Welcome to the PALFORZIA REMS (Risk Evaluation and Mitigation Strategy) Program

The PALFORZIA REMS (Risk Evaluation and Mitigation Strategy) Program is a safety program that manages the risk of anaphylaxis associated with PALFORZIA®. The PALFORZIA REMS Program is required by the Food and Drug Administration (FDA) to ensure the potential benefits of PALFORZIA outweigh its risks.

**Healthcare Settings**
Healthcare settings must become certified in the PALFORZIA REMS Program to administer PALFORZIA.

**Prescribers**
Prescribers must become certified in the PALFORZIA REMS Program to prescribe PALFORZIA.

**Pharmacies**
Pharmacies must become certified in the PALFORZIA REMS Program to dispense PALFORZIA.

**Patients**
Patients who are prescribed PALFORZIA must be enrolled in the PALFORZIA REMS Program.

**GOALS**

The goal of the PALFORZIA REMS Program is to mitigate the risk of anaphylaxis associated with PALFORZIA by:

1. 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.
2. 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.
3. 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.

If you have questions about the PALFORZIA REMS Program or need help with certification or enrollment, call 1-844-PALFORZ (1-844-725-3679) Monday-Friday, 8:00am – 8:00pm ET

To learn more about the serious risks associated with PALFORZIA, please refer to the Prescribing Information including Boxed Warning and the Medication Guide.

**INDICATION**

PALFORZIA is 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.
Healthcare Setting Overview

Palfiza is only available through the Palfiza REMS Program. In order for a healthcare setting to administer Palfiza, they must become certified.

To Become Certified in the Palfiza REMS Program, Healthcare Settings Must:

1. Designate an Authorized Representative to review the Education Program for Healthcare Settings.
2. Have the Authorized Representative carry out the certification process and oversee implementation and compliance with the REMS Program:
   - A healthcare provider(s) must be on-site to counsel the patient and monitor for and manage anaphylaxis.
   - Have a certified prescriber on-site.
   - Be able to manage anaphylaxis on-site.
   - Train all relevant staff involved in dispensing and administering Palfiza.
3. Complete and submit the Healthcare Setting Enrollment Form to the Palfiza REMS Program:
   - Online.
   - By fax at 1-844-285-2013

Healthcare settings will be notified of successful certification in the Palfiza REMS Program within 2 business days.

The Healthcare Setting Must Establish Processes and Procedures to Ensure That the Following Take Place:

Before treatment initiation, the healthcare setting will:

1. Verify the Initial Dose Escalation is for the enrolled patient.

During treatment, before dispensing the first dose of each Up-Dosing level, the healthcare setting will:

1. Verify that the patient is enrolled in the REMS.
2. Have a healthcare provider counsel the patient on the need to be monitored for anaphylaxis.
3. Verify that the dose, as determined by the certified prescriber, is dispensed from either the Office Dose Kit or the Daily Dose Pack.
4. Verify that the patient has injectable epinephrine.

During and after administering the Initial Dose Escalation and the first dose of each Up-Dosing level, for at least 60 minutes, the healthcare setting will:

1. Assess the patient for anaphylaxis.

During treatment, before dispensing a Daily Dose Pack directly to the patient for home use, the healthcare setting will:

1. Verify the patient was monitored and previously tolerated the first dose of the Up-Dosing level.

At all times, the healthcare setting will:

1. Report anaphylaxis including suspected cases managed as anaphylaxis to the Palfiza REMS Program using the Anaphylaxis Adverse Event Reporting Form:
   - Online.
   - By fax at 1-844-285-2013

2. Only use patient-specific Initial Dose Escalation and Daily Dose Packs for the intended patient.
PALFORZIA REMS Healthcare Setting Enrollment Form

PALFORZIA® is available only through the PALFORZIA REMS Link Education and Intake Program, a restricted program. Only prescribers, healthcare settings, pharmacies, and patients enrolled in the program can prescribe, administer, dispense, and receive PALFORZIA.

INSTRUCTIONS

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 the implementation and compliance with the REMS Program on behalf of the healthcare setting.
3. COMPLETE AND SUBMIT the Healthcare Setting Enrollment Form below or by fax to 1-844-280-203.

