

FDA Approves Merck's RAGWITEK™ (Short Ragweed Pollen Allergen Extract) Sublingual Tablet as Immunotherapy to Treat Short Ragweed Pollen-Induced Allergic Rhinitis with or without Conjunctivitis in Adults

Release Date:

Thursday, April 17, 2014 6:22 pm EDT

Terms:

[Prescription Medicine News](#) [Corporate News](#) [Latest News](#)

Dateline City:

WHITEHOUSE STATION, N.J.

RAGWITEK is the First and Only FDA Approved Sublingual Allergen Immunotherapy Tablet Indicated for the Treatment of Short Ragweed Pollen Allergies

WHITEHOUSE STATION, N.J.--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has approved RAGWITEK™ (Short Ragweed Pollen Allergen Extract) Tablet for Sublingual Use (12 Amb a 1-U). RAGWITEK is an allergen extract indicated as immunotherapy 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 adults 18 through 65 years of age. RAGWITEK is not indicated for the immediate relief of allergic symptoms.

The prescribing information for RAGWITEK includes a boxed warning regarding severe allergic reactions. RAGWITEK is 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; or hypersensitivity to any of the inactive ingredients contained in the product.

"RAGWITEK provides a new sublingual approach to allergen immunotherapy for adult patients suffering from moderate to severe ragweed pollen allergies who have declined allergy shots," said Dr. David Skoner, director, Division of Allergy and Immunology, Allegheny Health Network, and a clinical investigator in Merck's sublingual allergen immunotherapy tablet program. "While there are regional variations, ragweed season typically starts in mid-August across the United States. During the season, many patients with moderate to severe allergic rhinitis experience nasal and ocular allergy symptoms at their worst while taking symptom-relieving medication. These patients often have multiple sensitivities. To help prepare for the upcoming ragweed season, I would encourage patients diagnosed with ragweed pollen allergies to make an appointment now with an allergy specialist to discuss options."

Symptoms of short ragweed pollen-induced allergic rhinitis with or without conjunctivitis may include sneezing, a runny or itchy nose, stuffy or congested nose, or itchy and watery eyes, and typically intensify during the ragweed pollen season.

"The FDA approval of RAGWITEK brings an important new option for allergy specialists treating adults with allergic rhinitis with or without conjunctivitis caused by short ragweed pollen," said Dr. Sean Curtis, vice president, Respiratory and Immunology, Merck Research Laboratories. "Merck is proud to add this second sublingual allergen immunotherapy tablet to our respiratory portfolio."

About short ragweed pollen allergy

While regional variation exists, in many areas of the United States ragweed pollen season occurs from August to November. Ragweed pollen levels usually peak in mid-September in many parts of the country.

Dosing and administration of RAGWITEK (Short Ragweed Pollen Allergen Extract)

The recommended dose of RAGWITEK is one tablet daily to be placed under the tongue, where it will dissolve.

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. The physician should observe the patient for at least 30 minutes after receiving the first dose of RAGWITEK 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. The physician should prescribe auto-injectable epinephrine, and instruct and train the patient on its appropriate use.

Initiate RAGWITEK at least 12 weeks before the expected onset of ragweed pollen season and continue throughout the season. The safety and efficacy of initiating treatment in season have not been established.

RAGWITEK will be available in U.S. pharmacies by the end of April.

About the clinical study program for RAGWITEK (Short Ragweed Pollen Allergen Extract)

The efficacy of RAGWITEK was supported by two Phase 3 clinical studies over a single ragweed pollen season in patients 18 through 50 years of age. In both randomized, double-blind, parallel group, multi-center studies:

- Patients had a history of short ragweed pollen-induced allergic rhinitis with or without conjunctivitis, and sensitivity to short ragweed confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for short ragweed;
- Patients with non-ragweed sensitivities were included as long as the patients did not require treatment as a result of symptoms from those non-ragweed allergies during the ragweed season;
- RAGWITEK or placebo was administered as a sublingual tablet and initiated approximately 12 weeks before the start of the ragweed pollen season;
- Patients in both arms of the study were allowed to take symptom-relieving medications (including systemic and topical antihistamines, and topical and oral corticosteroids) as needed;
- Efficacy was established by self-reporting of rhinoconjunctivitis daily symptom scores (DSS) and daily medication scores (DMS), the sums of which were combined into the total combined score (TCS);
- Daily rhinoconjunctivitis symptoms included four nasal symptoms (runny nose, stuffy nose, sneezing and itchy nose), and two ocular symptoms (gritty/itchy eyes and watery eyes).

The FDA criteria for clinically relevant efficacy of allergen immunotherapy is based on the TCS, which must have an average difference relative to placebo of less than or equal to -15 percent, and the upper bound of the 95 percent confidence interval (CI) must be less than or equal to -10 percent.

