STEPS
New Drug Reviews

Timothy Grass Pollen Allergen Extract (Grastek) for Allergic Rhinitis

AALIYAH Y. RIZVI, MD, and AMIESHA S. PANCHAL, MD, *Tufts University Family Medicine Residency at Cambridge Health Alliance, Malden, Massachusetts*

STEPS new drug reviews cover Safety, Tolerability, Effectiveness, Price, and Simplicity. Each independent review is provided by authors who have no financial association with the drug manufacturer.

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Timothy grass pollen allergen extract (Grastek) is a sublingual immunotherapy used to treat confirmed grass pollen–induced allergic rhinitis with or without conjunctivitis in patients five to 65 years of age.[1]

Drug	*Dosage*	*Dose form*	*Cost**
Timothy grass pollen allergen extract (Grastek)	One sublingual tablet daily	One tablet contains 2,800 bioequivalent allergy units	$262

**—Estimated retail price of one month's treatment based on information obtained at http://www.goodrx.com (accessed October 13, 2015).*

SAFETY

The initial dose should be administered under the supervision of a physician because anaphylaxis and laryngopharyngeal edema have occurred in rare cases.[1] The manufacturer suggests that timothy grass pollen allergen extract be avoided in patients taking beta blockers, alpha blockers, ergot alkaloids, tricyclic antidepressants, levothyroxine, monoamine oxidase inhibitors, chlorpheniramine, diphenhydramine (Benadryl), cardiac glycosides, or diuretics. These medications may interfere with epinephrine should it be needed to treat an anaphylactic reaction. Timothy grass pollen allergen extract is also contraindicated in patients with severe, unstable, or uncontrolled asthma; a history of allergic reaction to allergy immunotherapy; and eosinophilic esophagitis.[1] There have been no reports of the fatal or near-fatal reactions that have occurred with use of subcutaneous immunotherapy.[2] Timothy grass pollen allergen extract is U.S. Food and Drug Administration pregnancy category B. It is not known whether it is excreted in breast milk.[1]

TOLERABILITY

The most common reactions are oral pruritus (26.7%), throat irritation (22.6%), ear pruritus (12.5%), and mouth edema (11.1%).[1,3,4] About 5% of patients will discontinue treatment because of adverse effects.[1,5] Patients typically continue treatment for an average of 0.6 years (vs. 1.7 years for subcutaneous immunotherapy), and only 7% of users will continue treatment for at least three years (vs. 23% of subcutaneous users).[6] Patients of primary care physicians are more likely to continue treatment than those who see allergists or other subspecialists.[6]

EFFECTIVENESS

Timothy grass pollen allergen extract has been compared with placebo in four clinical studies in North American patients with known timothy grass allergy.[3,4,7,8] In each study, the allergen was started four months before the onset of pollen season and continued throughout the season, with patients adding allergy symptom relief medications in a stepwise fashion to control breakthrough symptoms. On average, timothy grass pollen allergen extract decreases

ocular symptoms (gritty, itchy, or watery eyes) and nasal symptoms (runny, stuffy, or itchy nose and sneezing) by about 20%. In three of the trials, treatment with timothy grass pollen allergen extract reduced the average daily symptom scores (2.49 to 3.83 with treatment vs. 3.13 to 4.91 with placebo out of a possible score of 18; $P < .05$). One of the four studies found no significant reduction in symptoms.[8] Patients taking timothy grass pollen allergen extract will also use fewer allergy relief medications, although the difference is small (average medication score of 0.88 to 0.91 out of a possible score of 36 vs. 1.33 to 1.36 in patients receiving placebo).[3,7] A meta-analysis evaluated the effectiveness of all commercially available grass pollen sublingual tablets worldwide and had similar findings.[5]

Long-term, continuous use of timothy grass pollen allergen extract may result in a sustained but temporary reduction in symptoms. In one long-term study of 634 patients who took it daily for three years, symptoms were reduced in the first season after cessation of treatment, but not in the second post-cessation season.[2]

Timothy grass pollen allergen extract has not been directly compared with antihistamines, nasal corticosteroids, oral leukotriene inhibitors, decongestants, or subcutaneous immunotherapy. It also has not been compared with another sublingual immunotherapy for grass pollen allergy, Oralair.

PRICE

A one-month supply of timothy grass pollen allergen extract costs approximately $262. The price of Oralair is about $346 per month.[2]

SIMPLICITY

Treatment consisting of one sublingual tablet daily should begin at least three months before the onset of each grass pollen season and should continue throughout the season.[1] Patients should not eat or drink while taking the tablet or for five minutes after. The initial dose should be administered in an office setting with appropriate resources to handle life-threatening reactions, and patients should be observed for at least 30 minutes. After this dose, patients can continue daily administration at home, but all patients should receive a prescription for an autoinjectable epinephrine pen and be instructed in proper use.

Bottom Line

Timothy grass pollen allergen extract produces small improvements in allergic rhinitis symptoms and the use of allergy relief medications, with a high rate of adverse effects. It may, however, be an option for patients who desire an alternative to standard allergy symptom relief but who do not want to begin injectable desensitization treatment. It has not been compared with established allergy treatments or subcutaneous desensitization treatment.

Address correspondence to Aaliyah Y. Rizvi, MD, at arizvi@bu.edu. Reprints are not available from the authors.

Author disclosure: No relevant financial affiliations.

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