



**Palforzia**  
Peanut (*Arachis hypogaea*)  
Allergen Powder-dnfp

# Because accidental exposure may be unavoidable:<sup>1</sup> PALFORZIA<sup>®</sup>

The first and only FDA-approved oral immunotherapy (OIT) for children (1 through 17 years) with peanut allergy.<sup>2,3</sup>

The patient images in this document are AI generated and are not real patients treated with PALFORZIA. Individual results will vary with each patient.

## WHAT IS PALFORZIA?

PALFORZIA is a treatment for people who are allergic to peanuts. PALFORZIA can help reduce the severity of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. PALFORZIA may be started in patients aged 1 through 17 years old. If you turn 18 years of age while on PALFORZIA treatment you should continue taking PALFORZIA unless otherwise instructed by your doctor.

PALFORZIA does NOT treat allergic reactions and should not be given during an allergic reaction.

You must maintain a strict peanut-free diet while taking PALFORZIA.

## **PALFORZIA can cause severe allergic reactions called anaphylaxis that may be life-threatening.**

- You will receive your first dose in a healthcare setting under the observation of trained healthcare staff.
- You will receive the first dose of all dose increases in a healthcare setting.
- In the healthcare setting, you will be observed for at least 1 hour for signs and symptoms of a severe allergic reaction.
- If you have a severe reaction during treatment, you will need to receive an injection of epinephrine immediately and get emergency medical help right away.
- You will return to the healthcare setting for any trouble tolerating your home doses.

**Please see additional Important Safety Information throughout this brochure. Find full Prescribing Information and Medication Guide, including an important warning about anaphylaxis at [palforzia.com](https://www.palforzia.com) or scan the QR code on the back of this brochure.**

# Peanuts are perceived as a threat<sup>4</sup>

Understanding the body's response to an allergen

When your child has a peanut allergy, **the immune system mistakenly reacts to peanut as if it is harmful.**<sup>4</sup>

It creates special antibodies called **immunoglobulin E (IgE)** which causes your child's body to have an allergic reaction.<sup>4</sup>



**Common allergic reaction symptoms may include.**<sup>6,5</sup>



**hives**



**vomiting**



**stomach pain or coughing**



**anaphylaxis (a severe life-threatening reaction)**

Peanuts shown are for illustrative purposes only.

## IMPORTANT SAFETY INFORMATION (Continued)

Stop taking PALFORZIA® and get emergency medical treatment right away if you have any of the following symptoms after taking PALFORZIA: trouble breathing or wheezing, chest discomfort or tightness, throat tightness, trouble swallowing or speaking, swelling of your face, lips, eyes, or tongue, dizziness or fainting, severe stomach cramps or pain, vomiting, diarrhea, hives (itchy, raised bumps on skin), or severe flushing of the skin.

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# Many children are impacted by peanut allergy<sup>7</sup>



More than **40%** of children with food allergies have experienced a severe allergic reaction such as anaphylaxis.<sup>9</sup>



**23%** of children with a peanut allergy had 1 peanut-related emergency room (ER) visit within 1 year.<sup>9\*</sup>



A study showed that peanut protein was detected in **7.3%** of products with advisory/precautionary labeling for peanut.<sup>10</sup>

\*In a US representative sample of 38,408 children <18 years with peanut allergy within 1 year (surveyed in 2015–2016).<sup>9</sup>

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# Avoiding peanuts may not be enough

Avoiding foods and other products that contain peanut is essential to protect against the risk of a severe allergic reaction.<sup>6</sup>



It can take **as little as 3 mg** of peanut (~1/100 of a peanut) **for a child to experience an allergic reaction.**<sup>11,12</sup> Keep in mind that one peanut is about 300 mg.<sup>12</sup>

Peanuts shown are for illustrative purposes only.

**Your child may still accidentally eat small amounts of peanut, which may cause an allergic or anaphylactic reaction due to:**



Widespread use of peanuts in common food items<sup>13,14</sup>



Cross-contact in kitchens<sup>15</sup>



Inconsistent food labeling<sup>16</sup>

## IMPORTANT SAFETY INFORMATION (Continued)

Because of the risk of severe allergic reactions, PALFORZIA is only available through a restricted program called the PALFORZIA Risk Evaluation and Mitigation Strategy (REMS) Program. PALFORZIA is a prescription only medication. Talk to your healthcare provider for more information about the PALFORZIA REMS program and how to enroll.

