ODACTRA®
House Dust Mite (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) Allergen Extract Tablet for Sublingual Use 12 SQ-HDM

GRASTEK®
Timothy Grass Pollen Allergen Extract Tablet for Sublingual Use 2800 BAU

RAGWITEK®
Short Ragweed Pollen Allergen Extract Tablet for Sublingual Use 12 Amb a 1-U

ALK

START TREATING THE UNDERLYING CAUSE OF ALLERGIES

Indications

GRASTEK®, RAGWITEK®, and ODACTRA® are allergen extracts indicated as immunotherapy for the treatment of grass pollen-induced (GRASTEK), short ragweed pollen-induced (RAGWITEK), and house dust mite (HDM)-induced (ODACTRA) allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens (GRASTEK), short ragweed pollens (RAGWITEK), and *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts (ODACTRA). GRASTEK and RAGWITEK are approved for use in persons 5 through 65 years of age. ODACTRA is approved for use in persons 12 through 65 years of age. GRASTEK, RAGWITEK, and ODACTRA are not indicated for the immediate relief of allergic symptoms.

Important Safety Information

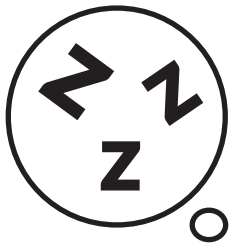
WARNING: SEVERE ALLERGIC REACTIONS

GRASTEK, RAGWITEK, and ODACTRA can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal restriction. Do not administer GRASTEK, RAGWITEK, or ODACTRA to patients with severe, unstable or uncontrolled asthma. Observe patients in the office for at least 30 minutes following the initial dose. Prescribe auto-injectable epinephrine, instruct and train patients or parents/guardians on its appropriate use, and instruct patients or parents/guardians to seek immediate medical care upon its use. GRASTEK, RAGWITEK, and ODACTRA may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction. GRASTEK, RAGWITEK, and ODACTRA may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

Before prescribing GRASTEK, RAGWITEK, or ODACTRA, please read the Boxed WARNING, full Prescribing Information, and Medication Guide, for additional Important Safety Information.

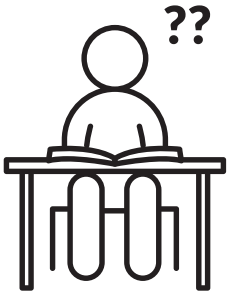
Suboptimally controlled allergies come with many burdens

In a published survey of 500 parents and pediatric patients with allergic rhinitis



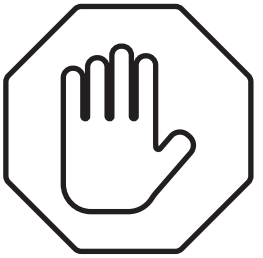
88%

of adolescent and pediatric patients reported **trouble sleeping**, leading to daytime drowsiness[1]



40%

of parents say their child's allergies **interferes with performance at school**[1]



3-4x

more likely to **limit outdoor activities**[1]

Symptomatic treatments can be limiting

Loss of efficacy

More than half of parents reported their child's **nasal spray lost effectiveness** during the day or night[1]

Were dissatisfied with medication

According to a survey, **2 out of 3 patients and caregivers** were dissatisfied with their symptomatic medications[1]

Change in prescription

40% of parents reported they asked their child's doctor to change their prescription due to ineffectiveness[1]

Survey design: The 2009 Pediatric Allergies in America™ survey was conducted via telephone and included children aged 4 to 17 years. A sample of 500 children who were diagnosed with AR by a health care professional and who had symptoms and had taken medication in the previous 12 months was compared with 504 children without allergies.[1]

