

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.

Before prescribing ODACTRA, please read the Boxed WARNING, full <u>Prescribing Information</u>, and <u>Medication Guide</u>, for additional Important Safety Information.



farinae and Dermatophagoides pteronyssinus) Allergen Extract
Tablet for Sublingual Use 12 SQ-HDM



House dust mites—they're almost everywhere!

Your doctor may have talked to you about house dust mites (HDMs), which are tiny bug-like creatures. HDMs are everywhere around your home, but they're so small that you can't see them. About half of people with allergies are allergic to dust mites.

NEARLY 50% OF PEOPLE WITH ALLERGIES ARE ALLERGIC TO DUST MITES.

NEARLY 70% OF INNER-CITY TEENS WITH ALLERGIES REPORT A SENSITIVITY TO HOUSE DUST MITES.

Can I get rid of HDMs?

Unfortunately, **it's very hard to get rid of HDMs or even to reduce their number**. Vacuuming or using air filters may help, but only a little bit. That's because they may be on your furniture, bedding, carpeting, clothes, and more. But this does not mean your house is dirty.

HDMs like your home because

- The temperature and humidity inside are just right for them
- They eat the flakes of skin that people and pets constantly shed around the home

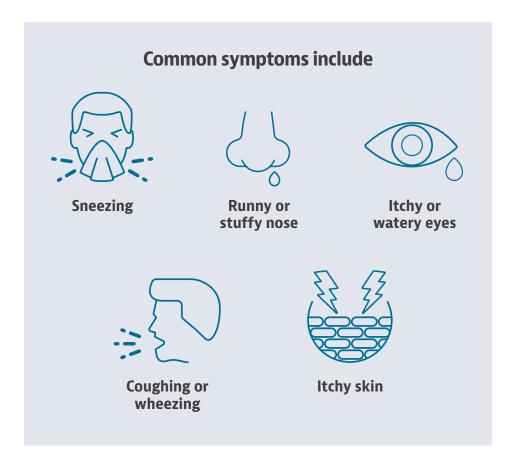


DID YOU KNOW?

HDM allergies can add on to the symptoms caused by seasonal allergies, making the overall effect even worse

What is house dust mite allergy?

House dust mites (HDMs) cause many people to have allergy symptoms, or allergic reactions. They are in your home all the time and there is no way to fully get rid of them.



An allergic reaction happens when your body comes into contact with substances you are sensitive to (allergens), and your immune system overreacts.

How do I know if I have HDM allergy?

Because HDM allergy symptoms are just like cold symptoms, people who are allergic may think they just have a cold. HDM allergy can flare up in the fall when the weather gets colder and you turn on the heat, which may stir up HDM particles in your home but you may have symptoms all year long.



Can I test for HDM allergy?

Only a healthcare professional can find out if you have HDM allergy. They may do a skin prick test or a blood test to find out.

For a skin prick test, your doctor puts a small amount of dust mite allergen—the part that causes allergy symptoms—into your skin to see how your skin reacts. A raised bump or red spot (called a hive or wheal) may appear in a few minutes. Your allergy specialist will likely test for other allergies at the same time.

A blood test can also be done to find out if you have HDM allergy. It may take a few days to get the results.

Are HDMs dangerous?

HDMs are not dangerous. They don't bite, sting, or carry diseases. But HDMs can be a big problem if you're allergic to them, making you feel like you have a cold year round.

HOW ARE HDM ALLERGIES TREATED?

While there are many medicines you can buy over-the-counter (OTC) to treat the symptoms of HDM allergy, **these medicines do not treat the cause of HDM allergies.**

ODACTRA is a different type of medicine that can actually help **change the way your body reacts** to HDMs over time. ODACTRA is a type of treatment called "allergy immunotherapy" (im-yuh-noh-thAIR-uh-pee).

Because it's taken under the tongue, it's also called a "sublingual immunotherapy tablet" (SLIT-tablet, for short).



Selected Important Safety Information about ODACTRA

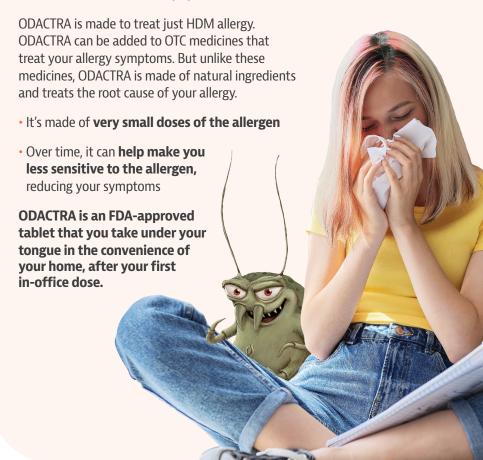
What is the most important information I should know about ODACTRA?

