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info@reachmd.com  
(866) 423-7849

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## Addressing House Dust Mite Allergies in Pediatric Patients

### ReachMD Announcer:

Welcome to *Clinician's Roundtable* on ReachMD.

This medical industry feature, titled "Addressing House Dust Mite Allergies in Pediatric Patients," is sponsored by ALK.

Here's your host, Dr. Jennifer Caudle.

### Dr. Caudle:

This is *Clinician's Roundtable* on ReachMD, and I'm your host, Dr. Jennifer Caudle. Today, we'll explore early recognition and intervention strategies for pediatric patients five years and older with house dust mite-induced allergic rhinitis. Joining me for our discussion today is Dr. Payel Gupta, a triple board-certified allergist and immunologist who's the Director of Allergy and Immunology at Tono Health. She's also an Assistant Clinical Professor at SUNY Downstate Medical Center and a Clinical Instructor at Mt. Sinai Medical Center in New York City. Dr. Gupta, welcome to the program.

### Dr. Gupta:

Thank you, I'm looking forward to our discussion today.

### Dr. Caudle:

Well, let's dive right in. As I understand it, pediatric patients with allergic rhinitis are commonly managed in primary care settings with symptomatic medications. From your perspective, Dr. Gupta, what role does symptom management typically play in treating allergic rhinitis, and where does immunotherapy fit into the picture?

### Dr. Gupta:

That's such an important question because primary care and pediatric healthcare professionals who are experienced in diagnosis and treatment of allergic rhinitis are often where children present first with allergic rhinitis symptoms that can mimic frequent colds, like nasal congestion, sneezing, and itchy eyes.<sup>1,2</sup>

And because the symptoms are ongoing and often normalized over time, both families and providers may not fully recognize just how much allergic rhinitis is affecting a child's life. Kids might not verbalize symptoms the same way adults do, but the impact on their daily life is very real.<sup>1</sup>

For example, house dust mite-induced allergic rhinitis can disrupt sleep, impair concentration at school, and even affect participation in sports or social activities.<sup>1</sup>

Now, while medications like antihistamines or intranasal corticosteroids are commonly used, for some patients they may not be enough to control symptoms.<sup>3-5</sup> Allergy immunotherapy works by introducing small amounts of allergens into the body so the immune system can gradually learn to tolerate them better.<sup>6</sup> By targeting the specific, underlying allergy trigger that causes the immune system to overreact, allergy immunotherapy may reduce the overall allergic burden for patients.<sup>7</sup>

Consider house dust mite allergy, which often gets overlooked because it doesn't always present with the obvious seasonal flare-ups we're used to seeing in allergic rhinitis. Instead, we're talking about potential year-round nasal congestion, especially at night or first thing in the morning, and frequent use of symptomatic medications like antihistamines.<sup>2,4,8</sup> This is important because house dust mites are perennial and can heighten sensitivity to other allergens throughout the year.<sup>9,10</sup>

And what many don't realize is that house dust mites are incredibly common—about 84 percent of US homes were shown to have detectable levels.<sup>11</sup> In fact, up to half of patients with allergic rhinitis are sensitized to them, which is why testing is key.<sup>3,12</sup>

Early intervention is key as addressing house dust mite allergy may reduce the impact of allergic rhinitis in children. Targeted treatment can lower the cumulative allergic burden and treating a relevant allergy like house dust mites can help move patients to below their allergy threshold.<sup>7,10</sup>

When evaluating a patient, start with a history and exam to identify whether the patient's symptoms are consistent with allergic rhinitis versus other causes, such as an upper respiratory infection.<sup>13,14</sup> If the presentation is suspect for allergies, then the next step is to identify the allergen. The symptom history can offer clues here. For example, a patient with allergic rhinitis and/or conjunctivitis symptoms year-round, in indoor environments, and worse at bedtime or upon waking may have a house dust mite allergy.<sup>4,7,9</sup> A serum-specific IgE or skin prick test for *Dermatophagoides pteronyssinus* and *D. farinae* can help confirm the diagnosis.<sup>15</sup> And when specific IgE levels are 0.10 kilounits per liter or higher, in combination with a symptom history consistent with the allergen, we'll consider initiating house dust mite-specific immunotherapy in appropriate patients.<sup>6</sup>

