

FDA-Approved Standardized Allergen Extract SLIT-tablets



Sweet vernal, orchard, perennial rye, Timothy, and Kentucky blue grass (100 or 300 IR)¹

indicated for grass pollen-induced
AR ± conjunctivitis

Children and adults 5-65 years



Timothy grass (2800 BAU)²

indicated for grass pollen-induced
AR ± conjunctivitis

Children and adults 5-65 years



Short ragweed (12 Amb 1-U)³

indicated for short ragweed
pollen-induced
AR ± conjunctivitis

Children and adults 5-65 years



12 SQ-HDM⁴

indicated for HDM-induced
AR ± conjunctivitis

Adults 18-65 years

Visuals shown here are not actual depictions of the SLIT-tablet size or appearance.

AR, allergic rhinitis; BAU, bioequivalent allergen units; FDA, US Food and Drug Administration; HDM, house dust mite; IR, index of reactivity; SLIT, sublingual immunotherapy.

1. Sweet vernal, orchard, perennial rye, Timothy, and Kentucky blue grass mixed pollens allergen extract tablet [package insert]. Antony, France: Stallergenes SA; 2018. 2. Timothy grass pollen allergen extract tablet [package insert]. Bedminster, NJ: ALK-Abelló A/S; 2019.

3. Short ragweed pollen allergen extract tablet [package insert]. Bedminster, NJ: ALK-Abelló A/S; 2021. 4. House dust mite allergen extract tablet [package insert]. Bedminster, NJ: ALK-Abelló A/S; 2020.

Standardized Allergen Extracts

Most of the commercially available allergen extracts in North America are nonstandardized and noncharacterized, meaning that they are not evaluated or labeled for potency, the allergen profile has not been visualized (eg, by crossed radioimmuno-electrophoresis or immunoblot), and the presence or lack of major or minor allergens is unknown.¹

For the standardized allergen extracts, manufacturers compare the allergen extract to a US reference standard for potency.² CBER maintains these reference standards and distributes them to manufacturers. There are currently 19 standardized allergenic extracts.²

A list of the 13 standardized allergen extracts available in the United States for AR/C is shown below.^{1,2*}

Allergen source	Extract	Potency labeling	Labeled potency or concentrations available
Epithelia	Cat hair	BAU/mL based on Fel d 1 content	5000 and 10,000 BAU/mL
	Cat pelt	BAU/mL based on Fel d 1 content	10,000 BAU/mL
House dust mite	<i>Dermatophagoides pteronyssinus</i>	AU/mL	10,000 and 30,000 AU/mL
	<i>Dermatophagoides farinae</i>	AU/mL	10,000 and 30,000 AU/mL
Pollen	Short ragweed	w/v and antigen E or Amb a 1 concentration	1:10, 1:20 w/v, 100,000 AU/mL
	Bermuda grass	BAU/mL	10,000 BAU/mL
	Kentucky bluegrass	BAU/mL	100,000 BAU/mL
	Perennial ryegrass	BAU/mL	100,000 BAU/mL
	Orchard grass	BAU/mL	100,000 BAU/mL
	Timothy grass	BAU/mL	100,000 BAU/mL
	Meadow fescue grass	BAU/mL	100,000 BAU/mL
	Redtop grass	BAU/mL	100,000 BAU/mL
	Sweet vernal grass	BAU/mL	100,000 BAU/mL

AR/C, allergic rhinitis with or without conjunctivitis; AU, allergy unit; BAU, bioequivalent allergy unit; CBER, Center for Biologics Evaluation and Research; w/v, weight per volume.

*The 6 standardized venom extracts are not included here.²

1. Tankersley M, Han JK, Nolte H. Clinical aspects of sublingual immunotherapy tablets and drops. *Ann Allergy Asthma Immunol.* 2020;124(6):573-582. 2. US FDA website. Injectable Allergen Extracts - Standardized. Accessed July 26, 2021. <https://www.fda.gov/vaccines-blood-biologics/allergenics/injectable-allergen-extracts-standardized>