DOSE ADMINISTRATION OVERVIEW

Administer PALFORZIA using these recommendations for dosing in office and at home.

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 additional Important Safety Information on back cover.

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

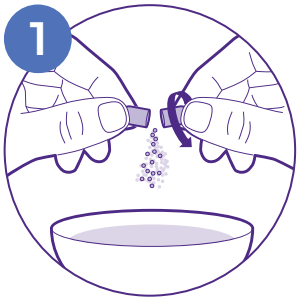
Palforzia®
Peanut (*Arachis hypogaea*) Allergen Powder-dnfp

DOSE PREPARATION AND ADMINISTRATION RECOMMENDATIONS

Proper preparation and administration of PALFORZIA are critical in all treatment phases. The following guidance should be used for in-office and at-home dosing.

Instructions to Prepare and Administer a Dose[1]

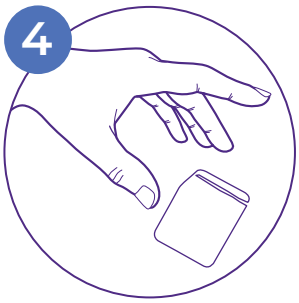
IMPORTANT: Capsules should not be swallowed whole.



Open capsule(s) or sachet, and empty the entire dose of PALFORZIA powder onto a few spoonfuls of refrigerated or room-temperature semi-solid food (e.g., applesauce, yogurt, pudding). Do not use liquid (e.g., milk, water, juice) to prepare.

Mix well.

Consume the entire volume of the prepared mixture promptly.



Dispose of the opened capsule(s) or sachet.

Wash hands immediately after handling PALFORZIA capsule(s) or sachet.

Dispose of all unused PALFORZIA.

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DOSE PREPARATION AND ADMINISTRATION RECOMMENDATIONS (CONTINUED)

DOs and DON'Ts during Up-Dosing and Maintenance

PATIENTS SHOULD[1]:

- Take each daily dose to maintain the effect of PALFORZIA
- Take PALFORZIA at about the same time every day with a meal
- Resume dosing at the same time as usual the next day if 1 or 2 daily doses are missed
- Consult with their physician if 3 or more doses are missed

PATIENTS SHOULD NOT[1]:

- Consume more than 1 dose per day
- Consume a dose at home on the same day as a dose consumed in office
- Mix dose with liquids or hot foods
- Swallow capsules
- Inhale powder
- Freeze PALFORZIA
- Take hot showers or baths immediately prior to or within 3 hours after dosing
- Consume PALFORZIA dose after strenuous exercise until signs of a hypermetabolic state subside

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

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