Allergen immunotherapy options for house dust mites include subcutaneous injections, which are given in an office setting, and sublingual tablets, which can be administered to appropriate patients as young as five years old at home under the supervision of an adult, after the initial dose is administered in clinic.<sup>12,15</sup>

**Dr. Caudle:**

Now, can you explain what treatment with sublingual immunotherapy might look like—particularly in children—and how it differs from injection immunotherapy?

**Dr. Gupta:**

Absolutely. So sublingual immunotherapy, or SLIT, is a type of allergy desensitization therapy that's taken as a tablet placed under the tongue. It's important to understand how this differs from the more traditional subcutaneous injections.<sup>12</sup>

Injection immunotherapy offers lasting relief from one or more allergens, including pollen, pet dander, and house dust mites.<sup>12</sup> It often requires frequent clinic visits, which can be challenging for families with their busy school, work, and extracurricular activity schedules.<sup>16</sup> And while both approaches require a long-term commitment to achieve meaningful benefit, SLIT offers a more convenient route of administration which may fit better into a family's daily routine.<sup>6</sup>

**Dr. Caudle:**

So I'd like to now zero in on ODACTRA sublingual immunotherapy. Before we do, let's take a moment to hear some important safety information.

**ReachMD Announcer:**

- ODACTRA® is an allergen extract indicated as immunotherapy for the treatment of house dust mite (HDM)–induced allergic rhinitis, with or without conjunctivitis, confirmed by positive in vitro testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or by positive skin testing to licensed house dust mite allergen extracts.
- ODACTRA is approved for use in individuals 5 through 65 years of age.
- ODACTRA is not indicated for the immediate relief of allergic symptoms.

### **WARNING: SEVERE ALLERGIC REACTIONS**

ODACTRA can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal restriction. Do not administer ODACTRA to patients with severe, unstable or uncontrolled asthma. Observe patients in the office for at least 30 minutes following the initial dose. Prescribe epinephrine, instruct and train patients or parents/guardians on its appropriate use, and instruct patients or parents/guardians to seek immediate medical care upon its use. ODACTRA may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction. ODACTRA may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

Additional important safety information will be discussed throughout and at the conclusion of the discussion.

**Dr. Caudle:**

Now that we've heard that important safety information, Dr. Gupta, what do we know about ODACTRA's safety and efficacy profile based on clinical trials in children?

**Dr. Gupta:**

ODACTRA's approval for pediatric patients aged five to 11, was supported by a Phase 3 randomized, double-blind, placebo-controlled trial of nearly 1,500 children. In fact, this was the largest pediatric study of house dust mite immunotherapy to date.<sup>15,17</sup>

The trial included children diagnosed with allergic rhinitis, with or without conjunctivitis, and with or without controlled asthma, who had persistent symptoms despite receiving symptom-relieving medication.<sup>15,17</sup> All study participants could continue using their symptom-relieving medications as needed during the trial. Also of note, 54 percent of study participants were polysensitized, meaning they tested positive to house dust mite and one or more additional common environmental allergens, such as grass, trees, or weeds.<sup>15</sup>

The primary measure was the Total Combined Rhinitis Score, which is a combination of the daily symptom score and daily medication score.<sup>15,17</sup>

Let's review the study results, starting with efficacy. The trial showed a 22 percent reduction in the average Total Combined Rhinitis Score in children aged five to 11 years.<sup>15,17</sup> These results exceeded the 20 percent threshold defined by the World Allergy Organization as clinically meaningful.<sup>18</sup> In addition, symptom improvement was observed as early as week eight.<sup>17</sup>

Additional secondary endpoints include a 22.2 percent reduction in daily symptom scores and a 25.3 percent reduction in daily medication score.<sup>15,17</sup>

A similar effect was noted across patient subgroups that included children with or without controlled asthma, children who were monosensitized to house dust mites, and children who were polysensitized.<sup>17</sup>

**Dr. Caudle:**

Now, let's take a moment to discuss safety. Dr. Gupta, what should we know about the adverse reactions, tolerability, and other safety aspects for ODACTRA in children?

