SYLVIE, 6 years old

Thinks it's funny that her dad calls her "peanut," even though she can't go near them

HER PARENTS ARE CURIOUS ABOUT PALFORZIA

MEET SYLVIE

She's ready for a proactive approach to treatment

Clinical history

- Diagnosed at age 3 with peanut allergy
  - Current treatment strategies include avoidance and carrying injectable epinephrine
- Last known reaction was about 3 months ago, when she accidentally had a bite of a peanut butter cookie. She immediately had trouble breathing, and her face began to swell. Her mother used injectable epinephrine right away
- Peanut-specific IgE > 100 kU/L
- Skin prick test wheal size (peanut) = 11 mm

Help patients mitigate allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut with the first and only FDA-approved oral immunotherapy for peanut allergy.[1]

Not actual patient.

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 4 through 17 years. Up-Dosing and Maintenance may be continued in patients 4 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.**

IgE = immunoglobulin E.

Please see additional Important Safety Information on the following pages.

Please see full Prescribing Information, including Boxed WARNING, and Medication Guide at PALFORZIAPro.com.

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

SYLVIE, 6 years old

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MEET SYLVIE (CONTINUED)

She's ready for a proactive approach to treatment

Additional notes

- Father works full-time, and mother stays at home with Sylvie and her 2 other siblings
- Older sibling is lactose intolerant
- Parents are hypervigilant about managing Sylvie's peanut allergy
- They are hopeful that PALFORZIA may be a good option
- Sylvie and her family live 30 minutes from the clinic

Assessment and plan

- Sylvie does not have uncontrolled asthma or a history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease
- Based on her confirmed peanut allergy and given that her anaphlyactic reaction occurred more than 60 days prior, Sylvie may be a good candidate for PALFORZIA
- Discuss PALFORZIA treatment with Sylvie and her parents
- If all agreed, initiate the first steps to getting Sylvie enrolled for PALFORZIA treatment

Not actual patient.

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.

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.

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IDENTIFYING APPROPRIATE PATIENTS FOR PALFORZIA[1]

PALFORZIA is indicated for patients who:

- Are 4 through 17 years of age
- Have a confirmed diagnosis of peanut allergy
- Practice a peanut-avoidant diet and carry injectable epinephrine

PALFORZIA is NOT for patients who have:

- Uncontrolled asthma
- A history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease
- 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 disease
  - Cardiovascular disease
- Patients taking medications that can inhibit or potentiate the effects of epinephrine

Before a patient can begin PALFORZIA treatment, the patient, the prescriber, and the healthcare setting must be enrolled in the **PALFORZIA REMS Program**.

IMPORTANT SAFETY INFORMATION (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.

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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ADDITIONAL CONSIDERATIONS TO IDENTIFY ELIGIBLE, MOTIVATED PATIENTS AND CAREGIVERS

Non-clinical characteristics

- Unified: Family and child with peanut allergy work together to avoid accidental exposure
- Hypervigilant: Caregivers are always on the lookout for any potential allergens
- Determined: Family still tries to engage their child in as many regular day-to-day activities as possible
- Motivated: Caregivers seek out different treatment options for peanut allergy

Additional PALFORZIA considerations

- Commit to regularly scheduled office visits and in-office Up-Dosing time requirements
- Commit to daily dosing and understand at-home dosing instructions and protocol
- Commit to following a strict peanut-avoidant diet
- Be able to recognize the signs/symptoms of allergic reactions
- Have injectable epinephrine and are trained in its use

IMPORTANT SAFETY INFORMATION (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 a diagnosis of eosinophilic esophagitis.

ADVERSE REACTIONS

The most common adverse events reported in subjects 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 full Prescribing Information, including Boxed WARNING, and Medication Guide at PALFORZIAPro.com.

Reference: 1. PALFORZIA [package insert]. Brisbane, CA: Aimmune Therapeutics, Inc.

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