

# PALFORZIA™ Education Program For Healthcare Settings

Risk Evaluation and Mitigation Strategy (REMS)



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

# What is PALFORZIA™?

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- PALFORZIA 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.
- PALFORZIA is available only through a restricted program called the PALFORZIA REMS.

# PALFORZIA has a Boxed Warning

## **WARNING: ANAPHYLAXIS** **SEE PRESCRIBING INFORMATION FOR COMPLETE BOXED WARNING.**

- **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.**
- **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.**

# What is a REMS? (Risk Evaluation and Mitigation Strategy)

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- A Risk Evaluation and Mitigation Strategy (**REMS**) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

# Goal of the PALFORZIA REMS

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- The goal of the PALFORZIA REMS is to mitigate the risk of anaphylaxis associated with PALFORZIA by:
  - Ensuring that healthcare providers who prescribe and healthcare settings that dispense and administer PALFORZIA are educated on the following:
    - the risk of anaphylaxis associated with the use of PALFORZIA
    - the Initial Dose Escalation and first dose of each Up-Dosing level must only be administered to patients in a healthcare setting equipped to monitor patients, and to identify and manage anaphylaxis.
  - Ensuring that the Initial Dose Escalation and the first dose of each Up-Dosing level of PALFORZIA are only dispensed and distributed to certified healthcare settings and only administered to patients in certified healthcare settings.
  - Ensuring that PALFORZIA is only dispensed and administered to patients who are informed, by enrolling in the PALFORZIA REMS Program, of the need to have injectable epinephrine available for immediate use at all times, the need for monitoring with the Initial Dose Escalation and first dose of each Up-Dosing level, the need for continued dietary peanut avoidance, and how to recognize the signs and symptoms of anaphylaxis.

# Overview of PALFORZIA REMS Stakeholder Requirements

## Prescriber

- **Review** the PALFORZIA *Prescribing Information*.
- **Enroll** in the REMS by completing the *Prescriber Enrollment Form* and submitting it to the REMS.
- **Enroll each patient** in the PALFORZIA REMS by completing and submitting the *Patient Enrollment Form* and provide a completed copy of the form to the patient.
- **Counsel the patient** on the need to have injectable epinephrine available for immediate use at all times, monitoring with the Initial Dose Escalation and first dose of each Up-Dosing level, the need for continued peanut avoidance in the diet, and how to recognize the signs and symptoms of anaphylaxis.
- **Assess the patient's** supply of injectable epinephrine and provide prescription if necessary
- **Assess the patient's** tolerability of the previous dosing level and appropriateness of continuing the Up-Dosing
- **Report** treatment discontinuation or transfer of care to the REMS Program

## Patient

- **Enroll** in the PALFORZIA REMS by completing the *Patient Enrollment Form* with a prescriber.
- **Receive counseling** from the prescriber on the need to have injectable epinephrine available for immediate use at all times, the need for monitoring with the Initial Dose Escalation and the first dose of each Up-Dosing level, the need for continued peanut avoidance in the diet, and how to recognize the signs and symptoms of severe allergic reaction (anaphylaxis)
- **During treatment** (before the first dose of each Up-Dosing level):
  - **Receive counseling** from a healthcare provider on the need to be monitored for severe allergic reaction (anaphylaxis)
- **During treatment** (during and after administration of the Initial Dose Escalation and the first dose of each Up-Dosing level, for at least 60 minutes):
  - **Be monitored** for severe allergic reaction (anaphylaxis) at the healthcare setting
- **Report anaphylaxis** to your healthcare provider
- **Request more** injectable epinephrine as needed
- Have **injectable epinephrine available** for immediate use at all times
- **Avoid peanuts** and foods that contain peanuts in the diet