Complete all mandatory fields on this form to avoid a delay in the enrollment process. Upon completion of these steps, the REMS Program will notify the healthcare setting of successful certification within 2 business days.

(* Indicates required field)

HEALTHCARE SETTING INFORMATION

*National Provider Identifier (NPI)

CONTINUE

AUTHORIZED REPRESENTATIVE INFORMATION

*First Name

*Last Name

*Role

- Physician
- Physician Assistant
- Nurse Practitioner
- Pharmacist
- Nurse
- Other (Specify Individual designated by healthcare setting)

*Phone Number

*Fax Number

*Address 1

Address 2

*City

*State

ZIP

*Email Address

*Reason for Form (please select one)

- New Enrollment
- New Authorized Representative

HEALTHCARE SETTING AUTHORIZED REPRESENTATIVE AGREEMENT

I am the Authorized Representative designated by my Healthcare Setting to coordinate the activities of the PALFORZIA REMS. By completing, signing, and submitting this form, I agree, on behalf of myself and my Healthcare Setting, to comply with the following REMS requirements:

I WILL:

- Ensure implementation and compliance with the PALFORZIA REMS requirements
- Review the Education Program for Healthcare Settings
- Have a certified provider on-site
- Have healthcare providers 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, and establish processes and procedures to ensure that all patients receive care in my healthcare setting:

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-DOSES 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 certifying pharmacist, is dispensed from either the Office Dose Kit or the Daily Dose Pack.
- Verify that the patient has active epinephrine.

DURING AND AFTER ADMINISTERING THE INITIAL DOSE ESCALATION AND THE FIRST DOSE OF EACH UP-DOSES LEVEL:

- Assess the patient for anaphylaxis for at least 60 minutes.

DURING TREATMENT BEFORE DISPENSING A DAILY DOSE PACK DIRECTLY TO THE PATIENT FOR HOME USE:

- Verify the patient is monitored and previously tolerated the first dose of the Up-Dosing Level.

AT ALL TIMES:

- Report anaphylaxis including suspected cases managed as anaphylaxis to the REMS Program using the Anaphylaxis Advance Event Reporting Form
- 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
- Only use patient-specific initial Dose Escalation and Daily Dose Packs for the intended patient.
- 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
- Assist, distribute, transfer, loan, or sell PALFORZIA

*Authorized Representative Signature

CANCEL

CONTINUE
PALFORZIA® REMS Healthcare Setting Enrollment Form

PALFORZIA® is available only through the PALFORZIA REMS (Box Evaluation and Mitigation Strategy) restricted program. Only prescribers, healthcare settings, pharmacies, and patients enrolled in the program can prescribe, administer, dispense, and receive PALFORZIA.

To become certified in the PALFORZIA REMS Program and administer PALFORZIA, a healthcare setting (PHS) must designate an Authorized Representative to:

1. REVIEW the Education Program for Healthcare Settings.
2. CARRY OUT THE CERTIFICATION PROCESS and ensure implementation and compliance with the REMS Program on behalf of the healthcare setting.
3. COMPLETE AND SUBMIT the Healthcare Setting Enrollment Form before or by 1444-06-15.

Complete all mandatory fields on this form to avoid a delay in the enrollment process. Upon completion of these steps, the REMS Program will notify the healthcare setting of successful certification within 2 business days.

*Indicates required field

**HEALTHCARE SETTING INFORMATION**

- Health Setting Name & Address
- *Street Address 1*
- *City*
- *State*
- *Zip*

Note: If the healthcare setting name/address does not match what is displayed below, please contact the PALFORZIA REMS Call Center at 1-888-PALFORZIA (1-888-725-3699).