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# Gradually lessening the sensitivity of your child's immune system<sup>2</sup>

While there is no cure for peanut allergy,<sup>17</sup> oral immunotherapy (OIT) is a type of medically-supervised treatment that helps the immune system gradually increase a person's tolerability to peanut.<sup>2,18</sup>

Unlike other ways to manage food allergies, OIT aims to slowly increase the amount of peanut your child can consume in small, controlled doses, so the immune system gradually becomes less sensitive.<sup>18</sup>

STEP

1

Body is gradually exposed to increasing amounts of peanut.<sup>18</sup>

STEP

2

The body's immune system, over time, builds up the threshold of exposure to peanut that may cause a severe allergic reaction.<sup>18</sup>

STEP

3

The immune system becomes less sensitive\*, and allergic reactions may become more mild or may not occur at all, in the event of accidental exposure.<sup>2,18</sup>



Building your child's tolerability to peanut and decreasing their sensitivity may help reduce the risk of a severe reaction due to an accidental exposure.<sup>2,19</sup>

\*Daily immunotherapy must be continued to maintain treatment effect.<sup>2</sup> OIT is not a cure for peanut allergy.<sup>18</sup>

# What is PALFORZIA®?



**PALFORZIA** is the only FDA-approved prescription OIT for people who are allergic to peanuts.<sup>2</sup>



**PALFORZIA** may be started in patients aged 1 through 17 years old.<sup>2</sup>



**PALFORZIA** does NOT treat allergic reactions and should not be given during an allergic reaction.<sup>2</sup>



**PALFORZIA** is intended to gradually decrease your child's sensitivity to small amounts of peanuts that may be hidden in foods.<sup>20</sup>



**PALFORZIA** was proven in clinical studies to reduce the severity of allergic reactions, including anaphylaxis, to peanuts in children 1 through 17 years.<sup>2</sup>



**Your child** must maintain a strict peanut-free diet while taking PALFORZIA, and will need to be prescribed and carry epinephrine at all times.<sup>2</sup>

**PALFORZIA can cause severe allergic reactions called anaphylaxis that may be life-threatening.**

**It is important to speak with your child's allergist regarding any questions about food allergies and/or PALFORZIA and any associated allergic reactions.**

# What is PALFORZIA?

It is an oral peanut allergen powder prescription treatment that is manufactured under strict quality standards to support consistent dosing.<sup>2,20</sup>

**Each batch of PALFORZIA is carefully tested to ensure it contains the right amount of key peanut proteins (Ara h1, Ara h2, and Ara h6) responsible to help train the immune system to gradually reduce sensitivity to peanut.<sup>2,21</sup>**



**Why this matters:**  
These proteins are the **main triggers** of peanut allergies.<sup>21</sup>



Each once-daily dose is pre-packaged to provide **consistent dosing** throughout the treatment.<sup>2</sup>



Manufactured to **FDA-approved** standards.<sup>2</sup>

## IMPORTANT SAFETY INFORMATION (Continued)

You should NOT take PALFORZIA if you have uncontrolled asthma, or if you ever had eosinophilic esophagitis (EoE) or other eosinophilic gastrointestinal disease.

