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 years of age and 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 additional Important Safety Information throughout.
Please see full Prescribing Information, including Boxed WARNING, in pocket, and Medication Guide at PALFORZIAPro.com.

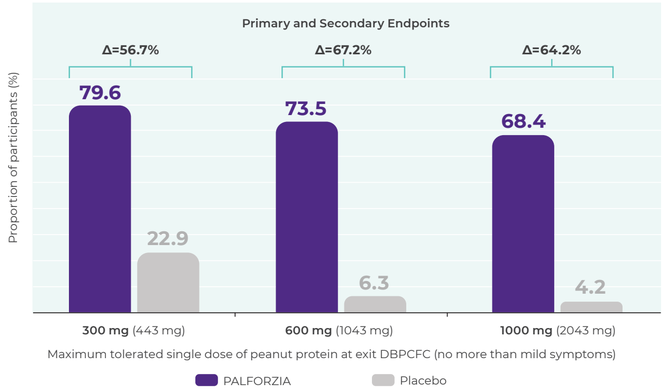
Palforzia®
Peanut (*Arachis hypogaea*) Allergen Powder-dnfp

The first and only FDA-approved OIT for peanut allergy—available for toddlers[1,2]

PALFORZIA helped reduce peanut allergy reactions beginning at age 1 year[1,3]

PALFORZIA was studied in a phase 3, international, randomized, double-blind, placebo-controlled study in 146 subjects (PALFORZIA, N=98; placebo, N=48; *P*<0.0001) aged 1 through 3 years in the ITT population who received at least 1 dose of study treatment.[1]

Primary and secondary endpoints: Percentage of subjects tolerating peanut protein in the exit DBPCFC with no more than mild allergic symptoms after 6 months[1,3]



Note: 15 subjects in the PALFORZIA arm and 3 subjects in the placebo arm did not have an exit DBPCFC.
Subjects without an exit DBPCFC were counted as nonresponders.
Secondary endpoint was met if the Farrington-Manning test for a nonzero treatment difference was significant at the two-sided 0.05 level.
The primary endpoint was considered met if the lower bound of the Farrington-Manning 95% CI was greater than the prespecified margin of 15 percentage points.
CI=confidence interval; DBPCFC=double-blind, placebo-controlled food challenge; ITT=intent-to-treat; OIT=oral immunotherapy.

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.

WARNINGS AND PRECAUTIONS

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.

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.

PALFORZIA offers proven safety and efficacy in early treatment[1,4]

PALFORZIA has been shown to be safe and well tolerated in toddlers[1]

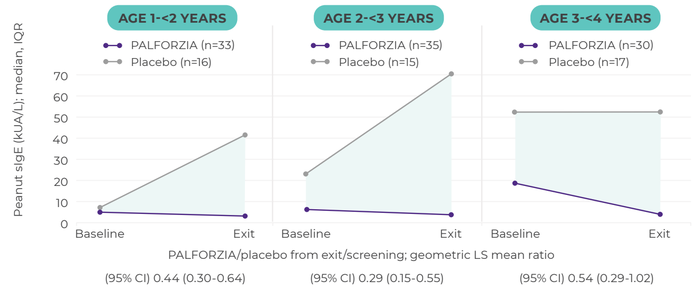
The most common treatment-emergent adverse reactions in ≥5% of those taking PALFORZIA (N=87) were urticaria (10.3%), abdominal pain (8%), oral pruritus (8.0%), rash (8%), and rhinitis (5.7%).[1] See full safety and adverse events in the accompanying full Prescribing Information.

Anaphylactic reactions, by subject[1,3-5]	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)[1,3]	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%

Early treatment with PALFORZIA helped prevent progression of peanut sensitization[4]

Peanut allergen sensitization progressively increased in ages 1–<3 years with placebo vs PALFORZIA[4]

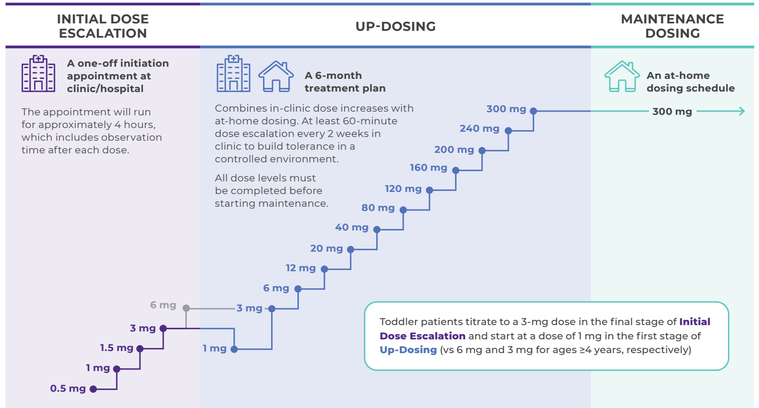


*Anaphylactic reactions were graded as Mild (skin and subcutaneous issues, gastrointestinal, and/or mild respiratory), Moderate (mild symptoms + features suggesting moderate respiratory, cardiovascular, or gastrointestinal symptoms), or Severe (hypoxia, hypotension, or neurological compromise).[4]
†Most 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.[1,3]
‡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).[4]
§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.[4]
¶No eosinophilic esophagitis.[1]
AE=adverse event; GI=gastrointestinal; IQR=interquartile range; LS=least squares; sIgE=specific immunoglobulin.

