

House dust mites can cause allergic rhinitis...

Treat it in a different way



Indication

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.

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



ODACTRA™
House Dust Mite (*Dermatophagoides
farinae* and *Dermatophagoides
pteronyssinus*) Allergen Extract
Tablet for Sublingual Use 12 SQ-HDM

**Before taking ODACTRA, please read
the enclosed Boxed WARNING, full Prescribing
Information, and Patient Medication Guide.**

If allergic rhinitis is making you miserable, **it could be due to house dust mites**



Depending on its age, your mattress may house **BETWEEN 100,000 AND 10 MILLION HOUSE DUST MITES.**

Allergic rhinitis [rhi-**ni**-tis] is also known as hay fever. It occurs when you come in contact with an allergen (substance that causes allergic reactions). In millions of cases, house dust mites are the cause of this allergy.

House dust mites are too small to be seen by the human eye and can live almost anywhere. They're especially fond of warm, humid environments. They feed on the tiny flakes of skin you shed every day. That makes carpets, bedding, and upholstery some of their favorite spots.

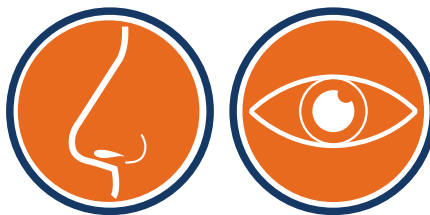
House dust mites love your home almost as much as you do. Getting them to leave is nearly impossible.

If you have allergic rhinitis due to house dust mites, you're not alone.

Nearly 4 out of 5 households in the United States contain detectable levels of house dust mites. When you come in contact with house dust mites, your immune system releases chemicals to fight them. This is what causes your symptoms. Since house dust mites live in your home year-round, treatment is necessary all year long.

Allergic rhinitis
due to house dust
mites can make you
feel like you have a
**cold that lasts
all year long.**

Symptoms can include stuffy nose, runny nose, itchy nose,
sneezing, and itchy and watery eyes.



While you may suffer from many allergies, one allergy may be more prevalent. This allergy could cause the strongest reaction by your immune system.

Read on to learn more about a treatment option that may be right for you.



ODACTRA is not like anything you've taken before for your house dust mite allergies

"Allergy shots work well, but they just don't fit my schedule.

I'D RATHER TREAT MY ALLERGIES WITH SOMETHING THE DOCTOR GIVES ME TO TAKE AT HOME."

Roy, 58

Image portrayed is not an actual patient.

What is allergy immunotherapy?

- Allergy immunotherapy [im-mu-no-**ther**-a-py] is a long-term treatment (3-5 years) that desensitizes your immune system to the cause of your allergic symptoms
- It is the only treatment that addresses the underlying cause of allergy symptoms
- Managing your main allergy with a targeted medicine can reduce the overall impact of your allergic symptoms
- Allergy immunotherapy works gradually, so you might not see results right away

What is ODACTRA?

ODACTRA is a once-daily sublingual (under the tongue) immunotherapy tablet that you take at home, year-round, for your house dust mite allergy. It's not an allergy shot. And it's not an over-the-counter medication that just relieves your allergy symptoms. It works differently.

Over time, ODACTRA helps treat the underlying cause of your house dust mite allergy and helps reduce your symptoms. This means it may also decrease your need for symptom-reducing medications, such as antihistamines and nasal corticosteroids.

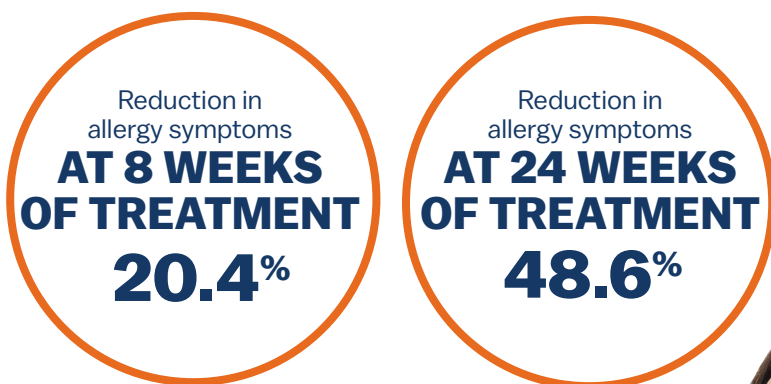
Selected Important Safety Information about ODACTRA (continued)

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.

