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

For children or patients ages 1 through 17 years[1]

Early Intervention could transform their tomorrow

building protection from accidental exposure[1]

PALFORZIA®: the first and only FDA-approved oral immunotherapy (OIT) treatment for children with peanut allergy[1]

Learn more about PALFORZIA and the REMS program
www.palforziapro.com

INDICATION

PALFORZIA is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. PALFORZIA is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients aged 1 through 17 years. Up-Dosing and Maintenance may be continued in patients 1 year of age or older.

PALFORZIA is to be used in conjunction with a peanut-avoidant diet.

Limitation of Use: Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

IMPORTANT SAFETY INFORMATION

WARNING: ANAPHYLAXIS

- **PALFORZIA can cause anaphylaxis, which may be life-threatening and can occur at any time during PALFORZIA therapy.**
- **Prescribe injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use.**
- **Do not administer PALFORZIA to patients with uncontrolled asthma.**
- **Dose modifications may be necessary following an anaphylactic reaction.**
- **Observe patients during and after administration of the Initial Dose Escalation and the first dose of each Up-Dosing level, for at least 60 minutes.**
- **PALFORZIA is available only through a restricted program called the PALFORZIA REMS.**

Please see accompanying full Prescribing Information, including Boxed WARNING, and Medication Guide.

JUST HALF A KERNEL*†

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OF PEANUT CAN PUT A PEANUT-ALLERGIC PATIENT AT RISK[1–4]

PALFORZIA® is the first and only FDA-approved oral immunotherapy (OIT) for peanut allergy in children ages 1 through 17 years.[1]

It is:

- Manufactured with precision, ensuring reliable dose consistency[5]
- Efficacious, proven, and supported by robust clinical data[3,6,7]
- Demonstrated to have a consistent safety profile across studies[3,6–9]
- Demonstrated to help protect against potentially life-threatening reactions from accidental exposure to peanuts[10]

Building tolerability over time[1]

Daily, continued dosing along with a peanut-avoidant diet can help patients achieve immunomodulation and help protect against peanut exposure.[1]

UNDERSTANDING PEANUT ALLERGY

Accidental peanut exposure can be difficult to avoid and may have serious consequences

Accidental exposure to peanuts is the leading cause of death from anaphylaxis caused by food.[11]

35%
of children
experienced an anaphylactic reaction within 5 years.[12‡]

80%
of children
with a peanut allergy have been shown to be **burdened** with **managing their allergy** throughout their lifetime.[13]

23%
of children
with a peanut allergy had 1 peanut-related emergency room visit within 1 year.[14§]

Full avoidance is challenging due to:

- Widespread use of peanuts in food[15]
- Cross contamination in kitchens[15]
- Inconsistencies in food labelling[15]

Did you know?

The median amount of peanut protein that causes a reaction during accidental exposure:[2]

Administering oral immunotherapy to patients at a younger age, during the maturation of their immune system, may result in more effective immune system modification which may help provide protection from accidental exposure.[16]

1/10 patients experience an adverse event from accidental peanut exposure, despite avoidance,[17] potentially leading to ER visits and elevated stress for patients and caregivers.[15,18,19]

IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

PALFORZIA is contraindicated in patients with uncontrolled asthma, or with a history of eosinophilic esophagitis and other eosinophilic gastrointestinal disease.

Please see accompanying full Prescribing Information, including Boxed WARNING, and Medication Guide.

*The median amount of peanut protein that causes a reaction during accidental exposure is less than half of a peanut kernel.[2]
†One peanut kernel is equivalent to approximately 300 mg.[3]

ER = emergency room.
‡In an epidemiologic analysis of 1,070 children with confirmed peanut allergy or sensitization over 5 years.[12]
§In a US representative sample of 38,408 children <18 years with peanut allergy (surveyed 2015–2016).[17]

The patient images are AI generated and are not real patients treated with PALFORZIA. Individual results may vary with each patient.

