HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use RAGWITEK safely and effectively. See full prescribing information for RAGWITEK.

RAGWITEK™ (Short Ragweed Pollen Allergen Extract)
Tablet for Sublingual Use
Initial U.S. Approval: 2014

WARNING: SEVERE ALLERGIC REACTIONS
See full prescribing information for complete boxed warning.

- **RAGWITEK can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal restriction. (5.1)**
- **Do not administer RAGWITEK to patients with severe, unstable or uncontrolled asthma. (4)**
- **Observe patients in the office for at least 30 minutes following the initial dose. (5.1)**
- **Prescribe auto-injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use. (5.2)**
- **RAGWITEK may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction. (5.2)**
- **RAGWITEK may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers. (5.2)**

----------INDICATIONS AND USAGE----------
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. (1)

---------- DOSAGE AND ADMINISTRATION ----------
For sublingual use only.
- One tablet daily. (2.1)
- Initiate treatment at least 12 weeks before the expected onset of ragweed pollen season and continue treatment throughout the season. (2.2)
- Place the tablet immediately under the tongue. Allow it to remain there until completely dissolved. Do not swallow for at least 1 minute. (2.2)
- Administer the first dose of RAGWITEK under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases. Observe patients in the office for at least 30 minutes following the initial dose. (2.2)

---------- DOSAGE FORMS AND STRENGTHS ----------
- Tablet, 12 Amb a 1-Unit (Amb a 1-U) (3)

----------CONTRAINDICATIONS----------
- Severe, unstable or uncontrolled asthma. (4)
- History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy. (4)
- A history of eosinophilic esophagitis. (4)
- Hypersensitivity to any of the inactive ingredients contained in this product. (4)

---------- WARNINGS AND PRECAUTIONS ----------
- Inform patients of the signs and symptoms of serious allergic reactions and instruct them to seek immediate medical care and discontinue therapy should any of these occur. (5.1)
- In case of oral inflammation or wounds, stop treatment with RAGWITEK to allow complete healing of the oral cavity. (5.7)

---------- ADVERSE REACTIONS ----------
- Adverse reactions reported in ≥5% of patients were: throat irritation, oral pruritus, ear pruritus, oral paraesthesia, mouth edema, and tongue pruritus. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., at 1-877-888-4231 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 06/2014

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FULL PRESCRIBING INFORMATION

WARNING: SEVERE ALLERGIC REACTIONS

- **RAGWITEK can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal restriction. (5.1)**
- **Do not administer RAGWITEK to patients with severe, unstable or uncontrolled asthma. (4)**
- **Observe patients in the office for at least 30 minutes following the initial dose. (5.1)**
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- **RAGWITEK may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction. (5.2)**
- **RAGWITEK may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers. (5.2)**

1 INDICATIONS AND USAGE

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.

2 DOSAGE AND ADMINISTRATION

For sublingual use only.

2.1 Dose

One RAGWITEK tablet daily.

2.2 Administration

Administer the first dose of RAGWITEK in a healthcare setting under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases. After receiving the first dose of RAGWITEK, observe the patient for at least 30 minutes 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.

Take the tablet from the blister unit after carefully removing the foil with dry hands.

Place the tablet immediately under the tongue. Allow it to remain there until completely dissolved. Do not swallow for at least 1 minute.

Wash hands after handling the tablet.

Do not take the tablet with food or beverage. Food or beverage should not be taken for the following 5 minutes after taking the tablet.

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

Data regarding the safety of restarting treatment after missing a dose of RAGWITEK are limited. In the clinical trials, treatment interruptions for up to seven days were allowed.

Prescribe auto-injectable epinephrine to patients prescribed RAGWITEK and instruct them in the proper use of emergency self-injection of epinephrine *[see Warnings and Precautions (5.2)]*.

3 DOSAGE FORMS AND STRENGTHS

RAGWITEK is available as 12 Amb a 1-Unit (Amb a 1-U) tablets that are white to off-white, circular with a debossed double hexagon on one side.

4 CONTRAINDICATIONS

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
- Hypersensitivity to any of the inactive ingredients [gelatin, mannitol, and sodium hydroxide] contained in this product *[see Description (11)].*

5 WARNINGS AND PRECAUTIONS

5.1 Severe Allergic Reactions

RAGWITEK can cause systemic allergic reactions including anaphylaxis which may be life-threatening. In addition, RAGWITEK 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. *[See Warnings and Precautions (5.2).]*

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.