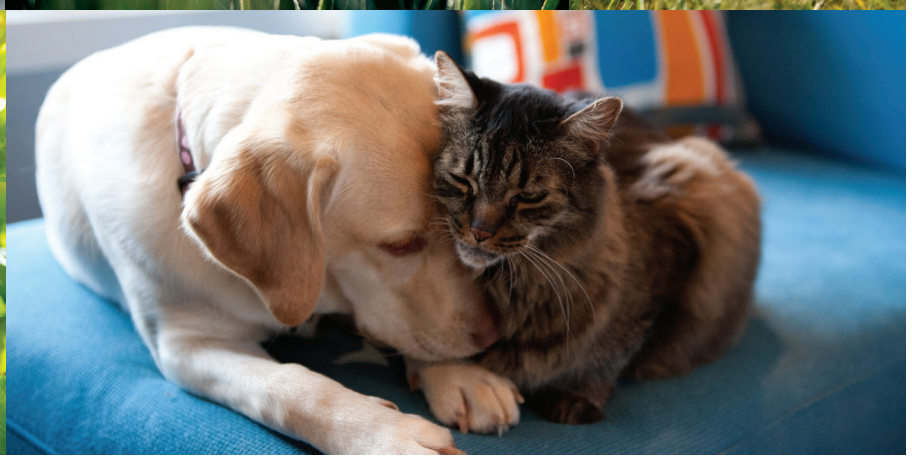
When allergic rhinitis/conjunctivitis (AR/C) is suboptimally controlled with symptomatic treatments, options are limited

COULD ALLERGY IMMUNOTHERAPY (AIT) BE THE NEXT STEP?

Allergy immunotherapy (AIT) treats the root cause, not just the symptoms







- ✓ **Helps desensitize the immune system through repeated, controlled doses[2]**
- ✓ **Proven to reduce symptoms and symptomatic medication use[3]**
- ✓ **Goes beyond symptomatic medication to treat the underlying cause[2]**

Choosing the right AIT for your patient matters

Allergy shots

- Treats numerous allergens[4]
- Typically requires a referral to a specialist[4]
- Requires weekly to monthly in-office injections[4]
- Up to 90 appointments throughout the course of treatment[4]

OR

Sublingual immunotherapy tablets (SLIT-t)

- Taken once daily[5,6,7]
- First dose under medical supervision, after which patients take on their own[5,6,7]
- No titration[5,6,7]
- Treats 3 common allergens

According to the Joint Task Force on Practice Parameter guidelines by AAAAI, ACAAI, AND JCAAI, AIT should be considered when positive test results for specific immunoglobulin E (IgE) antibodies correlate with triggers and patient exposure. There are benefits to starting treatment early[8]:

Decrease in the development of new sensitivities

Improvement in symptom control

Reduction in pharmacy, outpatient, and total health care costs

AAAAI=American Academy of Allergy, Asthma and Immunology; ACAAI=American College of Allergy, Asthma and Immunology; JCAAI=Joint Council of Allergy, Asthma and Immunology.

SLIT-tablets are an AIT option that may fit kids' and parents' needs

- Treats the underlying cause of allergic rhinitis/conjunctivitis (AR/C) symptoms[2]
- Can be easily added to a patient's allergy management plan
- May be a better fit for busy families or patients who are needle-averse
- Convenient, once-daily, at-home administration following first in-office dose
- In a survey, 73% of patients stated they would be willing to try a SLIT-tablet[9]

Meet your patients' needs—and their preferences—with the ALK SLIT-tablet portfolio

ODACTRA®
House Dust Mite (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) Allergen Extract Tablet for Sublingual Use 12 SQ-HDM

Offers polysensitized HDM patients year-round efficacy, including during pollen seasons.[7,10]

Indicated for patients 12-65 years of age[7]

GRASTEK®
Timothy Grass Pollen Allergen Extract Tablet for Sublingual Use 2800 BAU

Helps provide long-term desensitization to grass pollen.

Indicated for patients 5-65 years of age[5]

RAGWITEK®
Short Ragweed Pollen Allergen Extract Tablet for Sublingual Use 12 Amb a 1-U

Prepares patients for ragweed pollen season, including peak season, when pollen levels are at their worst.

Indicated for patients 5-65 years of age[6]

ODACTRA, GRASTEK, and RAGWITEK have not been studied in subjects who are receiving concomitant allergen immunotherapy. Concomitant dosing with other allergen immunotherapy may increase the likelihood of local or systemic adverse reactions to either subcutaneous or sublingual allergen immunotherapy.

AIT=allergy immunotherapy; AR/C=allergic rhinitis/conjunctivitis; HDM=house dust mite; SLIT=sublingual immunotherapy.