Dosing PALFORZIA in ages 1 through 3 years[1]

Treatment is administered in 3 phases:
Initial Dose Escalation, Up-Dosing, and Maintenance

- PALFORZIA patients are exposed to gradually increasing amounts of peanut allergen to help them decrease sensitivity over time to small amounts of peanuts that may be hidden in foods
- Treatment begins with a 0.5-mg dose during Initial Dose Escalation and culminates with a 300-mg dose, which is taken daily during Maintenance dosing



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.

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.

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 a diagnosis of eosinophilic esophagitis.

Please see additional Important Safety Information throughout.
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Getting started:

ENROLL IN THE PALFORZIA REMS PROGRAM

PALFORZIA is only available through the PALFORZIA REMS Program

The goal of the REMS Program is to mitigate the risk of anaphylaxis associated with PALFORZIA.

Before a patient can begin PALFORZIA treatment, the patient, prescriber, and healthcare setting must be enrolled in the PALFORZIA REMS Program. If you are already REMS-certified for PALFORZIA, there is no need for recertification for the toddler indication.

Follow 2 simple steps to streamline enrollment for PALFORZIA:

1. Before initiating a new patient, the prescriber must enroll the patient in the REMS Program via PalforziaREMS.com.
2. After your patient is enrolled in the REMS Program, you can prescribe PALFORZIA by filling out and submitting the Prescription and Enrollment Form at PALFORZIAPro.com.

To enroll a new prescriber or healthcare setting, get started at PalforziaREMS.com.

REMS=Risk Evaluation and Mitigation Strategy.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Anaphylaxis (continued)

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.

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.

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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For children ages 1 year and up[1]

EARLY INTERVENTION CAN TRANSFORM THEIR TOMORROW

Why wait? With PALFORZIA, help build protection from accidental exposure[1]

PALFORZIA was studied in a phase 3, international, randomized, double-blind, placebo-controlled study in 146 subjects (PALFORZIA, N=98; placebo, N=48) aged 1 through 3 years in the ITT population who received at least 1 dose of study treatment.[1]

Higher dose tolerability in ages 1 through 3 years
67.2% treatment difference in tolerance to 600 mg of peanut protein (vs placebo)[1]

Early intervention for desensitization
Treating ages <4 years with PALFORZIA **helped prevent natural progression** of peanut allergy[4]

Safe and well tolerated
The **most common TEAEs in ≥5% of toddlers** taking PALFORZIA were urticaria (10.3%), abdominal pain (8.0%), oral pruritus (8.0%), rash (8.0%), and rhinitis (5.7%)[1]

Co-Pay Savings Program
Eligible patients may **pay as little as $20 per month** for PALFORZIA*

Enroll in the PALFORZIA REMS Program today

If you are already REMS-certified for PALFORZIA, there is no need for recertification for the toddler indication.

Get started at PalforziaREMS.com

*Terms and conditions apply. See PALFORZIACoPay.com for full terms and conditions.

IMPORTANT SAFETY INFORMATION (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 reactions 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, urticaria, anaphylactic reaction, and ear pruritus.

Please see additional Important Safety Information throughout. Please see full Prescribing Information, including Boxed WARNING, in pocket, and Medication Guide at PALFORZIAPro.com.

References: 1. PALFORZIA [package insert]. Brisbane, CA: Aimmune Therapeutics, Inc.; 2024. **2.** XOLAIR [package insert]. South San Francisco, CA: Genentech, Inc; 2024. **3.** Du Toit G, Brown KR, Vereda A, et al. Oral immunotherapy for peanut allergy in children 1 to less than 4 years of age. *NEJM Evid*. 2023;2(11):EVIDoa2300145. doi:10.1056/EVIDoa2300145. **4.** Du Toit G, Brown KR, Vereda A, et al. Oral immunotherapy for peanut allergy in children 1 to less than 4 years of age [supplemental appendix]. *NEJM Evid*. 2023;2(11):EVIDoa2300145. doi:10.1056/EVIDoa2300145. Accessed October 10, 2024. https://evidence.nejm.org/doi/10.1056/EVIDoa2300145. **5.** US Food and Drug Administration. Drug approval package: Palforzia; BLA Clinical Review Memorandum. July 23, 2024. Accessed October 10, 2024. https://www.fda.gov/media/180546/download.

STALLERGENES GREER

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

MPN 092624H0106 10.24

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