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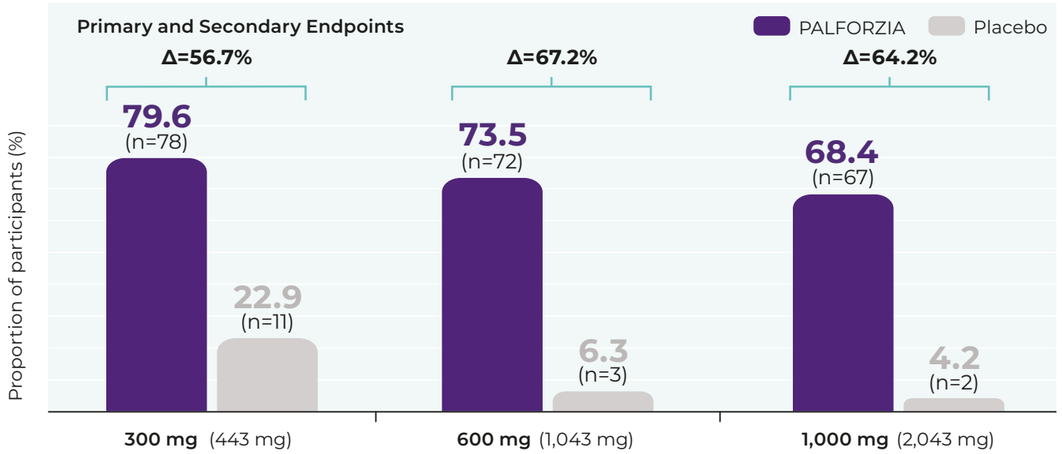
PALFORZIA® HELPS PROVIDE PROTECTION FOR TODDLERS

POSEIDON* was a phase 3, randomized, double-blind, placebo-controlled clinical trial in children I to <4 years of age with peanut allergy[1]

PALFORZIA was proven to reduce the severity of allergic reactions to peanut[20]

Primary and secondary endpoints: Percentage of subjects managing peanut protein in the exit double-blind placebo-controlled food challenge (DBPCFC) with no more than mild allergic symptoms after 1 year.[1,20†]



98 participants received PALFORZIA[1]*

48 participants received placebo[1]*

*The POSEIDON trial occurred at 14 sites in North America and 9 sites in Europe Data from all sites (North America and Europe) were pooled to form a single trial population.[20]

Key inclusion criteria:

- Persons 1 to <4 years of age with a documented history of physician-diagnosed IgE mediated peanut allergy or no known history of peanut ingestion and psIgE 5 kUA/l within 12 months[20]

Key exclusion criteria:

- Severe or life-threatening anaphylaxis requiring intubation or multiple doses of epinephrine[20]
- Medical conditions interfering with trial assessments or participation (e.g., uncontrolled asthma)[20]
- History of severe eosinophilic gastrointestinal disease or other contraindications to oral immunotherapy[20]

†Study duration was approximately 12 months with food challenges at entry and exit.[20]

THE POSEIDON TRIAL: 1–3 YEARS

Continued use of PALFORZIA may help provide protection

In 98 toddlers treated with PALFORZIA, at 1 year:[21]

~8 in 10 (79.6%) increased tolerability to **300 mg** (~1 kernel‡)

More than **7 in 10** (73.5%) increased tolerability to **600 mg** (~2 kernels‡)

~7 in 10 (68.4%) increased tolerability to **1,000 mg** (~3–4 kernels‡)

6 in 10 (61.2%) increased tolerability to **2,000 mg** (~6–7 kernels‡§)

Peanuts shown are for illustrative purposes only.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

ANAPHYLAXIS

PALFORZIA can cause anaphylaxis, which may be life threatening. PALFORZIA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the PALFORZIA REMS because of the risk of anaphylaxis. Only prescribers, healthcare settings, pharmacies, and patients certified and enrolled in the REMS Program can prescribe, receive, dispense or administer PALFORZIA.

Please see accompanying full Prescribing Information, including Boxed WARNING, and Medication Guide.