Important Safety Information (continued)

- GRASTEK, RAGWITEK, and ODACTRA are contraindicated in patients with:
  - Severe, unstable or uncontrolled asthma
  - A history of any severe systemic allergic reaction
  - A history of any severe local reaction after taking any sublingual allergen immunotherapy
  - A history of eosinophilic esophagitis
  - Hypersensitivity to any of the inactive ingredients [gelatin, mannitol and sodium hydroxide] contained in this product
- GRASTEK, RAGWITEK, and ODACTRA can cause systemic allergic reactions including anaphylaxis which may be life-threatening. In addition, GRASTEK, RAGWITEK, and ODACTRA can cause severe local reactions, including laryngopharyngeal swelling, which can compromise breathing and be life-threatening. Educate patients to recognize the signs and symptoms of these allergic reactions and instruct them to seek immediate medical care and discontinue therapy should any of these occur. Allergic reactions may require treatment with epinephrine.

Before prescribing GRASTEK, RAGWITEK, or ODACTRA, please read the Boxed WARNING, full Prescribing Information, and Medication Guide, for additional Important Safety Information.

Evaluating a patient for SLIT-tablet therapy

Take a history-first approach to allergen diagnosis

Step 1: Consider the clues through a history-first approach

- **House dust mite allergen is perennial and hard to avoid[11]**
  - **— Does the patient experience AR/C symptoms**
    - o Outside of pollen seasons with or without seasonal exacerbations?
    - o In indoor environments?
    - o At bedtime or upon waking?
- **Pasture-grass pollen is a major allergen during spring and summer[15]**
  - **— Does the patient experience AR/C symptoms**
    - o Outdoors during late spring or early summer, especially on windy days?
    - o Around fresh cut grass?
- **Ragweed pollen is a major allergen during fall[15]**
  - **— Does the patient experience AR/C symptoms typically in the late summer or fall?**

Did you know?

House dust mite allergy can be difficult to diagnose since it can make seasonal allergies worse, and winter symptoms can be mistaken for a cold[12,13,14]

Step 2: If the answer is "yes" to any of the above, rule in/out SLIT-tablets with an IgE panel that tests the following:

Allergen	ImmunoCap Test Product Code
D. pteronyssinus (dust mite)	d1
D. farinae (dust mite)	d2
Timothy grass	g6
Common ragweed (weed pollen)	w1
Total IgE	a-IgE;T

For patients who do not test positive for any allergen in this panel, wish to treat multiple allergens, have severe or uncontrolled asthma, or have multiple atopic comorbidities, consider referral to an allergy specialist.

After confirming with patient history and a diagnostic test, consider SLIT-tablets for your appropriate patients

AR/C=allergic rhinitis/conjunctivitis; IgE=immunoglobulin E; SLIT=sublingual immunotherapy.

Important Safety Information (continued)

- Prescribe auto-injectable epinephrine to patients receiving GRASTEK, RAGWITEK, or ODACTRA. Instruct patients or parents/guardians to recognize the signs and symptoms of a severe allergic reaction and in the proper use of emergency auto-injectable epinephrine. Instruct patients or parents/guardians to seek immediate medical care upon use of auto-injectable epinephrine and to stop treatment with GRASTEK, RAGWITEK, or ODACTRA. Review the epinephrine package insert for complete information.
- Administer the initial dose of GRASTEK, RAGWITEK, or ODACTRA in a healthcare setting under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases and prepared to manage a life-threatening systemic or local allergic reaction. Observe patients in the office for at least 30 minutes following the initial dose of GRASTEK, RAGWITEK, or ODACTRA.
- Patients who have persistent and escalating adverse reactions in the mouth or throat should be considered for discontinuation of GRASTEK, RAGWITEK, or ODACTRA.
- Eosinophilic esophagitis has been reported in association with sublingual tablet immunotherapy. Discontinue GRASTEK, RAGWITEK, or ODACTRA and consider a diagnosis of eosinophilic esophagitis in patients who experience severe or persistent gastro-esophageal symptoms including dysphagia or chest pain.
- GRASTEK has not been studied in patients with moderate or severe asthma or any patients who required daily medication to treat asthma. RAGWITEK has not been studied in patients with severe asthma.
- Immunotherapy with GRASTEK, RAGWITEK, or ODACTRA should be withheld if the patient is experiencing an acute asthma exacerbation. Re-evaluate patients who have recurrent asthma exacerbations and consider discontinuation of GRASTEK, RAGWITEK or ODACTRA.
- GRASTEK, RAGWITEK, and ODACTRA have not been studied in patients who are receiving concomitant allergen immunotherapy. Concomitant dosing with other allergen immunotherapy may increase the likelihood of local or systemic adverse reactions to either subcutaneous or sublingual allergen immunotherapy.
- Stop treatment with GRASTEK, RAGWITEK, or ODACTRA to allow complete healing of the oral cavity in patients with oral inflammation (e.g., oral lichen planus, mouth ulcers or thrush) or oral wounds, such as those following oral surgery or dental extraction.