**Dr. Gupta:**

The safety profile of ODACTRA in children is consistent with what we see in adults and adolescents. The most common adverse reactions in patients taking ODACTRA were itching in the mouth at 57.1 percent, throat irritation or tickle in 55.2 percent, and itching in the ear in 32.7 percent. In general the most common treatment-related adverse events were mild or moderate, localized and typically resolved within a few days.<sup>15</sup>

And 1.8 percent of participants discontinued treatment due to adverse reactions.<sup>17</sup>

No serious allergic reactions or anaphylaxis requiring epinephrine were reported in kids aged five to 11.<sup>15,17</sup> No pediatric participants treated with ODACTRA reported<sup>15</sup>:

- treatment-related serious adverse events,
- treatment-related anaphylaxis,
- or adverse reactions treated with epinephrine.

As mentioned earlier, ODACTRA carries a risk for serious allergic reactions, including anaphylaxis and throat tightness. So, patients should have access to epinephrine and know how to use it—and the first dose should always be given in the office under observation.<sup>15</sup>

**Dr. Caudle:**

I'd like to shift gears now and hear your thoughts on implementing ODACTRA in the clinic. But before we do, let's review some additional Important Safety Information.

**Dr. Gupta:**

ODACTRA shouldn't be used in patients with severe or unstable asthma, a history of severe allergic or local reactions to sublingual allergen immunotherapy, eosinophilic esophagitis, or known hypersensitivity to any of its inactive ingredients.

It can cause systemic allergic reactions, including anaphylaxis, and severe local reactions like throat swelling that can compromise breathing. So, patients should be prescribed epinephrine, know how to use it, and understand when to seek emergency care. Treatment should stop if epinephrine is used.

The first dose needs to be given in a healthcare setting under supervision, with patients observed for at least 30 minutes. And if someone has ongoing or worsening mouth or throat symptoms, discontinuation should be considered.

**Dr. Caudle:**

So now that we've reviewed the data on this treatment option, could you share some best practices for initiating ODACTRA in a pediatric or primary care setting?

**Dr. Gupta:**

So once you've completed a history and identified a child with a compatible clinical profile, you can confirm house dust mite sensitization with an exam and history followed by IgE testing with a blood test or skin prick testing. Once confirmed, you're in a good position to have a discussion about ODACTRA as a treatment option.

If the patient and family agree, the first step is to bring the patient and their parent or caregiver into the office for that initial dose under medical supervision. This is a safety requirement for monitoring any immediate hypersensitivity reactions. The observation period is usually around 30 minutes.<sup>15</sup>

At that visit, it's also essential to prescribe rescue epinephrine and properly educate them on when and how to administer it. This is an important precautionary step that's part of the safety protocol for all patients starting SLIT-tablets.<sup>15</sup>

After that first dose, the patient continues treatment at home under parental supervision, taking the sublingual tablet once daily.<sup>15</sup>

Another key piece is education. We spend time during that first visit walking families through the dosing schedule, when to administer epinephrine if needed, and how to recognize and respond to symptoms.<sup>19</sup> The goal is to make sure they leave the office feeling confident about addressing their child's allergic rhinitis.<sup>20</sup>

So from a practical standpoint, it's a feasible option for primary care, especially when there's a clear diagnostic picture and a motivated support system.

**Dr. Caudle:**

As we approach the end of our program, Dr. Gupta, do you have any final thoughts you'd like to share about caring for children with persistent allergic rhinitis symptoms?

