

	ORALAIR®	RAGWITEK®	GRASTEK®
<i>Manufacturer</i>	Stallergens	Merck & Co	Merck & Co
<i>Indications</i>	Grass pollen-induced allergic rhinitis and allergic rhinoconjunctivitis confirmed by skin prick test or in vitro pollen-specific IgE testing for any of the 5 grass species contained in the product	Short ragweed pollen-induced allergic rhinitis and allergic rhinoconjunctivitis confirmed by skin prick test or in vitro pollen-specific IgE testing for short ragweed pollen	Timothy grass pollen-induced allergic rhinitis and allergic rhinoconjunctivitis confirmed by skin prick test or in vitro pollen-specific IgE testing for timothy grass pollen
<i>Ages</i>	10-65 years	18-65 years	5-65 years
<i>Dosage</i>	100 IR, 300 IRA <u>Age 10-17 years:</u> Day 1: 100 IR Day2: 2 x 100 IR Day3 and following: 300 IR <u>Age 18-65 years</u> Day 1 and following: 300 IR	1 tablet daily, 12 Amb a 1-unit	1 tablet daily, 2800 Bioequivalent Allergy Units (BAUs)
<i>First dose administration</i>	Observe patients in the office for at least 30 minutes following the initial dose		
<i>Instructions for dose administration</i>	Place the tablet under the tongue for at least 1 minute, until completely dissolved, then swallow		
<i>Active ingredients</i>	Grass pollen mix: Sweet Vernal, Orchard, Perennial Rye, Timothy, Kentucky Blue Grass	Short Ragweed Pollen	Timothy Grass Pollen
<i>Inactive ingredients</i>	Mannitol, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate and lactose monohydrate	Gelatin NF (fish source)*, mannitol USP, and sodium hydroxide NF	
<i>Initiation of therapy in relation to pollen season</i>	Four months before the expected onset of each grass pollen season and continue throughout the season	At least 12 weeks before the expected onset of ragweed pollen season and continue throughout the season	At least 12 weeks before the expected onset of grass pollen season and continue throughout the season; for sustained effectiveness for one grass pollen season after cessation of treatment, GRASTEK may be taken daily for 3 consecutive years
<i>Contraindications</i>	-Severe, unstable or uncontrolled asthma -History of any severe	-Severe, unstable or uncontrolled asthma - History of any severe	-Severe, unstable or uncontrolled asthma - History of any severe

	systemic allergic reaction or any severe local reaction to SLIT -Hypersensitivity to any of the inactive ingredients contained in this product	systemic allergic reaction or any severe local reaction to SLIT - Hypersensitivity to any of the inactive ingredients contained in this product -A history of eosinophilic esophagitis	systemic allergic reaction or any severe local reaction to SLIT - Hypersensitivity to any of the inactive ingredients contained in this product -A history of eosinophilic esophagitis
<i>Precautions</i>	<p>-Prescribe auto-injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use.</p> <p>-ORALAIR® / RAGWITEK™/ GRASSTEK® may not be suitable for patients being treated with beta-blockers or with underlying medical condition that may reduce the ability to survive a serious allergic reaction</p> <p>-In case of oral inflammation or wounds, stop treatment to allow complete healing of the oral cavity</p>		

*Gelatin is derived from a skin of cold water fish source such as cod, pollock, or haddock. Gelatin constitutes a fraction of the 28 mg tablet weight. In one study, commercial, food-grade fish gelatin derived from the skins of codfish was evaluated in a double-blind, placebo-controlled food challenge. None of the 30 fish-allergic patients reacted adversely to the ingestion of cumulative dose of 2.6 g fish gelatin. Investigators concluded with a 95% certainty that 90% of fish-allergic consumers will not react to ingestion of a 3.61 g cumulative dose of fish gelatin. ¹

1. Hansen TK, Poulsen LK, Stahl Skov P, et al. A randomized, double-blinded, placebo-controlled oral challenge study to evaluate the allergenicity of commercial, food-grade fish gelatin. Food and chemical toxicology : an international journal published for the British Industrial Biological Research Association 2004;42:2037-44.