**AUTHORIZING PERSONAL INFORMATION**

- First Name
- Last Name
- *Phone Number*
- *Email Address*

**HEALTHCARE SETTING AUTHORIZED REPRESENTATIVE AGREEMENT**

I am the Authorized Representative designated by my Healthcare Setting to coordinate the activities of the PALFORZIA REMS. By completing, signing, and submitting this form, I agree, on behalf of myself and my healthcare setting, to comply with the following REMS requirements:

**I WILL:**

- Oversee implementation and ensure my healthcare setting’s compliance with the PALFORZIA REMS requirements;
- Review the Education Program for healthcare settings;
- Have a certified pharmacists on-site;
- Have healthcare providers on-site to counsel each patient, and monitor for and manage anaphylaxis;
- Be able to manage anaphylaxis on-site;
- Train all relevant staff in dispensing and administering PALFORZIA, and establish processes and procedures to ensure that the following take place in my healthcare setting:

**BEFORE TREATMENT INITIATION (FIRST DOSE):**

- Verify that the initial dose is administered by the healthcare setting;
- Verify that the dose is determined by the certified prescriber, is dispensed from either the OFFONO Kit or the Daily Dose Pack;
- Verify that the patient has been given instructions on the steps that will be taken for the allergic episode:

**DURING AND AFTER ADMINISTERING THE INITIAL DOSE ELEVATION AND THE FIRST DOSE OF EACH UP-DOSING LEVEL:**

- Assess the patient for allergy symptoms for at least 30 minutes;
- Verify that the patient was monitored and previously tolerated the first dose of the up-dosing level;

**DURING TREATMENT BEGINNING A DAILY Dose PACK DIRECTLY TO THE PATIENT FOR HOME USE:**

- Verify the patient was monitored and previously tolerated the first dose of the up-dosing level;

**At ALL TIMES:**

- Record all events including suspected cases managed as anaphylaxis to the REMS Program using the applicable adverse event reporting form;
- Have any new authorized representative enroll in the REMS by completing the Healthcare Setting Enrollment Form;
- Maintain records of dosing and that all processes and procedures are in place and are being followed;
- Only use patient-specific Initial Dose Elevation and Daily Dose Packs for the intended patient;
- Complete with packets certified by Immune Therapeutics, Inc., a third-party acting on behalf of Immune Therapeutics, Inc., to ensure that all processes and procedures are in place and are being followed;
- Submit notices, logs, or forms to PALFORZIA;

**Authorized Representative Signature**
**Palfzoria REMS Healthcare Setting Enrollment Form**

To become certified in the Palfzoria REMS Program and administer Palfzoria, 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 oversees implementation and compliance with the REMS Program on behalf of the healthcare setting
3. **COMPLETE AND SUBMIT** the Healthcare Setting Enrollment Form to the REMS Program by February 20, 2013.

Complete all mandatory fields on this form to avoid delays in the enrollment process. Upon completion of these steps, the REMS Program will notify the healthcare setting of successful verification within 2 business days.

**INSTRUCTIONS**

- Complete all mandatory fields on this form to avoid delays in the enrollment process. Upon completion of these steps, the REMS Program will notify the healthcare setting of successful verification within 2 business days.

### HEALTHCARE SETTING INFORMATION

- **Provider Identifier (NPI)**: [Enter]
- **Healthcare Setting Name**: [Enter]
- **Healthcare Setting Type**: [Enter]
- **Address 1**: [Enter]
- **City**: [Enter]
- **State**: [Enter]
- **ZIP**: [Enter]
- **NPI**: [Enter]

### AUTHORIZED REPRESENTATIVE INFORMATION

- **First Name**: [Enter]
- **Last Name**: [Enter]
- **Date of Birth**: [Enter]
- **Drivers License#: [Enter]
- **State**: [Enter]
- **Address 1**: [Enter]
- **City**: [Enter]
- **State**: [Enter]
- **ZIP**: [Enter]
- **Phone Number**: [Enter]
- **FAX Number**: [Enter]
- **E-mail Address**: [Enter]

### HEALTHCARE SETTING AUTHORIZED REPRESENTATIVE AGREEMENT

I am the Authorized Representative designated by my Healthcare Setting to coordinate the activities of the Palfzoria REMS. By completing, signing, and submitting this form, I agree, on behalf of myself and my Healthcare Setting, to comply with the following REMS requirements:

**I WILL:**
- Enroll the setting in the REMS Program which is compliant with the Palfzoria REMS requirements.
- Review the Education Program for healthcare Setting.
- Have a valid certification on site.
- Have Healthcare professionals on site to counsel each patient, and instruct for and manage aphasia.
- Use a standard management protocol for Palfzoria.
- Train all relevant staff involved in dispensing and administering Palfzoria, and establish procedures and procedures to ensure that the following takes place in my setting:
  - **Before Treatment Initiation (BRI)**:
    - Notify the Initial Dose Observation Program of any adverse event.
  - **During Treatment**:
    - Provide a daily dose pack to the patient for home use.
    - Monitor the patient for adverse events following the first dose.