5.2 Epinephrine

Prescribe auto-injectable epinephrine to patients receiving RAGWITEK. 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. *[See Patient Counseling Information (17).]*

See the epinephrine package insert for complete information.

RAGWITEK may not be suitable for patients with certain medical conditions that may reduce the ability to survive a serious allergic reaction or increase the risk of adverse reactions after epinephrine administration. Examples of these medical conditions include but are not limited to: markedly compromised lung function (either chronic or acute), unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension.

RAGWITEK may not be suitable for patients who are taking medications that can potentiate or inhibit the effect of epinephrine. These medications include:

Beta-adrenergic blockers: Patients taking beta-adrenergic blockers may be unresponsive to the usual doses of epinephrine used to treat serious systemic reactions, including anaphylaxis. Specifically, beta-adrenergic blockers antagonize the cardiostimulating and bronchodilating effects of epinephrine.

Alpha-adrenergic blockers, ergot alkaloids: Patients taking alpha-adrenergic blockers may be unresponsive to the usual doses of epinephrine used to treat serious systemic reactions, including anaphylaxis. Specifically, alpha-adrenergic blockers antagonize the vasoconstricting and hypertensive effects of epinephrine. Similarly, ergot alkaloids may reverse the pressor effects of epinephrine.

Tricyclic antidepressants, levothyroxine sodium, monoamine oxidase inhibitors, and certain antihistamines: The adverse effects of epinephrine may be potentiated in patients taking tricyclic antidepressants, levothyroxine sodium, monoamine oxidase inhibitors, and the antihistamines chlorpheniramine, and diphenhydramine.

Cardiac glycosides, diuretics: Patients who receive epinephrine while taking cardiac glycosides or diuretics should be observed carefully for the development of cardiac arrhythmias.

5.3 Upper Airway Compromise

RAGWITEK can cause local reactions in the mouth or throat that could compromise the upper airway *[see Adverse Reactions (6.1)]*. Consider discontinuation of RAGWITEK in patients who experience persistent and escalating adverse reactions in the mouth or throat.

5.4 Eosinophilic Esophagitis

Eosinophilic esophagitis has been reported in association with sublingual tablet immunotherapy *[see Contraindications (4)]*. Discontinue RAGWITEK and consider a diagnosis of eosinophilic esophagitis in patients who experience severe or persistent gastro-esophageal symptoms including dysphagia or chest pain.

5.5 Asthma

Subjects with asthma who participated in clinical trials had asthma of a severity that required, at most, a daily low dose of an inhaled corticosteroid. RAGWITEK has not been studied in subjects with moderate or severe asthma.

Withhold immunotherapy with RAGWITEK if the patient is experiencing an acute asthma exacerbation. Reevaluate patients who have recurrent asthma exacerbations and consider discontinuation of RAGWITEK.

5.6 Concomitant Allergen Immunotherapy

RAGWITEK has 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.

5.7 Oral Inflammation

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.

6 ADVERSE REACTIONS

Adverse reactions reported in ≥5% of patients were: throat irritation, oral pruritus, ear pruritus, oral paraesthesia, mouth edema, and tongue pruritus.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

In 4 placebo-controlled clinical trials, 1057 subjects 18 years of age and older with short ragweed pollen-induced rhinitis, with or without conjunctivitis, received at least one dose of RAGWITEK, of whom 327 (31%) completed at least 12 weeks of therapy. Of the subjects treated with RAGWITEK, 52% were male, 25% had mild asthma, and 82% were sensitized to other allergens in addition to ragweed pollen. The subject population was 83% White, 12% African American, and 2% Asian. Subject demographics in placebo-treated subjects were similar to the active group. The pooled analysis includes safety data from two 28-day safety studies and safety data from the first 28 days of two 52-week safety and efficacy studies. Adverse reactions reported in ≥1% of subjects in the 28-day pooled analysis treated with RAGWITEK are shown in Table 1.

The most common adverse reactions reported in subjects treated with RAGWITEK were throat irritation (16.6% vs 3.3% placebo), oral pruritus (10.9% vs 2.0%), ear pruritus (10.4% vs 1.1%), and oral paraesthesia (10.0% vs 4.0%). The percentage of subjects who discontinued from the clinical trials because of an adverse reaction while exposed to RAGWITEK or placebo was 4.4% and 0.8%,

respectively. The most common adverse reactions that led to study discontinuation in subjects who were exposed to RAGWITEK were mouth edema, swollen tongue, and dysphagia.