- ODACTRA can cause severe allergic reactions that may be life-threatening.
 If any of these symptoms occur, stop taking ODACTRA and immediately seek medical care:
 - 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

Please see full <u>Prescribing Information</u>, including Boxed WARNING and <u>Medication Guide</u>, for additional Important Safety Information.



HOW DOES ALLERGY IMMUNOTHERAPY WORK?



Selected Important Safety Information about ODACTRA (continued)

• 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.



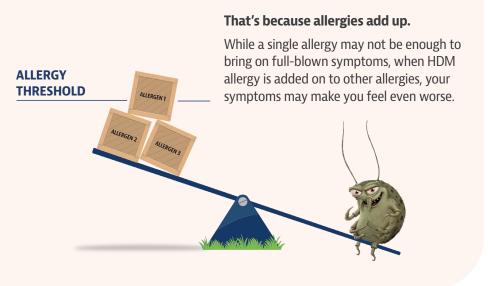
WHAT IS ODACTRA?

ODACTRA is a prescription allergy immunotherapy tablet that treats HDM allergy directly. You take ODACTRA every day to help change the way your body reacts to HDMs. ODACTRA is not meant to relieve allergy symptoms immediately. It can take some time to take effect.

HOW DOES ODACTRA WORK?

ODACTRA treats the cause of your HDM allergy.

By taking a tablet every day, your body may become less sensitive to HDMs over time. ODACTRA only works on HDM allergy, but it can be used even if you're allergic to things besides HDMs.



Selected Important Safety Information about ODACTRA (continued)

 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.

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HOW CAN ODACTRA HELP ME?



As a form of allergy immunotherapy, ODACTRA may help change how your body reacts to HDM allergy over time, which results in:





ODACTRA was studied in people with HDM allergy. Many of those people were also allergic to other things.



In a clinical trial, ODACTRA was shown to reduce symptoms after 8 weeks. Other allergy immunotherapy options for HDM allergy may require you to start with smaller doses and work your way up, which can take up to a year.

Want to learn more? Visit ODACTRA.com

Selected Important Safety Information about ODACTRA (continued)

- Do 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.



HOW DO I START ODACTRA?

If everything goes well with your first dose, you can take the rest of your doses at home—one tablet, every day, all year round.

HERE'S HOW TO TAKE IT...



With dry hands, carefully remove the foil and then the tablet from the blister pack.



Place the tablet under your tongue. It will dissolve in 10 seconds. DO NOT swallow for at least 1 minute. Wash your hands after handling the tablet.



Don't take the tablet with food or beverage.
Don't have anything to eat or drink for at least
minutes after taking the tablet. Children should
be given each tablet by an adult and observed for
any symptoms of a serious allergic reaction.

Selected Important Safety Information about ODACTRA (continued)

- 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 have hypertension that is not well controlled
 - is pregnant, plan to become pregnant during the time you will be taking ODACTRA, or are breast-feeding
 - is unable or unwilling to administer epinephrine to treat a severe allergic reaction to ODACTRA
 - 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

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Selected Important Safety Information about ODACTRA (continued)

- 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:
 - \cdot 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)



House Dust Mite (*Dermatophagoides* farinae and *Dermatophagoides* pteronyssinus) Allergen Extract
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SAVE ON ODACTRA WITH THE ALK SAVINGS PROGRAM

You may be able to lower the price of your ODACTRA prescription when you sign up for the ALK Savings Program before you pick up your medicine. And, by filling your prescription at an ALK Network Pharmacy, your cost could be even lower.

Learn more and sign up at ALKSavings.com



Patient Terms and Conditions: This offer is good for eligible patients purchasing ALK allergy immunotherapy tablets from an authorized retailer or distributor in the United States or its territories and may not be used for any other product. This offer is not insurance and is not valid for prescriptions purchased under Medicaid, Medicare, TRICARE or similar federal or state programs or for patients who are Medicare eligible and enrolled in an employer-sponsored group waiver health plan or government-subsidized prescription drug benefit program for retirees. Offer not valid where prohibited by law, or restricted. Your offer has its own unique ID number. This offer is not transferable, is limited to one per person and may not be combined with any other offer. Offer must be presented along with a valid prescription for ALK allergy immunotherapy tablets at the time of purchase. ALK reserves the right to change or discontinue this offer at any time without notice. If you have questions, please contact customer support at 1-877-643-8469.

Selected Important Safety Information about ODACTRA (continued)

- Stop taking ODACTRA and contact your doctor if you or your child has have any mouth surgery
 procedures (such as tooth removal), develop any mouth infections, ulcers or cuts in the mouth
 or throat, or has heartburn, difficulty swallowing, pain with swallowing, chest pain that
 does not go away or worsens, asthma or any other breathing condition that worsens,
 or any type of serious allergic reaction.
- 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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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