At all times:
- Report any adverse events following the first dose as required by the REMS Program using the Aphasia Adverse Event Reporting Form.
- Have my authorized representative enrolled in the REMS Program by responding to the Healthcare Setting Initiation Form.
- Maintain records of dispensing and any adverse event following the first dose and any adverse incident.
- In the event of a death, I will notify the REMS Program.
- Notify a designated product information agent in the event of an adverse event.
- Ensure that all processes and procedures are in place and are being followed.

**Authorized Representative Signatures**
PALFORZIA REMS Healthcare Setting Enrollment Form

PALFORZIA® is available only through a REMS Program Administrator (RP). The REMS Program Administrator is responsible for the monitoring and management of patients prescribed PALFORZIA®.

**Healthcare Setting Information**

If the healthcare setting is not valid, please contact the REMS Program Administrator for assistance.

**Healthcare Setting Name**

**Healthcare Setting Type**

- Hospital 
- Clinic 
- Ambulatory Surgical Center

**Address**

- City: 
- State: 
- Zip Code: 

**Healthcare Setting Information**

If the healthcare setting is not valid, please contact the REMS Program Administrator for assistance.

**Healthcare Setting Name**

**Healthcare Setting Type**

- Hospital 
- Clinic 
- Ambulatory Surgical Center

**Address**

- City: 
- State: 
- Zip Code: 

**Authorized Representative Information**

**First Name**

**Last Name**

**Title**

**Phone Number**

**E-mail Address**

**Affiliation**

**Authorized Representative Signature**

**Healthcare Setting Authorizing Representative Agreement**

I am the Authorized Representative Designated by the Healthcare Setting to coordinate the activities of the PALFORZIA REMS. By completing, signing, and submitting this form, I agree to do all that is required of me to create, maintain, and monitor the healthcare setting, as may be required by the REMS Program Administrator.

**Healthcare Setting Authorization Agreement**

I am the Authorized Representative Designated by the Healthcare Setting to coordinate the activities of the PALFORZIA REMS. By completing, signing, and submitting this form, I agree to do all that is required of me to create, maintain, and monitor the healthcare setting, as may be required by the REMS Program Administrator.
PALFORZIA REMS Healthcare Setting Certification Successful

You have successfully completed and submitted the Healthcare Setting Enrollment Form.

Confirmation of your certification has been sent to the email address provided.

To report side effects please contact
Aimmune Therapeutics, Inc. at 1-833-AIM2KNO (1-833-266-2566)
or FDA at www.fda.gov/medwatch
or call 1-800-FDA-1088 (1-800-332-1088).

Aimmune Therapeutics, Inc.
Prescriber Overview

PALFORZIA is only available through the PALFORZIA REMS Program. In order for a prescriber to prescribe PALFORZIA, they must become certified.

TO BECOME CERTIFIED IN THE PALFORZIA REMS PROGRAM, PREScriBers MUST:

1. REVIEW the PALFORZIA Prescribing Information

2. COMPLETE AND SUBMIT the Prescriber Enrollment Form to the PALFORZIA REMS Program
   - Online
   - By fax at 1-844-285-2015

Prescribers will be notified of successful certification in the PALFORZIA REMS Program within 1 business days.

HOW DO I ENROLL A PATIENT IN THE PALFORZIA REMS PROGRAM?