‡One peanut kernel is equivalent to 300 mg.[3]

§Prespecified exploratory endpoint included the proportion of patients who managed 2,000 mg single doses of peanut protein (Supplementary protocol)[20]

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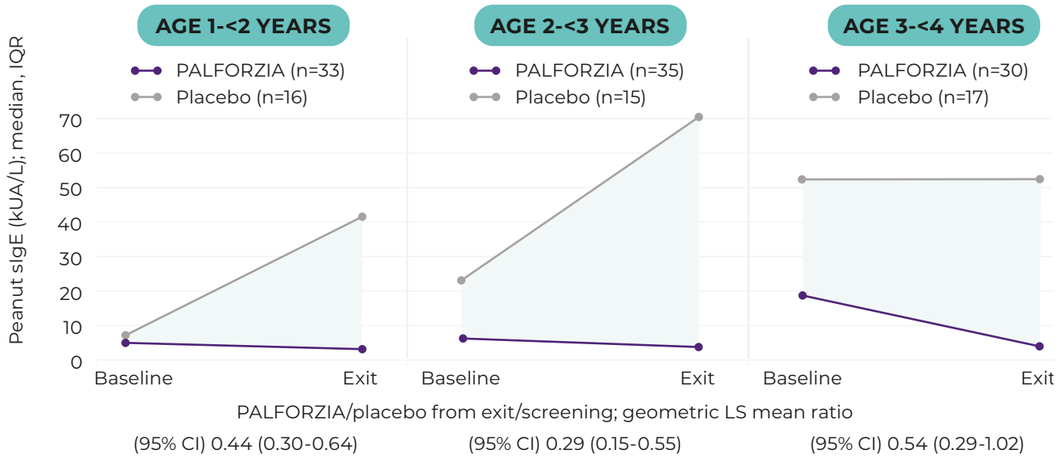
THE POSEIDON TRIAL: 1–3 YEARS

Early treatment with PALFORZIA® helped prevent progression of peanut sensitization[21]

Peanut allergen sensitization progressively increased in ages 1 to <3 years with placebo vs PALFORZIA[21]



Starting PALFORZIA in younger patients may help improve protection against peanut exposure.[20]

THE POSEIDON TRIAL: 1–3 YEARS

PALFORZIA demonstrated a consistent and established safety profile[1,22]

The most common treatment-emergent adverse reactions in ≥5% of those taking PALFORZIA (N=87) were urticaria (10.3%), abdominal pain (8%), rash (8%), and rhinitis (5.7%).[1] See full safety and adverse events in the accompanying full Prescribing Information.[1]

Anaphylactic reactions, by subject[1,22]	PALFORZIA (N=98)	Placebo (N=48)
Subjects with anaphylactic reaction*†	8.2%	8.3%
Mild	2.0%	4.2%
Moderate	6.1%	4.2%
Severe	0%	0%
Subjects with related anaphylactic reactions*	2.0%	0%
Mild	1.0%	0%
Moderate	2.0%‡	0%
Severe	0%	0%
Subjects who discontinued due to anaphylactic reaction	0%	0%

Treatment-emergent adverse events (TEAEs)[1,22]	PALFORZIA (N=98)	Placebo (N=48)
Subjects with TEAE	98.0%	97.9%
Treatment-related TEAE	75.5%	58.3%
Subjects with serious TEAE§	6.1%	4.2%
Treatment-related serious TEAE	0%	0%
Subjects with severe TEAE	5.1%	4.2%
Treatment-related severe TEAE	0%	0%
Subjects with AE that led to discontinuation	6.1%	0%
Chronic/recurrent GI AE¶	3.1%	0%

AE = adverse event; **GI** = gastrointestinal; **TEAE** = treatment emergent adverse event

*Anaphylactic reactions were graded as Mild (skin and subcutaneous issues, gastrointestinal and/or mild respiratory), Moderate (mild symptoms + features suggesting moderate respiratory, cardiovascular, or gastrointestional symptoms), or Severe (hypoxia, hypotension, or neurological compromise).[22]

†Most anaphylactic reactions were related to non-peanut food allergen exposure. Anaphylactic reactions by events: 13 anaphylactic reaction events (9 PALFORZIA, 4 placebo); 10 related to other food allergen exposure (6 PALFORZIA, 4 placebo); none related to accidental peanut exposure.[1,20]

‡Total percentage does not equal the sum of Mild and Moderate reactions because 1 subject experienced 2 related anaphylactic reactions (1 Mild and 1 Moderate).[1,22]

§PALFORZIA: 3 subjects with viral infections, 2 subjects with asthma, 1 subject with viral infection and asthma; placebo: 1 subject with asthma, 1 subject with carbon monoxide poisoning.[22]

¶No eosinophilic esophagitis.[22]

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

ANAPHYLAXIS (continued)

Anaphylaxis has been reported during all phases of PALFORZIA dosing, including Maintenance and in subjects who have undergone recommended Up-Dosing and dose modification procedures.