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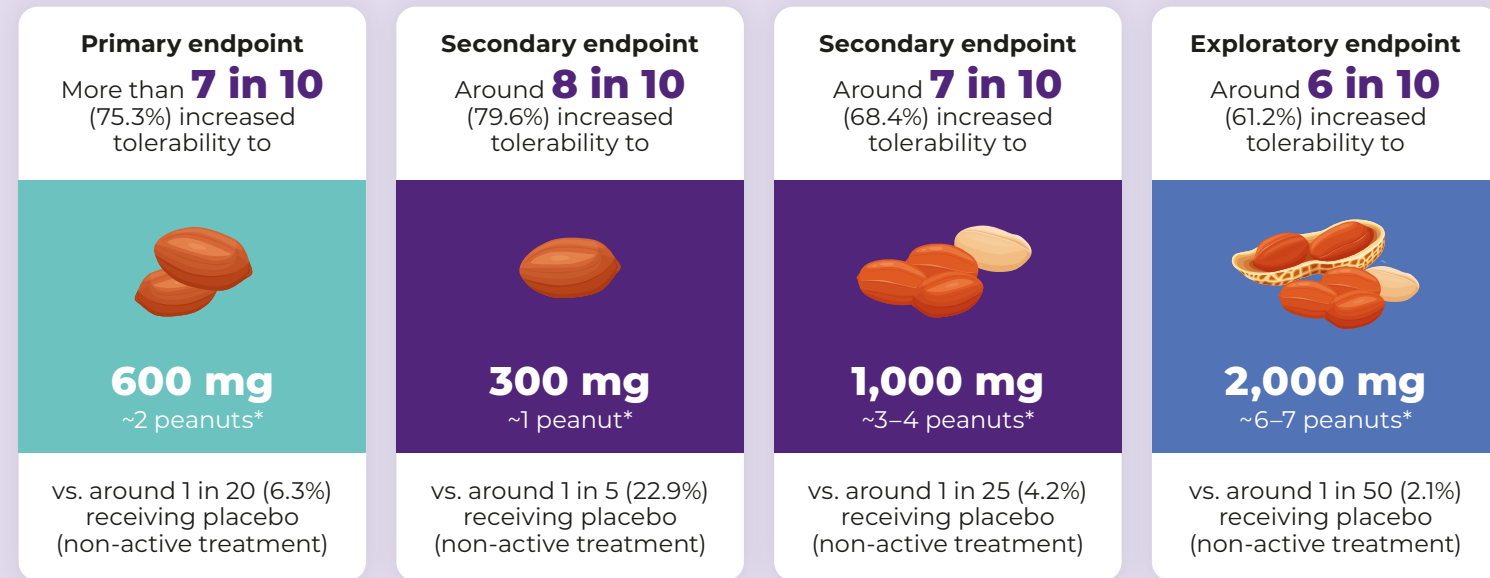
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# Evidence for PALFORZIA®

PALFORZIA can be started in children as young as 1 year old.<sup>22</sup>

**After one year on treatment, toddlers (aged 1 through 3 years):**



PALFORZIA was studied in North America and Europe in 146 toddlers over 12 months. This study was named POSEIDON.<sup>22</sup>

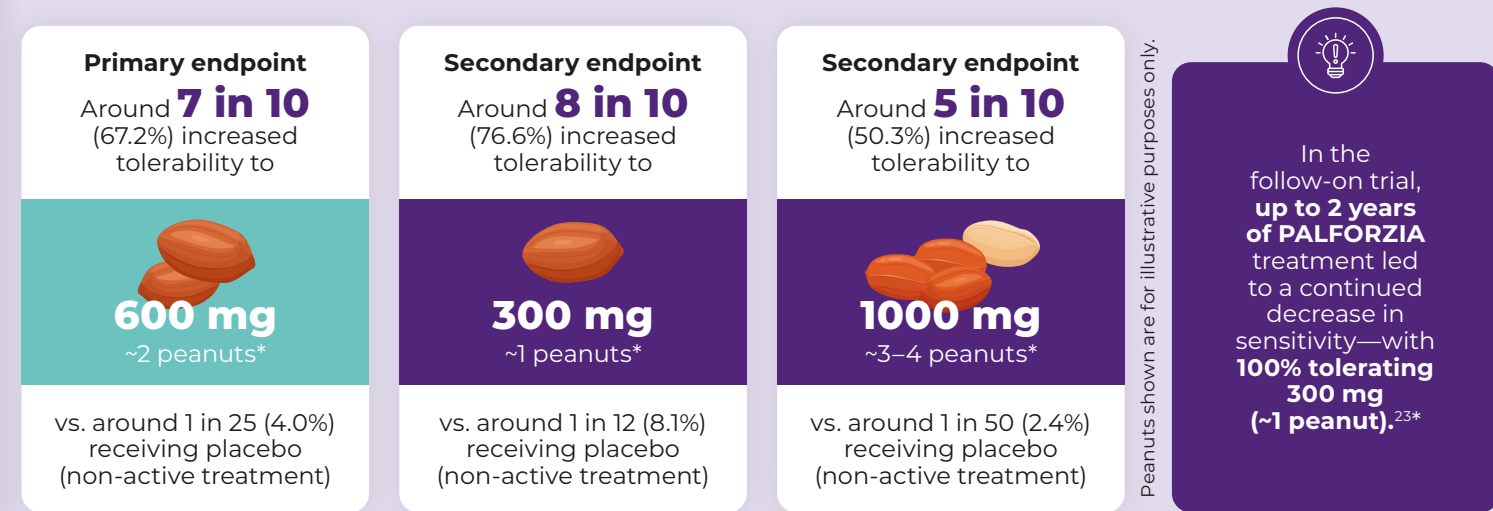
\*One peanut is equivalent to 300 mg.<sup>12</sup>

Peanuts shown are for illustrative purposes only.