1. COMPLETE the PALFORZIA Patient Enrollment Form with each patient prior to administering PALFORZIA:
   - Online
   - By fax at 1-844-285-2015
   - Patient Enrollment Form (English)
   - Patient Enrollment Form (Spanish)

ADMINISTRATION REQUIREMENTS:

Before treatment initiation, the prescriber will:

1. Enroll the patient

2. Provide the patient with a completed copy of the Patient Enrollment Form

3. Counsel the patient on:
   - 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 peanut avoidance in the diet
   - how to recognize the signs and symptoms of anaphylaxis

4. Assess the patient's supply of injectable epinephrine and provide prescription if necessary

During treatment and before dispensing the first dose of each Up-Dosing level, the prescriber will:

1. Assess the patient's tolerability of the previous dosing level and appropriateness of continuing the Up-Dosing

During treatment and before prescribing a Daily Dose Pack to be dispensed from a certified pharmacy to a patient for home use, the prescriber will:

1. Verify the patient was monitored and previously tolerated the first dose of the Up-Dosing level

During treatment and before dispensing a Daily Dose Pack directly from the healthcare setting to the patient for home use, the prescriber will:

1. Verify the patient was monitored and previously tolerated the first dose of the Up-Dosing level

At all times, the prescriber will:

1. Report anaphylaxis including suspected cases managed as anaphylaxis to the PALFORZIA REMS Program using the Anaphylaxis Adverse Event Reporting Form
   - Online
   - By fax at 1-844-285-2015

2. Report patient treatment discontinuation or transfer of care
PALFORZIA® REMS Prescriber Enrollment Form

PALFORZIA® is available only through the PALFORZIA REMS (Risk Evaluation and Mitigation Strategy), a restricted program. Only prescribers, healthcare settings, pharmacies, and patients enrolled in the program can prescribe, administer, disperse, and receive PALFORZIA.

**INSTRUCTIONS**

1. **REVIEW** the PALFORZIA Prescribing Information (PI).
2. **COMPLETE AND SUBMIT** the Prescriber Enrollment Form below or by fax to 1-844-285-3013.

Complete all mandatory fields on this form to avoid a delay in the enrollment process. Upon completion of these steps, the REMS Program will notify the prescriber of successful certification within 2 business days.

(*) Indicates required field.

**PRESCRIBER INFORMATION**

*National Provider Identifier (NPI) [ ]

[ ] CONTINUE

**OFFICE CONTACT INFORMATION**

First Name [ ]

Last Name [ ]

Office Phone Number - Same as above [ ]

Office Fax Number - Same as above [ ]

Office Phone Number [ ]

Office Fax Number [ ]

Email Address [ ]

To provide additional Office Contacts please contact the PALFORZIA REMS Coordinating Center at 1-844-PALFORZ (1-844-725-3679)

**PRESCRIBER AGREEMENT**

By completing, signing, and submitting this form, I agree to comply with the following REMS requirements:

• Review the PALFORZIA Prescribing Information (PI)

BEFORE TREATMENT INITIATION, TO PRESCRIBE PALFORZIA TO A PATIENT, I WILL:

• 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, the need for 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.

DURING TREATMENT BEFORE DISPENSING THE FIRST DOSE OF EACH UP-DOSING LEVEL, I WILL:

• Assess the patient’s tolerability of the previous dosing level and appropriateness of continuing the Up-Dosing.

DURING TREATMENT BEFORE PRESCRIBING A DAILY DOSE PACK TO BE DISPENSED FROM A CERTIFIED PHARMACY TO A PATIENT FOR HOME USE, I WILL:

• Verify the patient was monitored and previously tolerated the first dose of the Up-Dosing level.

DURING TREATMENT BEFORE DISPENSING A DAILY DOSE PACK DIRECTLY FROM THE HEALTHCARE SETTING TO THE PATIENT FOR HOME USE, I WILL:

• Verify the patient was monitored and previously tolerated the first dose of the Up-Dosing level.

AT ALL TIMES:

• Report anaphylaxis including suspected cases managed as anaphylaxis to the REMS Program using the Anaphylaxis/Adverse Event Reporting Form.

• Report treatment discontinuation or transfer of care to the REMS Program.

[ ] Prescriber Signature [ ]

[ ] CANCEL [ ] CONTINUE
PALFORZIA REMS Prescriber Enrollment Form

PALFORZIA® is available only through the PALFORZIA REMS (Risk Evaluation and Mitigation Strategy), a restricted program. Only prescribers, healthcare settings, pharmacies, and patients enrolled in the program can prescribe, administer, dispense, and receive PALFORZIA.

