PACKAGING AND ORDERING OVERVIEW

An introduction to different types of PALFORZIA packaging and ordering throughout the treatment pathway

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.**

Please see Important Safety Information continued on last page.

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

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

CONVENIENT PACKAGING FOR EACH STAGE OF TREATMENT

You will encounter PALFORZIA in the following types of packaging throughout the PALFORZIA treatment pathway.

PALFORZIA INITIAL DOSE ESCALATION CARD

- Used exclusively in office during Initial Dose Escalation
- Contains 5 escalating doses ranging in strength from 0.5 to 6 mg
- Doses are administered at least 20 minutes apart under supervision in a healthcare setting on a single day
- Additional supervision time may be required in the event of an allergic reaction

PALFORZIA OFFICE DOSE KIT

- PALFORZIA Office Dose Kit use varies slightly depending on where PALFORZIA Up-Dosing Packs are shipped
- Contains test doses (the first dose of each Up-Dosing level) that are administered in office and doses that are given to patients in office to take at home
- Test doses range in strength from 3 to 300 mg
- Each kit contains 18 blisters each of 3-mg and 6-mg doses; 12 blisters each of 12-mg, 20-mg, 40-mg, 80-mg, 120-mg, 160-mg, 200-mg, and 240-mg doses; and fifteen 300-mg sachets

PALFORZIA UP-DOSING PACK

- Patients can receive PALFORZIA Up-Dosing packs in office or at home
- Available in 11 different strengths—one for each Up-Dosing level
- Contains 15 doses—enough PALFORZIA for at least 2 weeks of therapy, with an additional dose to cover missed appointments, etc
- Each patient receives 1 new pack every 2 weeks

PALFORZIA 30-DAY MAINTENANCE DOSE PACK

- Used exclusively at home during Maintenance Dosing
- Contains a 30-day supply of PALFORZIA 300-mg sachets
- Patients continue to take daily doses from the 30-day pack to maintain the effect of PALFORZIA

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HOW TO REQUEST PALFORZIA FOR YOUR PATIENTS AND PRACTICE

PALFORZIA is only available through a network of certified specialty pharmacies and distributors enrolled in the PALFORZIA REMS Program.

THE PALFORZIA REMS PROGRAM

Healthcare settings, prescribers, and their patients must complete enrollment requirements in the PALFORZIA REMS Program before prescribing, receiving, or administering PALFORZIA. More information is available at **www.PALFORZIAREMS.com**.

PALFORZIA Initial Dose Escalation Cards

- Order through specialty pharmacy or distributor; ship directly to your office

PALFORZIA Office Dose Kit Refills

- Order online through the HCP portal prior to prescribing PALFORZIA
- Ship directly to your office
- Reorder as necessary in order to ensure adequate inventory for your practice

PALFORZIA Up-Dosing Pack

- Order through specialty pharmacy or distributor; ship to your office or to patient's home
  - For office shipment: Request each dose level before the patient's appointment, then store it in office under refrigeration
  - For home shipment: Order a new pack directly after a patient's in-office Up-Dosing visit for overnight shipment to their home

PALFORZIA 30-Day Maintenance Dose Pack

- Prescriber orders first PALFORZIA 30-Day Maintenance Dose Pack through specialty pharmacy or distributor
- Patient coordinates with their specialty pharmacy to order subsequent packs for shipment to their home

For more information about ordering, call **1-844-PALFORZ** (1-844-725-3679).

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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.

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 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.

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