**Individual results will vary, continued daily treatment is required to maintain treatment effect. Patients must maintain a peanut free diet while on PALFORZIA treatment.**

PALFORZIA may help reduce the severity of allergic reactions in children and teens following accidental exposure.<sup>12</sup>

**After one year on treatment, children (ages 4 through 17 years):**



Peanuts shown are for illustrative purposes only.

PALFORZIA was studied in North America and Europe in 496 children and teens over 12 months. This study was named PALISADE.<sup>12</sup>

In the open-label PALISADE follow-on, most participants (n=358) continued treatment. Of these, ~100 switched from placebo, while 256 remained on PALFORZIA for up to 2 years.<sup>23</sup>

\*One peanut is equivalent to 300 mg.<sup>12</sup>

## IMPORTANT SAFETY INFORMATION (Continued)

Tell your doctor if you are not feeling well prior to starting treatment with PALFORZIA. Your doctor may decide to delay treatment until you are feeling better. Also tell your doctor about any medical conditions you have and if you are taking or have recently taken any other medicines, including medicines obtained without a prescription and herbal supplements.

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# Understanding the safety of PALFORZIA



PALFORZIA demonstrated a **consistent safety profile** across clinical studies for ages 1 through 17 years.<sup>2</sup>



**PALFORZIA can cause severe allergic reactions called anaphylaxis that may be life-threatening** and can occur at any time during PALFORZIA therapy.<sup>2</sup>



Stop taking PALFORZIA and get emergency medical treatment right away if you have any of the following symptoms after taking PALFORZIA: trouble breathing or wheezing, chest discomfort or tightness, throat tightness, heartburn, trouble swallowing or speaking, swelling of your face, lips, eyes, or tongue, dizziness or fainting, severe stomach cramps or pain, vomiting, or diarrhea, hives (itchy, raised bumps on skin), severe flushing of the skin.<sup>20</sup>



To ensure PALFORZIA is being administered correctly, your child, your child's doctor and their practice has to be enrolled in the **PALFORZIA REMS Program (Risk Evaluation and Mitigation Strategy) before treatment can begin**. This is a special safety program required by the FDA to help reduce the risk of serious allergic reactions like anaphylaxis.



PALFORZIA doesn't make it safe to eat peanuts freely. Your child will still need to avoid peanuts and carry epinephrine at all times.<sup>2</sup>

## IMPORTANT SAFETY INFORMATION (Continued)

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

- You are unwilling or unable to receive (or self-administer) injectable epinephrine.
- You have a condition or are taking a medication that reduces the ability to survive a severe allergic reaction.

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It is important to talk with your child's doctor about any questions or concerns you may have regarding PALFORZIA treatment or any potential side effects.

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# The PALFORZIA® 3-step dosing protocol

PALFORZIA is intended to gradually decrease sensitivity to small amounts of peanuts through a 3-step dosing protocol.<sup>2</sup>

## 1 Initial Dose Escalation<sup>2</sup>

The first dosing day appointment at the doctor's clinic or hospital.

Dosing is gradually increased throughout the day starting at:

- **0.5 mg and ending at 3 mg** in ages 1–3 years
- **0.5 mg and ending at 6 mg** in ages 4–17 years

Your child will be monitored for 20–30 minutes after each dose increase and for 60 minutes after the final dose in this phase.

## 2 Up-Dosing<sup>2</sup>

Starts within 1 to 4 days after Initial Dose Escalation appointment.

Combines clinic or hospital appointments and at-home treatment.

- 1–3 yrs: doses increase from **1 mg to 300 mg**
- 4–17 yrs: doses increase from **3 mg to 300 mg**

PALFORZIA should be taken at approximately the same time each day with a meal.