Do not initiate PALFORZIA treatment in a patient who has had severe or life-threatening anaphylaxis within the previous 60 days. PALFORZIA may not be suitable for patients with certain medical conditions that may reduce the ability to survive anaphylaxis, including but not limited to markedly compromised lung function, severe mast cell disorder, or cardiovascular disease. In addition, PALFORZIA may not be suitable for patients taking medications that can inhibit or potentiate the effects of epinephrine.

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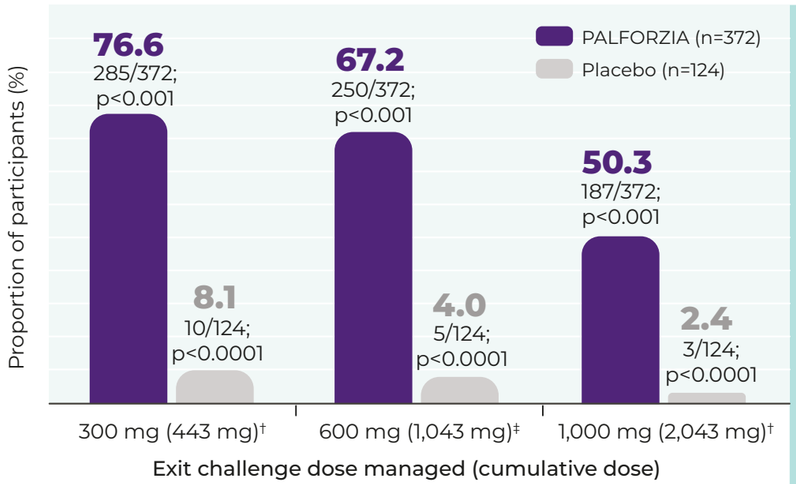
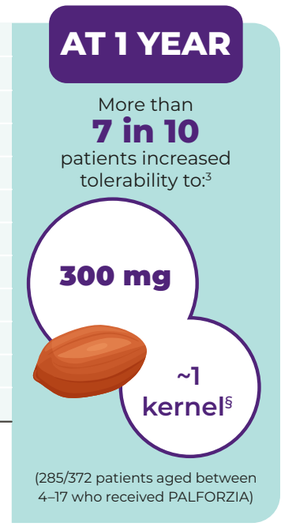
THE PALISADE TRIAL: 4–17 YEARS

PALFORZIA® may help provide protection from accidental peanut exposure

PALFORZIA was proven to reduce the severity of allergic reactions to peanut in ages 4 through 17 years

Primary and secondary endpoints. Percentage of patients managing peanut protein with no more than mild allergic symptoms at a DBPCFC.*[3]





Peanut shown is for illustrative purposes only

372 participants received PALFORZIA[3¶]

124 participants received placebo[3¶]

*The suspected allergen is eaten in an allergy clinic under medical surveillance, in small doses that increase in size over time until dose-limiting symptoms occur.

†The primary endpoint was the proportion of participants 4 to 17 years of age who had a response to the trial regimen, which was defined as the ability to ingest a single dose of at least 600 mg of peanut protein (cumulative dose, ≥1,043 mg) during the exit food challenge, with no dose-limiting symptoms.[3]

‡The key secondary endpoints included the proportion of participants who could manage single doses of 300 mg and 1,000 mg at the exit food challenge.[3]

§One peanut kernel is equivalent to 300 mg.[3]

¶The PALISADE trial is the largest, double-blind, placebo-controlled phase 3 clinical trial for peanut allergy treatment. It occurred at 66 sites in 10 countries in North America and Europe. Study duration: approximately 12 months with food challenges at entry and exit. 496 participants aged 4–17 years.[1,3]

Key inclusion criteria:[1,3]