ODACTRA works with your body to gradually help you become more tolerant to house dust mites. It also helps reduce nose and eye symptoms, such as stuffy nose, runny nose, itchy nose, sneezing, and itchy and watery eyes. ODACTRA should be taken every day because it works gradually, over time, to help your body become more tolerant to house dust mites.

Be sure to speak with your health care provider about how long you will need to take ODACTRA. This will depend on your response to therapy.

*In a clinical trial of patients with allergic rhinitis due to house dust mites held in a controlled environment, ODACTRA produced**



“When I first experienced allergic symptoms, I tried drugstore products. But my symptoms always came back.

ODACTRA TREATS THE CAUSE OF MY ALLERGY AND THAT’S GREAT.”

Allison, 19



Image portrayed is not an actual patient.

*Nolte H et al. *J Allergy Clin Immunol*. 2015;135(6):1494-1501.e6.

Selected Important Safety Information about ODACTRA (continued)

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.

Before taking ODACTRA, please read the enclosed Boxed WARNING, full Prescribing Information, and Patient Medication Guide.



ODACTRA™
House Dust Mite (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) Allergen Extract
Tablet for Sublingual Use 12 SQ-HDM

ODACTRA is not like anything you've taken before for your allergies

What should I know about side effects when **taking ODACTRA**?

Since treatment with ODACTRA involves an allergen, it's possible that you may have a local allergic reaction, such as itching or swelling in the mouth. These reactions may start within minutes of your first dose of ODACTRA. However, it's likely they will not last long and should resolve with continued treatment.

In clinical trials, the most frequent side effects included itching in the ear and mouth, swelling at the back of the mouth, swelling of the lips and tongue, nausea, tongue pain and tongue ulcers, stomach pain, mouth ulcers, food tasting different, throat irritation, and throat swelling.

As with all allergy immunotherapies, auto-injectable epinephrine [epi-**neph**-rine] is used to manage any serious reactions that may occur, such as anaphylaxis [an-a-phy-**lax**-is]. Anaphylaxis can include

- Trouble breathing
- Nausea
- Diarrhea
- Dizziness
- Vomiting
- Hives
- Throat tightness

Before starting ODACTRA, talk to your health care provider about how to properly identify a serious allergic reaction and take appropriate action.

Selected Important Safety Information about ODACTRA (continued)

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)



Selected Important Safety Information about ODACTRA (continued)

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

- 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

Before taking ODACTRA, please read the enclosed Boxed WARNING, full Prescribing Information, and Patient Medication Guide.



ODACTRA™
House Dust Mite (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) Allergen Extract
Tablet for Sublingual Use 12 SQ-HDM

ODACTRA is not like anything you've taken before

How do I **start ODACTRA**?

Your first dose of ODACTRA will be given to you in your medical professional's office so that you can be observed (for at least 30 minutes). This is to make sure you don't have a serious allergic reaction. If you tolerate your first dose, you can take the rest of your doses at home—one tablet, every day, all year round. Please see the illustrations below to help you learn how to take ODACTRA.

How do I take ODACTRA at home?



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



- Place the tablet under your tongue. It will dissolve within 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 5 minutes after taking the tablet

Selected Important Safety Information about ODACTRA (continued)

Stop taking ODACTRA and contact your doctor if you have any mouth surgery procedures (such as tooth removal), develop 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.

Remember to take your ODACTRA tablet every day.

Keep in mind that because ODACTRA is an allergy immunotherapy, it makes you less likely to react to house dust mites. This is why you should continue to take ODACTRA every day, so that your immune system “remembers” not to react to house dust mites and you continue to avoid allergic symptoms.



Selected Important Safety Information about ODACTRA (continued)

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.

Before taking ODACTRA, please read the enclosed Boxed WARNING, full Prescribing Information, and Patient Medication Guide.



ODACTRA™
House Dust Mite (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) Allergen Extract
Tablet for Sublingual Use 12 SQ-HDM



A choice to find relief from house dust mite allergies

- ODACTRA is a tablet that dissolves under your tongue to treat the underlying cause of your allergic symptoms
- After the first dose, you take ODACTRA at home—one tablet, every day, all year round
- ODACTRA provided effective, well-tolerated, year-round therapy in clinical studies



Prescription savings information is available for eligible commercially insured patients at [odactra.com](https://www.odactra.com).

Indication

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.

Before taking ODACTRA, please read the enclosed Boxed WARNING, full Prescribing Information, and Patient Medication Guide.



Copyright ©2017 All rights reserved.
ALK, Inc. ODA-US-17-000022-000 10/17



ODACTRA™
House Dust Mite (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) Allergen Extract
Tablet for Sublingual Use 12 SQ-HDM