# Overview of PALFORZIA REMS Stakeholder Requirements (continued)

## Healthcare Setting

- **Designate a representative** to carry out the certification process and oversee implementation and compliance with the REMS.
- Have the Authorized Representative **review the *Education Program for Healthcare Settings*** (this document).
- Have the Authorized Representative **certify** in the REMS by completing the ***Healthcare Setting Enrollment Form*** and submitting it to the REMS.
- **Train** all relevant staff
- **Establish processes and procedures** to ensure that the following take place:
  - Have a certified prescriber on-site
  - Have **healthcare provider(s) on-site** to counsel each patient, and monitor for and manage anaphylaxis
  - Be able to **manage anaphylaxis on-site**
  - Before Treatment initiation (first dose):
    - **Verify the Initial Dose Escalation** is for the enrolled patient
  - During treatment before dispensing the first dose of each Up-Dosing level:
    - Verify that the **patient is enrolled** in the REMS
    - Have a **healthcare provider counsel the patient** on the need to be monitored for anaphylaxis
    - **Verify** that the dose, as determined by the certified prescriber, is dispensed from the **Office Dose Kit**
    - Verify that the **patient has injectable epinephrine**
  - During and after administering the Initial Dose Escalation and the first dose of each Up-Dosing level
    - Assess the patient for anaphylaxis for at least 60 minutes
- Have any **new Authorized Representative** enroll in the REMS by completing the ***Healthcare Setting Enrollment Form***
- **Maintain records** of dispensing and all processes and procedures
- Comply with **audits**
- **Do not distribute, transfer, loan, or sell PALFORZIA**

## Pharmacy

- **Designate a representative** to carry out the certification process and oversee implementation and compliance with the REMS.
- Have the Authorized Representative **review the *REMS Program Overview for Pharmacies***.
- Have the Authorized Representative **certify** in the REMS by completing the ***Pharmacy Enrollment Form*** and submitting it to the REMS.
- **Train** all relevant staff associated with PALFORZIA.
- **Support** electronic data exchanges and communication with the PALFORZIA REMS system.
- Prior to dispensing the PALFORZIA Initial Dose Escalation, my pharmacy will verify:
  - The prescriber is certified.
  - The patient is enrolled.
  - Initial Dose Escalation is only dispensed to certified healthcare settings.
- Prior to dispensing all Up-Dosing prescriptions, my pharmacy will verify:
  - The patient is enrolled.
  - The prescriber is certified.
  - Only one dose level is dispensed to the patient at a time.

# How to Become a Certified Healthcare Setting

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- To become certified in the PALFORZIA REMS Program and administer PALFORZIA, a healthcare setting (HCS) must designate an Authorized Representative to:
  1. Review the *Education Program for Healthcare Settings*
  2. Carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the healthcare setting
  3. Complete and submit the *Healthcare Setting Enrollment Form*
    - Online at [www.PALFORZIAREMS.com](http://www.PALFORZIAREMS.com) or by fax to 1-844-285-2013
- Upon completion of these steps, the REMS Program will notify the healthcare setting of successful certification within 2 business days.

