

MEDICATION GUIDE

GRASTEK® (GRAS-tek) (Timothy Grass Pollen Allergen Extract)

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

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

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

- 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 GRASTEK, your doctor will prescribe auto-injectable epinephrine, a medicine you can inject if you or your child has a severe allergic reaction after taking GRASTEK. 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 GRASTEK?

GRASTEK is a prescription medicine used for sublingual (under the tongue) immunotherapy to treat Timothy and related grass pollen allergies that can cause sneezing, runny or itchy nose, stuffy or congested nose, or itchy and watery eyes. GRASTEK may be prescribed for persons 5 through 65 years of age who are allergic to grass pollen.

GRASTEK is taken for about 12 weeks before grass pollen season and throughout grass pollen season. GRASTEK may also be taken daily for 3 years to provide a sustained effect for a fourth year in which you do not have to take GRASTEK.

GRASTEK is NOT a medication that gives immediate relief for symptoms of grass allergy.

Who Should Not Take GRASTEK?

You or your child should not take GRASTEK if:

- You or your child has severe, unstable or uncontrolled asthma
- You or your child had a severe allergic reaction in the past that included any of these symptoms:
 - Trouble breathing
 - Dizziness or fainting
 - Rapid or weak heartbeat

- You or your child has ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before.
- You or your child has ever been diagnosed with eosinophilic esophagitis.
- You or your child is allergic to any of the inactive ingredients contained in GRASTEK. The inactive ingredients contained in GRASTEK are: gelatin, mannitol and sodium hydroxide.

What Should I Tell My Doctor Before Taking GRASTEK?

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

- You or your child has asthma, depending on how severe it is.
- You or your child suffers from lung disease such as chronic obstructive pulmonary disease (COPD)
- You or your child suffers from heart disease such as coronary artery disease, an irregular heart rhythm, or you have hypertension that is not well controlled.
- You or your daughter is pregnant, plans to become pregnant during the time you will be taking GRASTEK, or is breast-feeding.
- You or your child is unable or unwilling to administer auto-injectable epinephrine to treat a severe allergic reaction to GRASTEK.
- You or your child is 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 or your child is 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 or your child is taking or has 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 GRASTEK. Ask your doctor or pharmacist for advice before taking GRASTEK.

Are there any reasons to stop taking GRASTEK?

Stop GRASTEK and contact your doctor if you or your child has any of the following after taking GRASTEK:

- 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 GRASTEK 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 GRASTEK?

Take GRASTEK exactly as your doctor tells you.

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

If you tolerate the first dose of GRASTEK, you or your child will continue GRASTEK therapy at home by taking one tablet every day. Children should be given each tablet of GRASTEK by an adult who will watch for any symptoms of a serious allergic reaction.

Take GRASTEK as prescribed by your doctor until the end of the treatment course. If you forget to take GRASTEK, 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 GRASTEK, contact your healthcare provider before restarting.

What are the possible side effects of GRASTEK?

In children and adults, 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.

GRASTEK can cause severe allergic reactions that may be life-threatening. Symptoms of allergic reactions to GRASTEK 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
- High-pitched unusual breathing sound that could be a sign of trouble breathing

For additional information on the possible side effects of GRASTEK, 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 GRASTEK?

Keep GRASTEK out of the reach of children.

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

Store GRASTEK in a dry place at room temperature, 15°C to 30°C (59°F to 86°F), in the original package.

General information about GRASTEK

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

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

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

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