).
- The recommended dose of Ragwitek is one tablet sublingually daily.
  - The first dose of Ragwitek should be administered in a healthcare setting under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases. After receiving the first dose, the patient should be observed for at least 30 minutes to monitor for signs or symptoms of a severe systemic or a severe local allergic reaction.
  - If the patient tolerates the first dose, the patient may take subsequent doses at home.
  - Treatment should be initiated at least 12 weeks before the expected onset of ragweed pollen season and continue treatment throughout the season.