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Important Safety Information (continued)

- The most common adverse reactions reported in clinical studies for patients 18 through 65 years of age treated with GRASTEK vs. placebo included oral pruritus (26.7% vs. 3.5%), throat irritation (22.6% vs. 2.8%), ear pruritus (12.5% vs. 1.1%), and mouth edema (11.1% vs. 0.8%). The most common adverse reactions for GRASTEK vs. placebo in clinical studies for pediatric patients between 5 and 17 years of age included oral pruritus (24.4% vs. 2.1%), throat irritation (21.3% vs. 2.5%), and mouth edema (9.8% vs. 0.2%).
- The most common adverse reactions reported in adults treated with RAGWITEK vs. placebo included throat irritation (16.6% vs. 3.3%), oral pruritus (10.9% vs. 2.0%), ear pruritus (10.4% vs. 1.1%), oral paresthesia (10.0% vs. 4.0%), mouth edema (6.1% vs. 0.5%), and tongue pruritus (5.1% vs. 0.5%). The most common solicited adverse reactions reported in children and adolescents 5 through 17 years of age treated with RAGWITEK vs. placebo included throat irritation/tickle (48.3% vs. 17.7%), itching in the mouth (47.8% vs. 11.2%), itching in the ear (33.9% vs. 6.3%), mouth pain (18.9% vs. 4.5%), swelling of the lips (13.8% vs. 1.2%), nausea (11.5% vs. 3.3%), swelling of the tongue (11.3% vs. 0.8%), throat swelling (10.7% vs. 1.6%), and stomach pain (10.1% vs. 4.5%). The most common unsolicited adverse reactions reported in children and adolescents 5 through 17 years of age treated with RAGWITEK vs. placebo included oral pruritus (7.8% vs. 1.0%), throat irritation (7.6% vs. 1.6%), ear pruritus (4.5% vs. 0.2%), and tongue pruritus (4.5% vs. 0.4%).
- The most common solicited adverse reactions reported in clinical studies for subjects 18 through 65 years of age treated with ODACTRA vs. placebo included throat irritation/tickle (67.0% vs. 20.8% placebo), itching in the mouth (61.3% vs. 14.1%), itching in the ear (51.7% vs. 11.7%), swelling of the uvula/back of the mouth (19.8% vs. 2.4%), swelling of the lips (17.7% vs. 2.7%), swelling of the tongue (15.8% vs. 2.1%). The most common unsolicited adverse reactions reported in clinical studies for subjects 18 through 65 years of age treated with ODACTRA vs. placebo included paraesthesia oral (9.2% vs. 3.2%), tongue pruritus (4.7% vs. 1.1%), oral pain (2.7% vs. 0.6%), stomatitis (2.5% vs. 1.1%), dyspepsia (2.2% vs. 0.0%). The most common solicited adverse reactions reported in clinical studies for adolescents 12 through 17 years of age treated with ODACTRA or placebo included throat irritation/tickle (73.4% vs. 35.8% placebo), itching in the mouth (73.4% vs. 14.7%), itching in the ear (50.0% vs. 11.6%), tongue pain (24.5% vs. 4.2%), stomach pain (23.4% vs. 15.8%), swelling of the uvula/back of the mouth (20.2% vs. 3.2%), swelling of the lips (20.2% vs. 1.1%), swelling of the tongue (19.1% vs. 3.2%), throat swelling (18.1% vs. 8.4%), nausea (17.0% vs. 9.5%). The most common unsolicited adverse reactions reported in clinical studies for adolescents 12 through 17 years of age treated with ODACTRA vs. placebo included oral pain (4.3% vs. 0.0%), paraesthesia oral (5.3% vs. 0.0%), pruritus (2.1% vs. 1.1%), stomatitis (2.1% vs. 1.1%), tongue pruritus (3.2% vs. 0.0%), and chest discomfort (2.1% vs. 0.0%).
- All pregnancies have a risk of birth defect, loss, or other adverse outcomes. Available data on GRASTEK, RAGWITEK, and ODACTRA administered to pregnant women are insufficient to inform associated risks in pregnancy.