**Dr. Gupta:**

I want to emphasize the importance of awareness. If you're seeing a child with persistent, year-round nasal or eye symptoms—especially symptoms that show up indoors or first thing in the morning<sup>4,7,9</sup>—it's time to think beyond just recurrent colds or seasonal triggers.<sup>13,14</sup> If these symptoms aren't resolving with standard symptomatic treatments, consider evaluating for house dust mite allergy, either through serum-specific IgE testing or skin prick testing.<sup>12-14</sup>

And if the test is positive and the symptom pattern fits, you don't necessarily need to wait for a referral to an allergist or immunologist.<sup>16,21</sup> We now have an approved SLIT-tablet option for patients aged five to 65 with ODACTRA.<sup>15</sup> And because pediatricians and primary care clinicians are often the front line in identifying allergic rhinitis in children, early recognition and initiation of SLIT can make a real difference by:

- reducing symptom burden,<sup>17</sup>
- reducing use of symptomatic medications.<sup>17</sup>

**Dr. Caudle:**

Well, that's a great way to round out our conversation today. And I want to thank my guest, Dr. Payel Gupta, for helping us better understand the role of sublingual immunotherapy tablets in managing pediatric allergic rhinitis from house dust mites. Dr. Gupta, it was great speaking with you today.

**Dr. Gupta:**

Thanks for having me. For additional information on ODACTRA, you can visit [odactraHCP.com](https://odactraHCP.com) or email [slittablets@alk.net](mailto:slittablets@alk.net)

**Dr. Caudle:**

For ReachMD, I'm your host Dr. Jennifer Caudle. Please stay tuned to hear some additional Important Safety Information.

**ReachMD Announcer:**

- Eosinophilic esophagitis has been reported in association with sublingual tablet immunotherapy. Discontinue ODACTRA and consider a diagnosis of eosinophilic esophagitis in patients who experience severe or persistent gastro-esophageal symptoms including dysphagia or chest pain.

- Withhold immunotherapy with ODACTRA if the patient is experiencing an acute asthma exacerbation. Re-evaluate patients who have recurrent asthma exacerbations and consider discontinuation.
- ODACTRA has not been studied in participants who are receiving concomitant allergen immunotherapy. Concomitant dosing with other allergen immunotherapy may increase the likelihood of local or systemic adverse reactions to either subcutaneous or sublingual allergen immunotherapy.
- Stop treatment with ODACTRA to allow complete healing of the oral cavity in patients with oral inflammation (e.g., oral lichen planus, mouth ulcers, or thrush) or oral wounds, such as those following oral surgery, tooth loss or dental extraction.
- The most common solicited adverse reactions reported in ≥10% of adult participants (18 through 65 years of age) treated with ODACTRA were throat irritation/tickle, itching in the mouth, itching in the ear, swelling of the uvula/back of the mouth, swelling of the lips, swelling of the tongue, tongue pain, nausea, throat swelling, stomach pain, tongue ulcer/sore on the tongue, mouth ulcer/sore in the mouth, and food tastes different.
- The most common solicited adverse reactions reported in ≥10% of adolescent participants (12 through 17 years of age) treated with ODACTRA were throat irritation/tickle, itching in the mouth, itching in the ear, tongue pain, stomach pain, swelling of the uvula/back of the mouth, swelling of the lips, swelling of the tongue, throat swelling, nausea, tongue ulcer/sore on the tongue, and mouth ulcer/sore in the mouth, and diarrhea.
- The most common solicited adverse reactions reported in ≥10% of pediatric participants (5 through 11 years of age) treated with ODACTRA were itching in the mouth, throat irritation/tickle, itching in the ear, stomach pain, swelling of the lips, tongue pain, food tastes different, nausea (feel like throwing up), swelling in the back of the mouth, swelling of the tongue, and mouth ulcer.
- Available data on ODACTRA administered to pregnant women are insufficient to inform associated risks in pregnancy. Data are not available to assess the effects of ODACTRA on the breastfed child or on milk production and excretion in the nursing woman.

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

This medical industry feature was sponsored by ALK. If you missed any part of this discussion or to find others in this series, visit *Clinician's Roundtable* on ReachMD.com, where you can Be Part of the Knowledge.

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