One subject (1/1057; 0.1%) who received RAGWITEK experienced a treatment-related severe systemic allergic reaction that led to discontinuation of RAGWITEK. The subject had local reactions starting on Day 1 of treatment with RAGWITEK. On Day 6 symptoms progressed and included swelling of the throat, dyspnea, nausea, and lightheadedness. The subject fully recovered after treatment with epinephrine (self-administered), antihistamines, and oral corticosteroids.

Table 1: Adverse Reactions Reported in ≥1% of Subjects Treated with RAGWITEK (28-day pooled analysis)

Adverse Reaction	RAGWITEK (N=1057)	Placebo (N=757)
Ear and Labyrinth Disorders		
Ear pruritus	10.4%	1.1%
Respiratory, Thoracic and Mediastinal Disorders		
Throat irritation	16.6%	3.3%
Oropharyngeal pain	1.5%	0.7%
Throat tightness	1.3%	0.5%
Gastrointestinal Disorders		
Oral pruritus	10.9%	2.0%
Paraesthesia oral	10.0%	4.0%
Mouth edema	6.1%	0.5%
Tongue pruritus	5.1%	0.5%
Lip swelling	3.0%	0.4%
Swollen tongue	2.9%	0.5%
Lip pruritus	1.5%	0.1%
Dry mouth	1.4%	0.7%
Tongue edema	1.3%	0.5%
Nausea	1.1%	0.3%
Palatal edema	1.1%	0%
Dysphagia	1.0%	0%
Skin and Subcutaneous Tissue Disorders		
Pruritus	1.8%	1.3%
General Disorders and Administration Site Conditions		
Chest discomfort	1.0%	0%

The overall safety profile beyond Day 28 in the two 52-week trials was similar to that observed in the pooled 28-day analysis.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C:

Animal reproduction studies have not been performed with RAGWITEK. It is also not known whether RAGWITEK can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. RAGWITEK should be used during pregnancy only if clearly needed.

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

8.3 Nursing Mothers

It is not known if RAGWITEK is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when RAGWITEK is administered to a nursing woman.

8.4 Pediatric Use

RAGWITEK is not approved for use in pediatric patients because safety and efficacy have not been established.

8.5 Geriatric Use

RAGWITEK is not approved for use in patients over 65 years of age because safety and efficacy have not been established.

11 DESCRIPTION

RAGWITEK tablets contain pollen allergen extract from Short Ragweed (*Ambrosia artemisiifolia*). RAGWITEK is a sublingual orally disintegrating tablet that dissolves rapidly.

RAGWITEK is available as a tablet of 12 Amb a 1-U of short ragweed pollen allergen extract.

Inactive ingredients: gelatin NF (fish source), mannitol USP, and sodium hydroxide NF.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The precise mechanisms of action of allergen immunotherapy are not known.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No studies have been performed in animals to evaluate the carcinogenic potential of RAGWITEK.

There were no positive findings in a combined *in vivo* Comet and micronucleus assay in rats using Short Ragweed (*Ambrosia artemisiifolia*) pollen allergen extract.

Fertility studies have not been performed with Short Ragweed pollen allergen extract.

14 CLINICAL STUDIES

The efficacy of RAGWITEK in the treatment of ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, was investigated in two double-blind, placebo-controlled clinical trials in adults 18 through 50 years of age. Subjects received RAGWITEK or placebo for approximately 12 weeks prior to the start of the ragweed pollen season and throughout the ragweed pollen season.

The subject population was 86% White, 9% African American, and 3% Asian. The subject population was almost equally divided between males and females. Overall, the mean age of subjects was 36 years. Subjects with asthma who participated in clinical trials had asthma of a severity that required, at most, a daily low dose of an inhaled corticosteroid. Approximately 16% of subjects had mild asthma at baseline.

Efficacy was established by self-reporting of rhinoconjunctivitis daily symptom scores (DSS) and daily medication scores (DMS). 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 rhinoconjunctivitis symptoms were measured on a scale of 0 (none) to 3 (severe). Subjects in clinical trials were allowed to take symptom-relieving medications (including systemic and topical antihistamines, and topical and oral corticosteroids) as needed. The daily medication score measured the use of standard open-label allergy medications. Predefined values were assigned to each class of medication. Generally, systemic and topical antihistamines were given the lowest score, topical steroids an intermediate score, and oral corticosteroids the highest score.

