MEDICATION GUIDE

RAGWITEK® (RAG-wi-tek)
(Short Ragweed Pollen Allergen Extract)

Carefully read this Medication Guide before you start taking RAGWITEK® and each time you get a refill. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment. Talk with your doctor or pharmacist if there is something you do not understand or if you want to learn more about RAGWITEK.

What is the Most Important Information I Should Know about RAGWITEK?

RAGWITEK can cause severe allergic reactions that may be life-threatening. Stop taking RAGWITEK and get medical treatment right away if you have any of the following symptoms after taking RAGWITEK:

- Trouble breathing
- Throat tightness or swelling
- Trouble swallowing or speaking
- Dizziness or fainting
- Rapid or weak heartbeat
- Severe stomach cramps or pain, vomiting, or diarrhea
- Severe flushing or itching of the skin

For home administration of RAGWITEK, your doctor will prescribe auto-injectable epinephrine, a medicine you can inject if you have a severe allergic reaction after taking RAGWITEK. Your doctor will train and instruct you on the proper use of auto-injectable epinephrine.

Talk to your doctor or read the epinephrine patient information if you have any questions about the use of auto-injectable epinephrine.

What is RAGWITEK?

RAGWITEK is a prescription medicine used for sublingual (under the tongue) immunotherapy to treat ragweed pollen allergies that can cause sneezing, runny or itchy nose, stuffy or congested nose, or itchy and watery eyes. RAGWITEK may be prescribed for persons 18 through 65 years of age who are allergic to ragweed pollen.

RAGWITEK is taken for about 12 weeks before ragweed pollen season and throughout ragweed pollen season.

RAGWITEK is NOT a medication that gives immediate relief for symptoms of ragweed allergy.

Who Should Not Take RAGWITEK?

You should not take RAGWITEK if:

- You have severe, unstable or uncontrolled asthma
- You had a severe allergic reaction in the past that included any of these symptoms:
    - Trouble breathing
    - Dizziness or fainting
    - Rapid or weak heartbeat
- You have ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before.
- You have ever been diagnosed with eosinophilic esophagitis.
- You are allergic to any of the inactive ingredients contained in RAGWITEK. The inactive ingredients contained in RAGWITEK are: gelatin, mannitol, and sodium hydroxide.

What Should I Tell My Doctor Before Taking RAGWITEK?

Your doctor may decide that RAGWITEK is not the best treatment if:

- You have asthma, depending on how severe it is.
- You suffer from lung disease such as chronic obstructive pulmonary disease (COPD)
- You suffer from heart disease such as coronary artery disease, an irregular heart rhythm, or you have hypertension that is not well controlled.
- You are pregnant, plan to become pregnant during the time you will be taking RAGWITEK, or are breast-feeding.
- You are unable or unwilling to administer auto-injectable epinephrine to treat a severe allergic reaction to RAGWITEK.
- You are taking certain medicines that enhance the likelihood of a severe reaction, or interfere with the treatment of a severe reaction. These medicines include:
    - beta blockers and alpha-blockers (prescribed for high blood pressure)
    - cardiac glycosides (prescribed for heart failure or problems with heart rhythm)
    - diuretics (prescribed for heart conditions and high blood pressure)
    - ergot alkaloids (prescribed for migraine headache)
    - monoamine oxidase inhibitors or tricyclic antidepressants (prescribed for depression)
    - thyroid hormone (prescribed for low thyroid activity).
- You are receiving allergy shots or other immunotherapy under the tongue. Use of more than one of these types of medicines together may increase the likelihood of a severe allergic reaction.

You should tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription and herbal supplements. Keep a list of them and show it to your doctor and pharmacist each time you get a new supply of RAGWITEK. Ask your doctor or pharmacist for advice before taking RAGWITEK.

RAGWITEK is not indicated for use in children under 18 years of age.

Are there any Reasons to Stop Taking RAGWITEK?

Stop RAGWITEK and contact your doctor if you have any of the following after taking RAGWITEK:

- Any type of a serious allergic reaction
- Throat tightness that worsens or swelling of the tongue or throat that causes trouble speaking, breathing, or swallowing
- Asthma or any other breathing condition that gets worse
- Dizziness or fainting
- Rapid or weak heartbeat
- Severe stomach cramps or pain, vomiting, or diarrhea
- Severe flushing or itching of the skin
- Heartburn, difficulty swallowing, pain with swallowing, or chest pain that does not go away or worsens

Also, stop taking RAGWITEK following: mouth surgery procedures (such as tooth removal), or if you develop any mouth infections, ulcers or cuts in the mouth or throat.

How Should I Take RAGWITEK?

Take RAGWITEK exactly as your doctor tells you.

RAGWITEK is a prescription medicine that is placed under the tongue.

- Take the tablet from the blister package 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.

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

Take the first tablet of RAGWITEK in your doctor's office. After taking the first tablet, you will be watched for at least 30 minutes for symptoms of a serious allergic reaction.

If you tolerate the first dose of RAGWITEK, you will continue RAGWITEK therapy at home by taking one tablet every day.

Take RAGWITEK as prescribed by your doctor until the end of the treatment course. If you forget to take RAGWITEK, do not take a double dose. Take the next dose at your normal scheduled time the next day. If you miss more than one dose of RAGWITEK, contact your healthcare provider before restarting.

What are the Possible Side Effects of RAGWITEK?

The most commonly reported side effects were itching of the mouth, lips, or tongue, swelling under the tongue, or throat irritation. These side effects, by themselves, were not dangerous or life-threatening.

RAGWITEK can cause severe allergic reactions that may be life-threatening. Symptoms of allergic reactions to RAGWITEK include:

- Trouble breathing
- Throat tightness or swelling
- Trouble swallowing or speaking
- Dizziness or fainting
- Rapid or weak heartbeat
- Severe stomach cramps or pain, vomiting, or diarrhea
- Severe flushing or itching of the skin

For additional information on the possible side effects of RAGWITEK talk with your doctor or pharmacist. You may report side effects to the U.S. Food and Drug Administration (FDA) at 1-800-FDA-1088 or www.fda.gov/medwatch.

How Should I Store RAGWITEK?

Keep RAGWITEK out of the reach of children.

Throw away any unused RAGWITEK after the expiration date which is stated on the carton and blister pack after "EXP."

Store RAGWITEK in a dry place at room temperature, 15ºC to 30ºC (59ºF to 86ºF), in the original package.

General Information about RAGWITEK

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use RAGWITEK for a condition for which it was not prescribed. Do not give RAGWITEK to other people, even if they have the same symptoms. It may harm them.

This Medication Guide summarizes the most important information about RAGWITEK. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about RAGWITEK that was written for healthcare professionals. For more information, go to: www.ragwitek.com or call 1-800-622-4477 (toll-free).

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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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