- Clinical history of peanut allergy
- pslgE of ≥0.35 kUA/L and/or mean peanut skin-prick test wheal diameter ≥3 mm larger than the negative control
- Reacted to 100 mg or less of peanut protein at entry DBPCFC

Key exclusion criteria:[1,3]

- Uncontrolled asthma, history of eosinophilic esophagitis, other eosinophilic gastrointestinal disease, or severe anaphylaxis within 60 days of screening

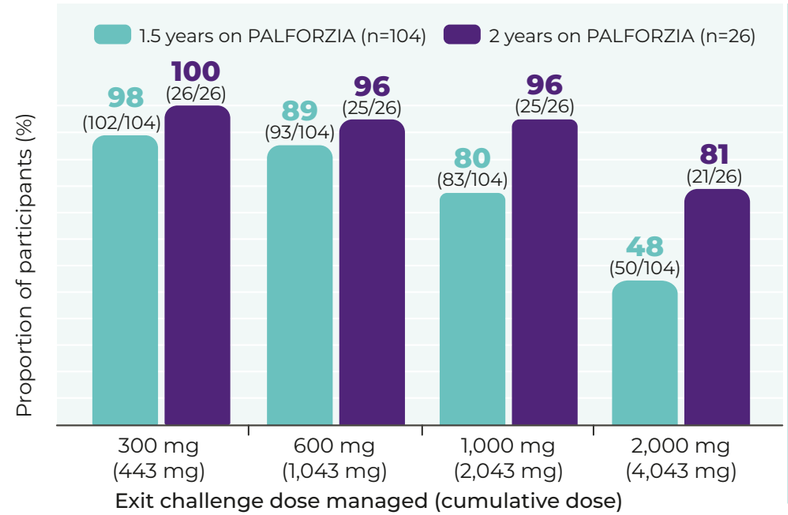
PALFORZIA was studied in highly peanut-allergic participants[3]
72% of participants reported a history of peanut-related anaphylaxis prior to enrolling in the study.[3]

THE PALISADE TRIAL: 4–17 YEARS

With continued use, PALFORZIA may be able to help build protection over time

In a follow-on trial to the PALISADE study, continued treatment for ~2 years demonstrated sustained desensitization to peanut protein in the population that completed the study and then continued treatment

Percentage of patients managing peanut protein with no more than mild allergic symptoms at a DBPCFC.*[3]



Peanut shown is for illustrative purposes only

47.3% of participants **with PALFORZIA** | VS | **2.6%** of participants **with placebo**

showed no symptoms
at any challenge dose up to 1,000 mg single dose, 2,043 mg cumulative.[2,3]

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

ANAPHYLAXIS (continued)

All Initial Dose Escalation doses and the first dose of each Up-Dosing level must be administered under observation in a certified health care setting.

Please see accompanying full Prescribing Information, including Boxed WARNING, and Medication Guide.

ΔData are descriptive only and are not included in the FDA-approved labelling for PALFORZIA.

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THE PALISADE TRIAL: 4–17 YEARS

PALFORZIA® demonstrated a well established and consistent safety profile across clinical studies

The most common adverse events for patients aged 4–17 were treated with PALFORZIA (incidence ≥ 5% and at least 5% greater than placebo) are abdominal pain, vomiting, nausea, oral pruritus, oral paresthesia, throat irritation, cough, rhinorrhea, sneezing, throat tightness, wheezing, dyspnea, pruritus, urticaria, anaphylactic reaction, and ear pruritus. See full safety and adverse events in the accompanying full Prescribing Information.[1]

Anaphylactic reactions:[2]

In PALFORZIA safety data, anaphylactic reaction includes systemic allergic reactions of **any severity**.[1]

INITIAL DOSE ESCALATION			UP-DOSING		
0.7% (5/709) of participants **with PALFORZIA**	vs	**0.3%** (1/292) of participants **with placebo**	**9.1%** (63/693) of participants **with PALFORZIA**	vs	**3.5%** (10/289) of participants **with placebo**

Severe anaphylaxis was reported in 0.6% of participants (4/709) during Up-Dosing, and 0.3% of participants (1/310) during maintenance across studies.[1]