## 3 Maintenance<sup>2</sup>

**Maintenance**, the final step, involves taking a 300 mg sachet once per day at home.

The **Maintenance** step requires ongoing dosing to help your child sustain reduced sensitivity to peanut allergens.

Your doctor will determine the frequency of follow-up visits and will determine a Maintenance plan\* appropriate for your child.

\*PALFORZIA was studied in clinical trials for a minimum of 6 months of Maintenance treatment.<sup>12,22</sup>

**The Initial Dose Escalation treatment and the first dose of each new dosing level will always take place at the doctor's office, and your child will be monitored closely during these appointments for any allergic or anaphylactic reactions.<sup>2</sup>**

Allergic reactions are more likely to develop within approximately 1 hour of taking PALFORZIA.<sup>23</sup> If a reaction occurs at any point in the treatment protocol, your child's allergist will treat the reaction as needed or may choose to discontinue PALFORZIA. Your child's doctor may adapt the treatment process to your child's unique needs at their discretion.<sup>2</sup> It is important to speak with your child's doctor if you have any questions and to follow their instructions.

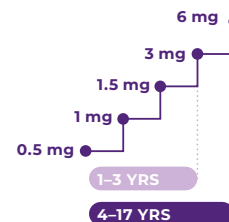
**Remember, PALFORZIA is not a cure for peanut allergy, so it is important to continue to maintain a peanut-free diet and always carry epinephrine.<sup>2</sup>**

## 1 Initial Dose Escalation<sup>2</sup>



**One-time initiation dose appointment in-clinic/hospital**

Approximately 4 hours



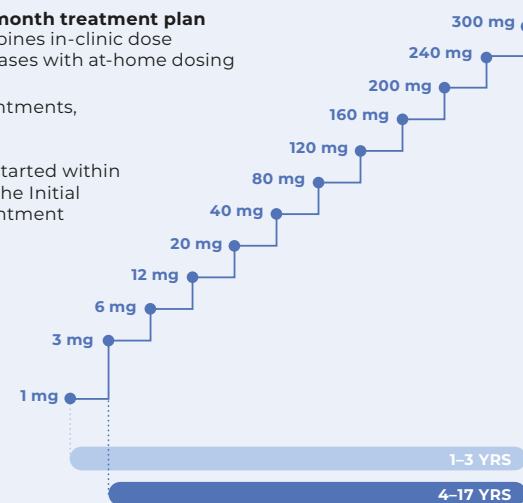
## 2 Up-Dosing<sup>2</sup>



**A 6-month treatment plan**  
Combines in-clinic dose increases with at-home dosing

With 60 minute appointments, about every 2 weeks

Up-Dosing should be started within one to four days after the Initial Dose Escalation appointment



## 3 Maintenance<sup>2</sup>



**An at-home dosing schedule**

300 mg

Continued **Maintenance** dosing is required to maintain treatment effect.

Capsules should not be swallowed.<sup>2</sup>

PALFORZIA® product within the dosed capsules/or sachets should be mixed into cool or room-temperature semi-solid food (pudding, apple sauce, salsa, etc.) and consumed in full to dose.<sup>2</sup>

### IMPORTANT SAFETY INFORMATION (Continued)

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# Accessing PALFORZIA®



Ask your child's doctor if PALFORZIA might be right for your child. If prescribed PALFORZIA, explore programs that can help:



## The PALFORZIA Risk Evaluation and Mitigation Strategy (REMS) Program

Because of the risk of anaphylaxis, PALFORZIA is only available through the PALFORZIA REMS Program. Your child's doctor can provide more information and assist with enrollment.



## The PALFORZIA Pathway™ Support Program

Our PALFORZIA Pathway™ team is available to help you understand your insurance coverage and financial assistance options.

Ask your child's doctor for assistance getting enrolled in PALFORZIA PATHWAY™.



## The PALFORZIA Pathway™ Co-Pay Savings Program\*

Eligible commercially insured patients may pay as little as \$20 per month for PALFORZIA.†

Learn more about enrolling in the PALFORZIA Pathway Co-Pay Savings Program at [www.PalforziaCopoly.com](http://www.PalforziaCopoly.com)



## The PALFORZIA Pathway™ Patient Assistance Program\*

If you do not have insurance coverage or for patients whose insurance does not cover PALFORZIA, you may be able to receive PALFORZIA at no cost if you meet specific eligibility and financial criteria. Call 844-PALFORZ to learn more and to determine eligibility.