The sums of the DSS and DMS were combined into the Total Combined Score (TCS) which was averaged over the peak ragweed pollen season. Also, in each study, the average TCS over the entire ragweed season was assessed. Other endpoints in both studies included the average DSS during the peak and entire ragweed season, and the average DMS during the peak ragweed season.

Trial 1

The first study was a placebo-controlled trial which evaluated subjects 18 through 50 years of age comparing RAGWITEK (n=187) and placebo (n=188) administered as a sublingual tablet daily. In this trial, approximately 22% of subjects had mild asthma and 85% were sensitized to other allergens in addition to short ragweed. Subjects with asthma who participated in this trial had asthma of a severity that required, at most, a daily low dose of an inhaled corticosteroid. Subjects with a clinical history of symptomatic allergies to non-short ragweed pollen allergens that required treatment during the ragweed pollen season were excluded from the trial. The subject population was 78% White, 12% African American, and 8% Asian, and almost equally divided between males and females. The mean age of subjects in this study was 35.4 years. The two treatment groups were balanced with regard to baseline characteristics. The results of this study are shown in Table 2.

Trial 2

The second study was a placebo-controlled trial which evaluated subjects 18 through 50 years of age comparing RAGWITEK (n=194) and placebo (n=198) administered as a sublingual tablet daily. Approximately 17% of subjects had mild asthma and 78% were sensitized to other allergens in addition to short ragweed. Subjects with asthma who participated in this trial had asthma of a severity that required, at most, a daily low dose of an inhaled corticosteroid. Subjects with a clinical history of symptomatic allergies to non-short ragweed pollen allergens that required treatment during the ragweed pollen season were excluded from the trial. The subject population was 88% White, 8.9% African American, 2% Asian, and almost equally divided between males and females. The mean age of subjects in this study was 36.4 years. The two treatment groups were balanced with regard to baseline characteristics. The results of this study are shown in Table 3.

A decrease in TCS during the peak ragweed season for subjects treated with RAGWITEK compared to placebo-treated subjects was demonstrated in both trials. Subjects treated with RAGWITEK also showed a decrease in the average TCS from the start of and throughout the entire ragweed pollen season. Similar decreases were observed in subjects treated with RAGWITEK for other endpoints (see Tables 2 and 3).

Table 2: Trial 1: Total Combined Scores (TCS), Rhinoconjunctivitis Daily Symptom Scores (DSS), and Daily Medication Scores (DMS) During the Ragweed Pollen Season

Endpoint*	**RAGWITEK (N)[†] Score[‡]**	**Placebo (N)[†] Score[‡]**	**Treatment Difference (RAGWITEK – Placebo)**	**Difference Relative to Placebo[§] Estimate (95% CI)**
TCS Peak Season[¶]	(159) 6.22	(164) 8.46	-2.24	-26% (-38.7, -14.6)
TCS Entire Season	(160) 5.21	(166) 7.01	-1.80	-26% (-37.6, -13.5)
DSS Peak Season	(159) 4.65	(164) 5.59	-0.94	-17% (-28.6, -4.6)
DSS Entire Season	(160) 4.05	(166) 4.87	-0.82	-17% (-28.5, -4.5)
DMS Peak Season	(159) 1.57	(164) 2.87	-1.30	-45% (-65.4, -27.0)

TCS=Total Combined Score (DSS + DMS); DSS=Daily Symptom Score; DMS=Daily Medication Score.

***** Parametric analysis using analysis of variance model for all endpoints.

† Number of subjects in analyses.

‡ The estimated group means are reported and difference relative to placebo is based on estimated group means.

§ Difference relative to placebo computed as: (RAGWITEK - placebo)/placebo x 100.

¶ Peak ragweed season was defined as maximum 15 days with the highest moving average pollen counts during the ragweed season.