The majority of adverse reactions were mild to moderate and were more frequently reported during Up-Dosing and decreased during Maintenance dosing.[1,19]

Symptoms during in-office PALFORZIA dosing had a median time to onset of 4 minutes for 71% of participants. Median time to resolution was 37 minutes.[1]

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

The views expressed in this quote reflect feedback gathered during market research and may not represent the opinions of all healthcare professionals.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

ANAPHYLAXIS (continued)

Patients may be more likely to experience allergic reactions following PALFORZIA administration in the presence of cofactors such as exercise, hot water exposure, intercurrent illness (e.g., viral infection), or fasting. Other potential cofactors may include menstruation, sleep deprivation, nonsteroidal anti-inflammatory drug use, or uncontrolled asthma. Patients should be proactively counseled about the potential for the increased risk of anaphylaxis in the presence of these cofactors. If possible, adjust the time of dosing to avoid these cofactors. If it is not possible to avoid these cofactors, consider withholding PALFORZIA temporarily.

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Progressive Desensitization: The PALFORZIA® 3 step dosing protocol[1]

Crafted precisely for consistent dosing

PALFORZIA is manufactured in a consistent and controlled process and contains a complete range of major and minor peanut proteins.[1]

Not actual size

Each once-daily dose

contains defined, pre-packaged amounts of peanut protein for standardized dosing and administration.[1]

INITIAL DOSE ESCALATION

One time initiation dose appointment in-clinic/hospital

The first day of PALFORZIA treatment will run for approximately 4 hours, which includes observation time after each dose of the Initial Dose Escalation Pack.

UP-DOSING

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

Approximately every 2 weeks, dose escalation with at least 60 minute in clinic monitoring in a controlled environment, then continued at home with daily dosing to build tolerability. All dose levels should be completed before starting maintenance.

MAINTENANCE DOSING

An at-home dosing schedule

300 mg

Continued daily Maintenance dosing is required to maintain treatment effect. (Approximately 6 months or more).

PALFORZIA product within capsules and/or sachets should be mixed into cool or room temperature semi-solid food (pudding, apple sauce, salsa, etc.) and consumed in full to dose.[1]

Capsules should not be swallowed.[1]

Temporary dose modification may be required for patients who experience allergic reactions during Up-Dosing or Maintenance, for patients who miss doses, or for practical reasons of patient management. Use clinical judgment to determine the best course of action, which can include maintaining the dose level for longer than 2 weeks or reducing, withholding, or discontinuing PALFORZIA doses.[1]

During treatment, patients and caregivers must be instructed to recognize the signs and symptoms of an allergic reaction and in the proper use of self-administrated epinephrine.[1]

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

ASTHMA

Uncontrolled asthma is a risk factor for a serious outcome, including death, in anaphylaxis. Ensure patients with asthma have their asthma under control prior to initiation of PALFORZIA.

PALFORZIA should be temporarily withheld if the patient is experiencing an acute asthma exacerbation. Following resolution of the exacerbation, resumption of PALFORZIA should be undertaken cautiously. Re-evaluate patients who have recurrent asthma exacerbations and consider discontinuation of PALFORZIA.

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Preparing to prescribe:
Getting started

Enroll in REMS (Risk Evaluation and Mitigation Strategy) at **PALFORZIAREMS.com**

- PALFORZIA is only available through the PALFORZIA REMS Program.
- The PALFORZIA REMS Program is an FDA required drug safety program that manages the risk of anaphylaxis associated prescription medications, such as PALFORZIA, to ensure the potential benefits outweigh the risks.
- The goal of the program is to help mitigate the possibility of anaphylaxis associated with PALFORZIA.

Submit a prescription enrollment via:

PALFORZIA® Quick Enroll Portal*

Complete and fax the PDF Enrollment Form*

*Access both at www.PalforziaPro.com

Exclusive Specialty Pharmacy

Walgreens Specialty Pharmacy will work with you and your patients to dispense the medication.

Access, coverage and reimbursement
Support to help patients access PALFORZIA

Stallergenes Greer is committed to supporting patient accessibility to PALFORZIA treatment by providing financial options to eligible patients.