Before prescribing GRASTEK, RAGWITEK, or ODACTRA, please read the Boxed WARNING, full Prescribing Information, and Medication Guide, for additional Important Safety Information.

Ready to rewrite allergy and treat the cause?

- Do you see patients returning to the office whose allergies are not effectively controlled with symptomatic medications?
- Have you ordered IgE tests for pediatric patients in whom you suspect perennial or seasonal allergies?
- Have you considered the benefits of treating the underlying cause of AR/C with AIT?

ALK is here to support you with prescribing SLIT-tablets

SLIT-tablet initiation support

Comprehensive in-service training on appropriate testing and managing the first dose

Patient savings/ access tools

Help patients save money on their prescriptions, if eligible

Specialty pharmacy options

Offers the convenience of at-home delivery and prior-authorization support

Scan here for more resources and information on saving on SLIT-tablets

AIT=allergy immunotherapy; AR/C=allergic rhinitis/conjunctivitis; IgE=immunoglobulin E; SLIT=sublingual immunotherapy.

References: 1. Meltzer EO, Blaiss MS, Derebery MJ, et al. Burden of allergic rhinitis: results from the Pediatric Allergies in America survey. *J Allergy Clin Immunol*. 2009;124(suppl 3): S43-S70. doi:10.1016/j.jaci.2009.05.013 **2.** Allergy Immunotherapy. American College of Allergy, Asthma & Immunology. Accessed March 15, 2023. https://acaai.org/allergies/management-treatment/allergy-immunotherapy/ **3.** Matsuoka T, Bernstein DI, Masuyama K, et al. Pooled efficacy and safety data for house dust mite sublingual immunotherapy tablets in adolescents. *Pediatr Allergy Immunol*. 2017;28(7):661-667. doi:10.1111/pai.12747 **4.** Tankersley M, Winders T, Aagren M, et al. Subcutaneous immunotherapy takes more than the time in the clinic. *Curr Med Res Opin*. 2021;37(11):1925-1931. doi:10.1080/03007995.2021.1976126 **5.** GRASTEK®. Prescribing information. ALK-Abelló A/S; Rev. 2019. **6.** RAGWITEK®. Prescribing information. ALK-Abelló A/S; Rev. 2021. **7.** ODACTRA®. Prescribing information. ALK-Abelló A/S; Rev. 2023. **8.** Cox L, Nelson H, Lockey R, et al. Allergen immunotherapy: a practice parameter third update [published correction appears in *J Allergy Clin Immunol*. 2011;127(3):840]. *J Allergy Clin Immunol*. 2011;127(suppl 1):S1-S55. doi:10.1016/j.jaci.2010.09.034 **9.** Tankersley M, Winders T, Aagren M, et al.Preference for immunotherapy with tablets by people with allergic rhinitis. *Patient Prefer Adherence*. 2021;15:2539-2549. doi:10.2147/PPA.S338337 **10.** Demoly P, Emminger W, Rehm D, Backer V, Tommerup L, Kleine-Tebbe J. Effective treatment of house dust mite–induced allergic rhinitis with 2 doses of the SQ HDM SLIT-tablet: results from a randomized, double-blind, placebo-controlled phase III trial. *J Allergy Clin Immunol*. 2016;137(2):444-451.e8. doi:10.1016/j.jaci.2015.06.036 **11.** Dust mite allergy. Asthma & Allergy Foundation of America. Published January 27, 2023. Accessed March 15, 2023. https://aafa.org/allergies/types-of-allergies/insect-allergy/dust-mite-allergy/ **12.** Calderón MA, Kleine-Tebbe J, Linneberg A, et al. House dust mite respiratory allergy: an overview of current therapeutic strategies. *J Allergy Clin Immunol Pract*. 2015;3(6):843-855. doi:10.1016/j.jaip.2015.06.019 **13.** Canonica GW, Campalati E. Minimal persistent inflammation in allergic rhinitis: implications for current treatment strategies. *Clin Exp Immunol*. 2009;158(3):260-271. doi:10.1111/j.1365-2249.2009.04017.x **14.** Wickman M. When allergies complicate allergies. *Allergy*. 2005;60(suppl 79):14-18. doi:10.1111/j.1398-9995.2005.00852.x **15.** Allergic rhinitis. Icahn School of Medicine at Mount Sinai. Accessed March 21, 2023. https://www.mountsinai.org/health-library/report/allergic-rhinitis