Table 3: Trial 2: Total Combined Scores (TCS), Rhinoconjunctivitis Daily Symptom Scores (DSS), and Daily Medication Scores (DMS) During the Ragweed Pollen Season

Endpoint*	RAGWITEK (N)† Score‡	Placebo (N)† Score‡	Treatment Difference (RAGWITEK – Placebo)	Difference Relative to Placebo§ Estimate (95% CI)
TCS Peak Season¶	(152) 6.41	(169) 8.46	-2.04	-24% (-36.5, -11.3)
TCS Entire Season	(158) 5.18	(174) 7.09	-1.92	-27% (-38.8, -14.1)
DSS Peak Season	(152) 4.43	(169) 5.37	-0.94	-18% (-29.2, -4.5)
DSS Entire Season	(158) 3.62	(174) 4.58	-0.96	-21% (-31.6, -8.8)
DMS Peak Season	(152) 1.99	(169) 3.09	-1.10	-36% (-55.8, -14.6)

TCS=Total Combined Score (DSS + DMS); DSS=Daily Symptom Score; DMS=Daily Medication Score.

* Parametric analysis using analysis of variance model for all endpoints.

† Number of subjects in analyses.

‡ The estimated group means are reported and difference relative to placebo is based on estimated group means.

§ Difference relative to placebo computed as: (RAGWITEK - placebo)/placebo x 100.

¶ Peak ragweed season was defined as maximum 15 days with the highest moving average pollen counts during the ragweed season.

16 HOW SUPPLIED/STORAGE AND HANDLING

RAGWITEK 12 Amb a 1-U tablets are white to off-white, circular sublingual tablets with a debossed double hexagon on one side.

RAGWITEK is supplied as follows:

3 blister packages of 10 tablets (30 tablets total). NDC 0006-5420-30

9 blister packages of 10 tablets (90 tablets total). NDC 0006-5420-54

Store at controlled room temperature, 20ºC-25ºC (68ºF-77ºF); excursions permitted between 15ºC-30ºC (59ºF-86ºF). Store in the original package until use to protect from moisture.

17 PATIENT COUNSELING INFORMATION

Advise patients to read the FDA-approved patient labeling (Medication Guide) and to keep RAGWITEK and all medicines out of the reach of children.

Severe Allergic Reactions

Advise patients that RAGWITEK may cause life-threatening systemic or local allergic reactions, including anaphylaxis. Educate patients about the signs and symptoms of these allergic reactions *[see Warnings and Precautions (5.1)]*. The signs and symptoms of a severe allergic reaction may include: syncope, dizziness, hypotension, tachycardia, dyspnea, wheezing, bronchospasm, chest discomfort, cough, abdominal pain, vomiting, diarrhea, rash, pruritus, flushing, and urticaria.

Ensure that patients have auto-injectable epinephrine and instruct patients in its proper use. Instruct patients who experience a severe allergic reaction to seek immediate medical care, discontinue RAGWITEK, and resume treatment only when advised by a physician to do so. *[See Warnings and Precautions (5.2).]*

Advise patients to read the patient information for epinephrine.

Inform patients that the first dose of RAGWITEK must be administered in a healthcare setting under the supervision of a physician and that they will be monitored for at least 30 minutes to watch for signs and symptoms of life-threatening systemic or local allergic reaction *[see Warnings and Precautions (5.1)]*.

Because of the risk of upper airway compromise, instruct patients with persistent and escalating adverse reactions in the mouth or throat to discontinue RAGWITEK and to contact their healthcare professional. *[See Warnings and Precautions (5.3).]*

Because of the risk of eosinophilic esophagitis, instruct patients with severe or persistent symptoms of esophagitis to discontinue RAGWITEK and to contact their healthcare professional. *[See Warnings and Precautions (5.4).]*

Asthma

Instruct patients with asthma that if they have difficulty breathing or if their asthma becomes difficult to control, they should stop taking RAGWITEK and contact their healthcare professional immediately *[see Warnings and Precautions (5.5)]*.

Administration Instructions

Instruct patients to carefully remove the foil from the blister unit with dry hands and then take the sublingual tablet immediately by placing it under the tongue where it will dissolve. Also instruct patients to wash their hands after handling the tablet, and to avoid food or beverages for 5 minutes after taking the tablet. *[See Dosage and Administration (2.2).]*

Manufactured for: Merck Sharp & Dohme Corp., a subsidiary of
MERCK & CO., INC., Whitehouse Station, NJ 08889, USA

Manufactured by:
Catalent Pharma Solutions Limited, Blagrove,
Swindon, Wiltshire, SN5 8RU UK

For patent information: www.merck.com/product/patent/home.html

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