Study 1:

The first study compared RAGWITEK (n=187) relative to placebo (n=188) in patients 18 through 50 years of age of whom approximately 22 percent had mild asthma of a severity that required, at most, a daily low dose of an inhaled corticosteroid, and 85 percent were sensitized to other allergens in addition to short ragweed. Patients treated with RAGWITEK had significant reduction of nasal and ocular symptoms, and reduction in use of symptom-relieving allergy medication, as measured by a decrease in the TCS for the peak ragweed pollen season, compared to placebo; difference of RAGWITEK (n=159) relative to placebo (n=164) was -26 percent (95% CI: -38.7%; -14.6%).

Study 2:

The second study compared RAGWITEK (Short Ragweed Pollen Allergen Extract) (n=194) to placebo (n=198) in patients 18 to 50 years of age, of whom approximately 17 percent had mild asthma of a severity that required, at most, a daily low dose of an inhaled corticosteroid, and 78 percent were sensitized to other allergens in addition to short ragweed. The results of Study 2 were similar to Study 1. Patients treated with RAGWITEK experienced significant reduction of nasal and ocular symptoms, and significant reduction in use of symptom-relieving allergy medication, as measured by decrease in the TCS for the peak ragweed pollen season compared to placebo; difference of RAGWITEK (n=152) relative to placebo (n=169) was -24 percent (95% CI: -36.5%; -11.3%).

About allergic rhinitis due to short ragweed pollen

It is estimated that approximately 4.5 million adults ages 20 to 64 in the U.S. have been diagnosed with moderate to severe allergic rhinitis and are sensitized to short ragweed pollen.

Important safety information about RAGWITEK

WARNING: SEVERE ALLERGIC REACTIONS

RAGWITEK can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal restriction. Do not administer RAGWITEK 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 on its appropriate use, and instruct patients to seek immediate medical care upon its use. RAGWITEK may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction. RAGWITEK may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

RAGWITEK is 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; or hypersensitivity to any of the inactive ingredients (gelatin, mannitol and sodium hydroxide) contained in the product.

RAGWITEK can cause systemic allergic reactions including anaphylaxis which may be life-threatening and 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. Prescribe auto-injectable epinephrine to patients receiving RAGWITEK (Short Ragweed Pollen Allergen Extract). Instruct patients to recognize the signs and symptoms of a severe allergic reaction and in the proper use of emergency auto-injectable epinephrine. Instruct patients to seek immediate medical care upon use of auto-injectable epinephrine and to stop treatment with RAGWITEK. Review the epinephrine package insert for complete information.

Administer the initial dose of RAGWITEK 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 RAGWITEK.

Patients who have persistent and escalating adverse reactions in the mouth or throat should be considered for discontinuation of RAGWITEK.

Eosinophilic esophagitis has been reported in association with sublingual tablet immunotherapy. Discontinue RAGWITEK and consider a diagnosis of eosinophilic esophagitis in patients who experience severe or persistent gastro-esophageal symptoms including dysphagia or chest pain.

RAGWITEK has not been studied in patients with moderate or severe asthma. Immunotherapy with RAGWITEK should be withheld if the patient is experiencing an acute asthma exacerbation. Reevaluate patients who have recurrent asthma exacerbations and consider discontinuation of RAGWITEK.

RAGWITEK has 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 RAGWITEK 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.

The most common adverse reactions reported in patients 18 years of age and older 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%) and oral paraesthesia (10.0% vs. 4.0%).

Because systemic and local adverse reactions with immunotherapy may be poorly tolerated during pregnancy, RAGWITEK should be used during pregnancy only if clearly needed.

Find an Allergy Specialist

To find an allergy specialist, please visit the websites of the [American Academy of Allergy, Asthma, and Immunology \(AAAAI\)](#); [American College of Allergy, Asthma & Immunology \(ACAAI\)](#); or [American Academy of Otolaryngic Allergy \(AAOA\)](#).

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit www.merck.com and connect with us on [Twitter](#), [Facebook](#) and [YouTube](#).

Forward-Looking Statement

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Merck's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Merck's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2013 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

#

Please see Prescribing Information, including Boxed Warning, for RAGWITEK [Short Ragweed Pollen Allergen Extract] Tablet for Sublingual Use at http://www.merck.com/product/usa/pi_circulars/r/ragwitek/ragwitek_pi.pdf and Medication Guide for RAGWITEK at http://www.merck.com/product/usa/pi_circulars/r/ragwitek/ragwitek_mg.pdf.

RAGWITEK™ is a registered trademark of Merck & Co., Inc., Whitehouse Station, N.J., USA.

Language:

English

Contact:

Merck
Media Contacts:
Pamela Eisele, 267-305-3558
Robert Consalvo, 908-423-6595
or
Investor Contacts:
Carol Ferguson, 908-423-4465
Justin Holko, 908-423-5088

Ticker Slug:

Ticker: MRK
Exchange: NYSE

Source URL: <http://www.mercknewsroom.com/news-release/prescription-medicine-news/fda-approves-mercks-ragwitek-short-ragweed-pollen-allergen-e>