## IMPORTANT SAFETY INFORMATION (Continued)

### What are the possible side effects of PALFORZIA?

The most commonly reported side effects of PALFORZIA in ages 1 through 3 years were: cough, sneezing, runny nose, nasal congestion, throat irritation, wheezing, stomach pain, vomiting, diarrhea, itchy mouth, pain in the throat, hives, rash, itchy skin, and/or inflammation of the skin around the mouth.

The most commonly reported side effects of PALFORZIA in ages 4 through 17 years were: stomach pain, vomiting, feeling sick, itching or burning in the mouth, throat irritation, cough, runny nose, sneezing, throat tightness, wheezing, shortness of breath, itchy skin, hives, and/or itchy ears.

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\*Terms and conditions apply.

†There is a maximum benefit per calendar year.

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**It can take as little as 3 mg of peanut (~1/100 of a peanut) for a child to experience an allergic reaction.<sup>11,12</sup>**



**Help reduce the risk of severe reactions, including anaphylaxis, with PALFORZIA®: the first and only FDA-approved OIT for children with peanut allergy.<sup>2,3</sup>**

### Important Safety Information (Continued)

PALFORZIA can cause stomach or gut symptoms including inflammation of the esophagus (called eosinophilic esophagitis). Symptoms of eosinophilic esophagitis can include trouble swallowing, food stuck in throat, burning in chest, mouth, or throat, vomiting, regurgitation of undigested food, or feeling sick.

**Please see additional Important Safety Information throughout. Find full Prescribing Information and Medication Guide, including an important warning about anaphylaxis at [palforzia.com](https://palforzia.com) or scan the QR code to the right.**

References: 1. Muraro A, et al. Clin Transl Allergy. 2021;11:e12064; 2. PALFORZIA [package insert]: Lenoir, NC. Stallergenes Greer; 3. Casale TB, et al. Expert Review of Clinical Immunology. 2022;19:253–265; 4. Husain Z, et al. J Am Acad Dermatol. 2012;66:136–143; 5. Berin MC. Clin Exp Allergy. 2015;45:1483–1496; 6. AAAAI. Available at <https://www.aaaai.org/tools-for-the-public/conditions-library/allergies/peanut-allergy>; 7. Gupta R, et al. Pediatrics. 2011;128:e9–17; 8. Children's Defense. Available at <https://www.childrensdefense.org/tools-and-resources/the-state-of-americas-children-soac-child-population/>; 9. Gupta RS, et al. Pediatrics. 2018;142:e20181235; 10. Hefle SL, et al. J Allergy Clin Immunol. 2007;120:171–6; 11. Baumert JL, et al. J Allergy Clin Immunol Pract. 2018;6:457–465.e4; 12. Vickery BP, et al. N Engl J Med. 2018;379:1991–2001; 13. Lieberman JA, et al. Allergy. 2021;76:1367–1384; 14. Dyer AA, et al. Allergy Asthma Proc. 2015;36:58–6; 15. Miller TA, et al. Ann Allergy Asthma Immunol. 2022;128:439–442; 16. Stankovich GA, et al. Frontiers in Allergy. 2023;4:1060932; 17. National Institutes of Health. Available at <https://www.nih.gov/news-events/nih-research-matters/oral-immunotherapy-peanut-allergy-young-children>; 18. American Academy of Allergy Asthma & Immunology. Available at <https://www.aaaai.org/tools-for-the-public/conditions-library/allergies/the-current-state-of-oral-immunotherapy>; 19. American Academy of Allergy Asthma & Immunology. Available at <https://www.aaaai.org/conditions-treatments/allergies/food-allergy>; 20. Medication Guide. Available at <https://www.palforzia.com/palforzia-med-guide.pdf>; 21. Fernandez-Rivas M, et al. Allergy. 2022;73:991–1003; 22. Du Toit G, et al. NEJM Evid. 2023;2:(11); 23. Vickery, BP, et al. J Allergy Clin Immunol Pract. 2021;9:1879–1889.e13.

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PALFORZIA Pathway™ Patient Hub  
1-844-PALFORZ (1-844-725-3679)  
Mon-Fri: 9 AM to 6 PM EST

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