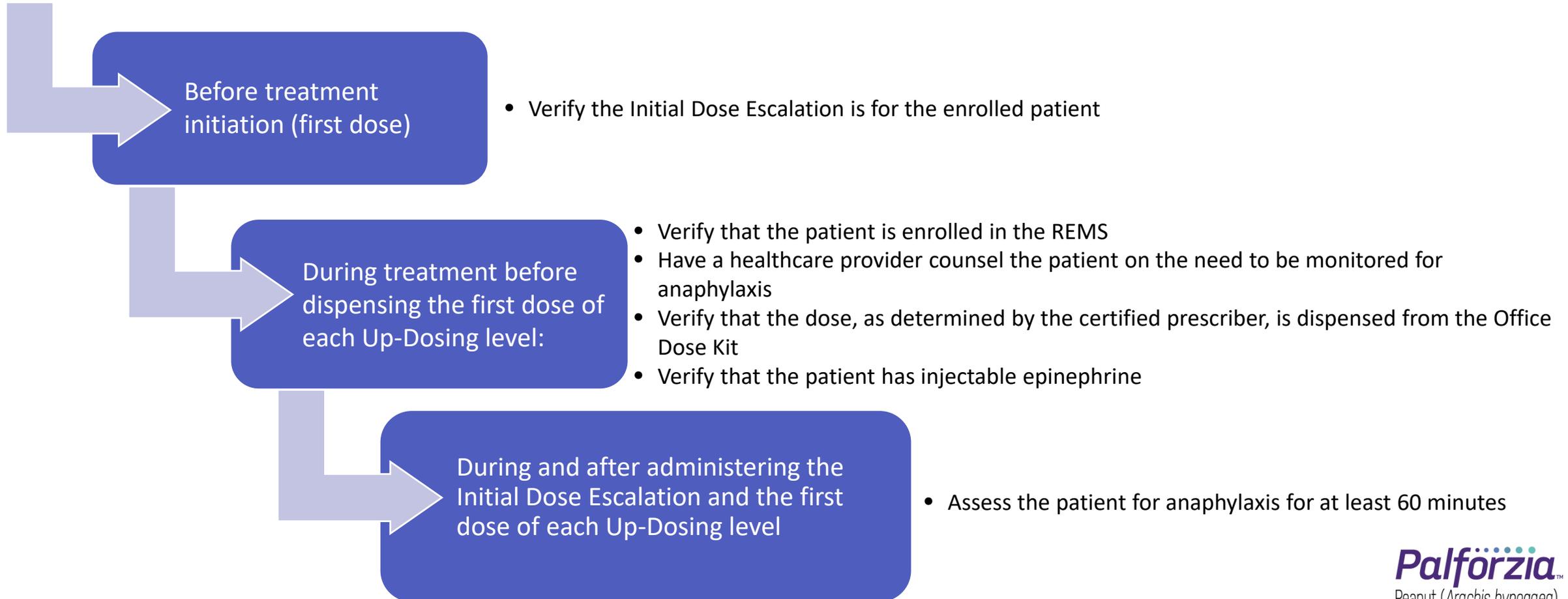
# Healthcare Setting Requirements

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- Oversee implementation of and ensure my healthcare setting's compliance with the PALFORZIA REMS requirements
- Review the *Education Program for Healthcare Settings* (this document)
- Have a certified prescriber on-site
- Have healthcare provider(s) on-site to counsel each patient, and monitor for and manage anaphylaxis
- Be able to manage anaphylaxis on-site
- Train all relevant staff involved in dispensing and administering PALFORZIA

# Healthcare Setting Requirements

- Establish processes and procedures to ensure that the following take place:



# Healthcare Setting Requirements

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- At All Times:
  - Have any new Authorized Representative enroll in the REMS by completing the *Healthcare Setting Enrollment Form*
  - Maintain records of dispensing and that all processes and procedures are in place and are being followed
  - Comply with audits carried out by Aimmune Therapeutics, Inc., or a third party acting on behalf of Aimmune Therapeutics, Inc., to ensure that all processes and procedures are in place and are being followed
  - Not distribute, transfer, loan, or sell PALFORZIA

# Adverse Event Reporting

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- To report negative side effects:
  - Contact Aimmune Therapeutics, Inc. at 1-833-AIM2KNO (1-833-246-2566), or
  - FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or
  - Call FDA at 1-800-FDA-1088 (1-800-332-1088)

# Ordering Instructions

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To order patient-specific PALFORZIA,  
contact a certified pharmacy



To order an Office Dose Kit  
contact a certified distributor



Visit the [www.PALFORZIAREMS.com](http://www.PALFORZIAREMS.com) website to obtain a list  
of pharmacies that are certified to dispense PALFORZIA



Call the REMS Program at 1-844-PALFORZ (1-844-725-3679)  
to obtain a list of  
wholesaler-distributors that are certified to supply  
PALFORZIA

# PALFORZIA REMS Resources

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- For more information about the PALFORZIA REMS, visit [www.PALFORZIAREMS.com](http://www.PALFORZIAREMS.com) or call the REMS Program at 1-844-PALFORZ (1-844-725-3679)

Please see PALFORZIA Prescribing Information, including Boxed Warning and Medication Guide,  
for additional Important Safety Information

# THANK YOU



***Palforzia***<sup>™</sup>  
Peanut (*Arachis hypogaea*)  
Allergen Powder-dnfp