



New Treatment for House Dust Mite (HDM) – Induced Allergic Rhinitis Now Available in US

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Global pharmaceutical company, ALK today announced that its sublingual allergy immunotherapy (SLIT) tablet ODACTRA™ is now available through prescription in the US for those 18 years through 65 years of age who suffer from house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis.

Allergic rhinitis affects as many as 50 million Americans. It is estimated that up to 50% of these patients could be sensitized to house dust mites. HDM is the most prevalent indoor allergen in the US with 84% of homes having detectable levels of the allergen. Symptoms that result can be present year-round. In some cases, these adults may have symptoms that are not well controlled, experiencing persistent moderate to severe symptoms despite the use of symptom-relieving medications.

For some of these patients, ODACTRA may be a relevant treatment option that can reduce the symptoms of house dust mite induced allergic rhinitis as well as the need for symptom-reducing medications.

ODACTRA is a prescription medicine used for sublingual (under the tongue) immunotherapy to treat house dust mite allergies that can cause sneezing, runny or itchy nose, stuffy or congested nose, or itchy and watery eyes. ODACTRA may be prescribed for persons 18 through 65 years of age who are allergic to house dust mites. ODACTRA is NOT a medication that gives immediate relief for symptoms of house dust mite allergy.

According to Bradley Chipps, MD, practicing Allergist & Immunologist and current President of American College of Allergy, Asthma and Immunology, *“The introduction of ODACTRA, a fast dissolving immunotherapy tablet for the treatment of dust mite allergy, provides another treatment option for physicians and patients. Many patients find traditional immunotherapy, by shots, to be inconvenient. ODACTRA, is an effective, once a day tablet that provides another option for those patients who could benefit from immunotherapy.”*

ODACTRA is the first HDM SLIT-tablet to be approved for use in the US and its safety and efficacy were evaluated in the world's largest allergy immunotherapy clinical trial program, involving more than 6,000 patients.

David Skoner, MD, a practicing Allergist & Immunologist from Pittsburgh, PA, states, *“Allergic rhinitis due to house dust mite sensitivity can have a significant impact on a patient's quality of life. Patients may suffer from nasal and eye symptoms that can interrupt sleep, impact daily activities and result in lost work and school days. Allergy immunotherapy is widely recognized as an effective way of treating the underlying cause of allergic disease. With the availability of ODACTRA, HDM-induced allergic rhinitis patients can now be prescribed FDA-approved immunotherapy that does not require injections administered by a healthcare professional. Such a therapy is ideal for busy people, who lack time and previously lacked access to a convenient form of allergen immunotherapy”.*

Patients should consult their allergy specialist to find out whether ODACTRA is an option for them.

Selected Important Safety Information about ODACTRA

ODACTRA can cause severe allergic reactions that may be life-threatening. Symptoms of allergic reaction to ODACTRA 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

If any of these symptoms occur, stop taking ODACTRA and immediately seek medical care. If you forget to take ODACTRA, do not take two tablets. Take the next tablet at your normal scheduled time the next day. If you miss more than one tablet of ODACTRA, contact your doctor before restarting. For home administration of ODACTRA, your doctor should prescribe auto-injectable epinephrine to treat a severe reaction, should one occur. Your doctor will train and instruct you on the proper use of auto-injectable epinephrine.

Do not take ODACTRA 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 in ODACTRA.

Your doctor may decide that ODACTRA 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 ODACTRA, or are breast-feeding.
- You are unable or unwilling to administer auto-injectable epinephrine to treat a severe allergic reaction to ODACTRA.
- 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).
- If 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.

Stop taking ODACTRA and contact your doctor if you have any mouth surgery procedures (such as tooth removal), develops any mouth infections, ulcers or cuts in the mouth or throat, or have heartburn, difficulty swallowing, pain with swallowing, or chest pain that does not go away or worsens.

The most commonly reported side effects were throat irritation/tickle, itching in the mouth or ears, swelling of the back of the mouth, lips or tongue. These side effects, by themselves, are generally not dangerous or life-threatening.

For more information on ODACTRA, visit ODACTRA.com for full Prescribing Information, including Boxed Warning and Medication Guide.

About house dust mite allergy

House dust mites (HDM) are the most common cause of allergy in the world. HDM-induced allergy is estimated to affect around 90 million people in Europe, North America and Japan, and more than 100 million in China.

About ALK

ALK is a global specialty pharmaceutical company focused on allergy and allergic asthma. It markets allergy immunotherapy treatments and other products and services for people with allergy and allergy doctors. Headquartered in Hørsholm, Denmark, ALK employs around 2,300 people worldwide and is listed on Nasdaq Copenhagen. Find more information at www.alk.net.

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