The PALFORZIA Pathway™ Patient Hub offers:

Palforzia Pathway™

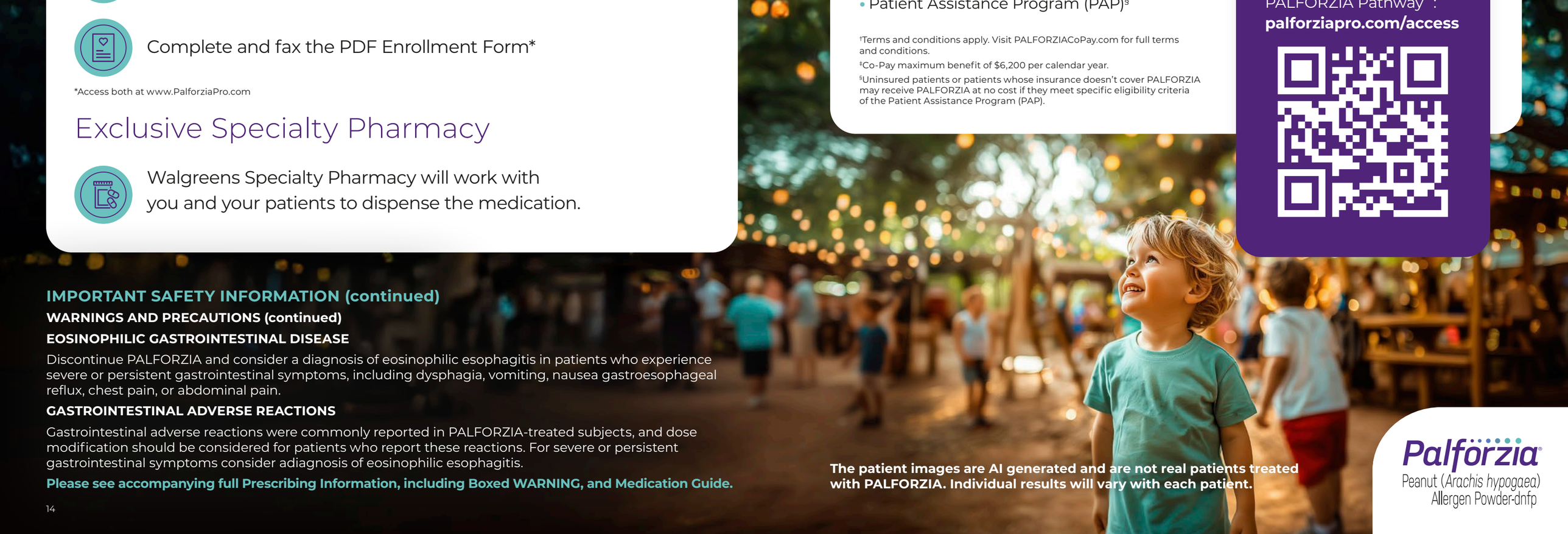
- Patient Support Program
- Co-Pay Savings Program†‡
  - Commercially insured patients who meet eligibility criteria may pay as little as $20 per month
- Patient Assistance Program (PAP)§

†Terms and conditions apply. Visit PALFORZIACoPay.com for full terms and conditions.

‡Co-Pay maximum benefit of $6,200 per calendar year.

§Uninsured patients or patients whose insurance doesn't cover PALFORZIA may receive PALFORZIA at no cost if they meet specific eligibility criteria of the Patient Assistance Program (PAP).

Learn more about PALFORZIA Pathway™: **palforziapro.com/access**



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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

EOSINOPHILIC GASTROINTESTINAL DISEASE

Discontinue PALFORZIA and consider a diagnosis of eosinophilic esophagitis in patients who experience severe or persistent gastrointestinal symptoms, including dysphagia, vomiting, nausea gastroesophageal reflux, chest pain, or abdominal pain.

GASTROINTESTINAL ADVERSE REACTIONS

Gastrointestinal adverse reactions were commonly reported in PALFORZIA-treated subjects, and dose modification should be considered for patients who report these reactions. For severe or persistent gastrointestinal symptoms consider adiagnosis of eosinophilic esophagitis.

Please see accompanying full Prescribing Information, including Boxed WARNING, and Medication Guide.

