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

Overview

PALFORZIA™ [Peanut (*Arachis hypogaea*) Allergen Powder-dnfp] is the first FDA-approved treatment for patients with peanut allergy in the United States. It 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.

PALFORZIA is not indicated for the emergency treatment of allergic reactions, including anaphylaxis. PALFORZIA can cause anaphylaxis, which may be life-threatening and can occur at any time during PALFORZIA therapy. Because of the risk of anaphylaxis, PALFORZIA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the PALFORZIA REMS.

PALFORZIA is a rigorously developed, pharmaceutical-grade oral immunotherapy for peanut allergy with a well-defined allergen profile to assure every dose, whether 0.5 mg (equivalent to 1/600th of a peanut) or 300 mg, has been prepared and analyzed for consistency.

How It Works

PALFORZIA is administered orally every day and supplied in pull-apart capsules or foil-laminate sachets. The contents are mixed thoroughly with a few spoonfuls of age-appropriate, unheated food – such as applesauce or pudding.

Following an initial dose escalation visit, PALFORZIA involves taking daily doses at home while precisely and carefully increasing the dose every two weeks under the supervision of a trained and certified allergist in a certified healthcare setting. After the up-dosing period, patients who reach a daily maintenance dose of 300 mg continue to take PALFORZIA to maintain desensitization.

Clinical Development Program

The Phase 3 clinical development program for PALFORZIA is a large, clinically robust dataset including more than 1,200 patients with peanut allergy in the trials. The program included the only Phase 3 clinical trial to meet its primary endpoint in children and teens with peanut allergy – PALISADE – and RAMSES, which further supported the safety profile of PALFORZIA first observed in the PALISADE study without use of a food challenge.

PALISADE (**P**eanut **AL**lergy Oral **I**mmunotherapy **S**tudy of **A**R101 for **DE**sensitization in Children and Adults) evaluated the efficacy and safety of PALFORZIA to treat peanut allergy.

PALISADE is a large randomized, double-blind, placebo-controlled clinical trial for peanut allergy and the first Phase 3 trial of its kind to meet its primary endpoint. The study enrolled more than 550 participants aged 4 through 55 in the U.S., Canada and Europe.[1] Results, published in the ***New England Journal of Medicine (NEJM)*** in November 2018, demonstrated that PALFORZIA increased peanut protein tolerability and reduced the frequency and severity of allergic reactions compared to placebo in the food exit challenge, with an expected adverse event profile that was most frequent during treatment initiation and decreased over time with continued exposure during maintenance treatment.

PALISADE was selected by the editors of ***NEJM*** as one of the "Notable Articles of 2018,"[2] underscoring the interest among the medical community around an FDA-approved peanut allergy treatment.

RAMSES (**R**eal-World **AR**101 **M**arket **S**upporting **E**xperience **S**tudy in Peanut-Allergic Children) evaluated the safety of PALFORZIA to treat peanut allergy and was designed to gain experience with PALFORZIA in a real-world setting, without the use of a food challenge. The study enrolled children and adolescents aged 4 through 17 in the U.S. and Canada. Data from RAMSES further supported the safety profile of PALFORZIA first observed in the PALISADE study.

Please see additional Important Safety Information, including Boxed WARNING, on the next page.

References:
1 The PALISADE Group of Clinical Investigators. AR101 oral immunotherapy for peanut allergy. *New Engl J Med*. 2018;379:1991-2001.
2 Notable Articles of 2018. *New Engl J Med*. January 2018. http://cdn.nejm.org/pdf/Notable-Articles-2018.pdf.

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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.

Limitations 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.**

CONTRAINDICATIONS

Uncontrolled asthma and history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease.

WARNING 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 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.

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.

ADVERSE REACTIONS

The most common adverse events reported in subjects treated with PALFORZIA (incidence ≥ 5% and ≥ 5% 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 www.PALFORZIA.com.

For more information about PALFORZIA, please call 1-844-PALFORZ (1-844-725-3679) or visit www.PALFORZIA.com.