

MEDICATION GUIDE
ODACTRA™ (OH-dack-trah)
House Dust Mite (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) Allergen Extract
Sublingual Tablets

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

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

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

- 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 ODACTRA, your doctor will prescribe epinephrine, a medicine you can use if you or your child has a severe allergic reaction after taking ODACTRA. Your doctor will train and instruct you on the proper use of epinephrine.

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

What is ODACTRA?

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 5 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.

Who Should Not Take ODACTRA?

You or your child should not take ODACTRA if you or your child:

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

What Should I Tell My Doctor Before Taking ODACTRA?

Your doctor may decide that ODACTRA is not the best treatment if you or your child:

- has asthma, depending on how severe it is.
- suffers from lung disease such as chronic obstructive pulmonary disease (COPD).
- suffers from heart disease such as coronary artery disease, an irregular heart rhythm, or you or your child has hypertension that is not well controlled.

- is pregnant, plans to become pregnant during the time you will be taking ODACTRA, or is breast-feeding.
- is unable or unwilling to administer epinephrine to treat a severe allergic reaction to ODACTRA.
- 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).
- 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 ODACTRA. Ask your doctor or pharmacist for advice before taking ODACTRA.

ODACTRA is not indicated for use in children under 5 years of age or adults over 65 years of age.

Are there any Reasons to Stop Taking ODACTRA?

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

- 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 ODACTRA following mouth surgery procedures (such as tooth removal), tooth loss or if you or your child develops any mouth infections, ulcers or cuts in the mouth or throat to allow complete healing.

How Should I Take ODACTRA?

Take ODACTRA exactly as your doctor tells you.

ODACTRA 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 where it will dissolve within 10 seconds. Do not swallow for at least 1 minute.
- Do not take ODACTRA 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 ODACTRA in the prescribing 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 tablet of ODACTRA, you or your child will continue ODACTRA therapy at home by taking one tablet every day. Children should be given each tablet of ODACTRA by an adult who will watch for any symptoms of a serious allergic reaction.

Take ODACTRA every day for as long as your doctor prescribes it, even if you have no allergy symptoms.

If you or your child forgets to take ODACTRA, do not take two tablets. Take the next tablet at your normal scheduled time the next day. If you or your child misses more than one dose of ODACTRA, contact your healthcare provider before restarting.

You or your child may begin to have relief of your house dust mite allergy symptoms within 2 to 3 months of starting ODACTRA.

What are the Possible Side Effects of ODACTRA?

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, tongue pain, nausea, throat swelling, stomach pain, tongue ulcer/sore on the tongue, and mouth ulcer/sore in the mouth, diarrhea, vomiting, and food tastes different. These side effects, by themselves, were not dangerous or life-threatening. Typically, these common side effects begin within the first week of starting ODACTRA and may reoccur for up to two weeks. These common side effects experienced after taking the first tablet typically last up to one hour.

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

For additional information on the possible side effects of ODACTRA 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 ODACTRA?

Keep ODACTRA out of the reach of children.

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

Store ODACTRA in a dry place at room temperature, 20°C to 25°C (68°F to 77°F), in the original package.

General Information about ODACTRA

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

This Medication Guide summarizes the most important information about ODACTRA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about ODACTRA that was written for healthcare professionals.

For more information, go to: www.ODACTRA.com or call 1-855-782-9323 (toll-free).

Manufactured for: ALK-Abelló A/S

ALK-Abelló A/S, Bøge Allé 6-8, DK-2970 Hørsholm, Denmark

U.S. License No. 1292

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

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