Palforzia
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Building protection from peanut allergy with PALFORZIA®

Just half a kernel can put patients at risk[2–4]*†

With PALFORZIA, at 1 year of treatment, ~8 in 10 patients (aged 1 through 3 years) **increased tolerability** to 300 mg (~1 kernel), and 6 in 10 patients (aged 1 through 3 years) increased tolerability to 2,000 mg (~6–7 kernels)[21†]

With PALFORZIA, at 1 year of treatment, **more than 7 out of 10 patients** (aged 4 through 17 years) increased tolerability to 300 mg/~1 kernel (285/372 patients)[3†]

PALFORZIA **has a well-established and consistent safety profile** across clinical studies[1]

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

ADVERSE REACTIONS

The most common adverse reactions reported in subjects ages 1 through 3 years treated with PALFORZIA (incidence ≥5%) are cough, sneezing, rhinitis, nasal congestion, throat irritation, wheezing, abdominal pain, vomiting, diarrhea, oral pruritus, oropharyngeal pain, urticaria, rash, pruritus, and perioral dermatitis.

The most common adverse events reported in subjects ages 4 through 17 years treated with PALFORZIA (incidence ≥5% and at least 5% greater than placebo) are abdominal pain, vomiting, nausea, oral pruritus, oral paresthesia, throat irritation, cough, rhinorrhea, sneezing, throat tightness, wheezing, dyspnea, pruritus, urticaria, anaphylactic reaction, and ear pruritus.

Please see accompanying full Prescribing Information, including Boxed WARNING, and Medication Guide.

*The median amount of peanut protein that causes a reaction during accidental exposure is less than half of a peanut kernel.[2–4]

†One peanut kernel is equivalent to 300 mg.[3]

Peanuts shown are for illustrative purposes only.

STALLERGENES GREER

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

MPN021225H0143

Learn more about PALFORZIA:
www.palforziapro.com

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1. PALFORZIA [package insert]. Lenoir, NC; Greer Laboratories, Inc; **2.** Deschildre A, et al. Clin Exp Allergy. 2016;46:610–620; **3.** Vickery BP, et al. N Engl J Med. 2018;379:1991–2001; **4.** Vickery BP, et al. J Allergy Clin Immunol Pract. 2021; 9:1879–1889.e14; **5.** Leonard SA, et al. Front Allergy. 2022;3:1004056; **6.** O'B Hourihane J, et al. Lancet. 2020;4:728–739; **7.** Fernandez-Rivas M, et al. Allergy. 2022;77:1545–1558; **8.** Ciaccio C, et al. Ann Allergy Asthma Immunol. 2022;129:758–768.e4; **9.** Brown KR, et al. J Allergy Clin Immunol. 2022;149:2043–2052.e9; **10.** Casale TB, et al. Expert Rev Clin Immunol. 2023;19:253–265; **11.** Iglesia IGA, et al. JAMA. 2024;331(6):510–521; **12.** Leickly FE, et al. J Pediatr. 2018;192:223–8.e1; **13.** Peters RL, et al. J Allergy Clin Immunol. 2015;135(5):1257–66.e1–2; **14.** Gupta RS, et al. Pediatrics. 2018;142(6). Available from: https://doi.org/10.1016/j.jpedsi.2017.09.026; **15.** Lieberman JA, et al. Allergy. 2021;76:1367–1384; **16.** Jones SM, et al. Lancet. 2022;399(10322):359–71; **17.** Lange L, et al. Allergo J Int. 2021;30:261–269; **18.** Cannon HE. Am J Manag Care. 2018;24:S428-S433; **19.** Couratier P, et al. Allergy Asthma Clin Immunol. 2020;16:86; **20.** Du Toit G, et al. NEJM Evid. 2023;2(11):EVIDoa2300145; **21.** Du Toit G, et al. [supplemental appendix]. NEJM Evid. 2023;2(11):EVIDoa2300145; **22.** US Food and Drug Administration. Drug approval package: PALFORZIA; BLA Clinical Review Memorandum. 23 Jul 2024. [cited December 9, 2024.] Available from: https://www.fda.gov/ media/180546/download; **23.** Data on file, AMPZ002.