INSTRUCTIONS

1. REVIEW the PALFORZIA Prescribing Information (PI).

2. COMPLETE AND SUBMIT the Prescriber Enrollment Form below or by fax to 1-844-286-2013.

Complete all mandatory fields on this form to avoid a delay in the enrollment process. Upon completion of these steps, the REMS Program will notify the prescriber of successful certification within 2 business days.

(*) Indicates required field

PRESCRIBER INFORMATION

*National Provider Identifier (NPI)

If the prescriber name/address does not match what is displayed below, please contact the PALFORZIA REMS Call Center at 1-844-PALFORZ (1-844-725-3797).

*First Name

*Last Name

*Credential (please select one)

- MD
- DO
- PA
- PA-PA
- Other

*Office Phone Number

*Office Fax Number

*Practice/Facility Name

Address 1

Address 2

*City

*State

*ZIP

OFFICE CONTACT INFORMATION

First Name

Last Name

Office Phone Number - Same as above

Office Fax Number - Same as above

Email Address

To provide additional Office Contacts please contact the PALFORZIA REMS Coordinating Center at 1-844-PALFORZ (1-844-725-3797).

PRESCRIBER AGREEMENT

By completing, signing, and submitting this form, I agree to comply with the following REMS requirements:

• Review the PALFORZIA Prescribing Information (PI).

BEFORE TREATMENT INITIATION, TO PRESCRIBE PALFORZIA TO A PATIENT, I WILL:

• Enroll each patient in the PALFORZIA REMS by completing and submitting the patient enrollment form and provide a complete copy of the form to the patient.

• Ensure the patient on the need to have anaphylaxis management 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 peanut avoidance in the diet, and how to recognize the signs and symptoms of anaphylaxis.

• Assess the patient’s supply of epinephrine and provide prescription if necessary.

DURING TREATMENT BEFORE DISPENSING THE FIRST DOSE OF EACH UP-DOSING LEVEL, I WILL:

• Assess the patient’s ability to use the previous dosing level and appropriateness of continuing the Up-Dosing.

DURING TREATMENT BEFORE DISPENSING A DAILY DOSE PACK TO BE DISPENSED FROM A CERTIFIED PHARMACY TO A PATIENT FOR HOME USE, I WILL:

• Verify the patient was monitored and previously tolerated the first dose of the Up-Dosing level.

DURING TREATMENT BEFORE DISPENSING A DAILY DOSE PACK DIRECTLY FROM THE HEALTHCARE SETTING TO THE PATIENT FOR HOME USE, I WILL:

• Verify the patient was monitored and previously tolerated the first dose of the Up-Dosing level.

AT ALL TIMES:

• Report anaphylaxis including suspected cases managed as anaphylaxis to the REMS Program using the Anaphylaxis Adverse Event Reporting Form.

• Report treatment discontinuation or transfer of care to the REMS Program.

*Prescriber Signature

CANCEL  CONTINUE
PALFORZIA REMS Prescriber Enrollment Successful

You have successfully completed and submitted the Prescriber Enrollment Form.

Confirmation of your certification has been sent to the email address provided.

To report side effects please contact:
Aimmune Therapeutics, Inc. at 1-833-AIM2ENG (1-833-246-2566)
or FDA at www.fda.gov/medwatch
or call 1-800-FDA-1088 (1-800-332-1088).

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Pharmacies

Dispensing of PALFORZIA is limited to contracted pharmacies that will be certified in the PALFORZIA REMS Program.

TO BECOME CERTIFIED IN THE PALFORZIA REMS PROGRAM, PHARMACIES MUST:

1. Designate an Authorized Representative to review the REMS Program Overview for Pharmacies
2. Have the Authorized Representative carry out the certification process and oversee implementation and compliance with the REMS Program
3. Complete and submit the Pharmacy Enrollment Form to the PALFORZIA REMS Program
   - By fax at 1-844-285-2013

Pharmacies will be notified of certification in the PALFORZIA REMS Program within 2 business days.

DISPENSING REQUIREMENTS:

1. 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

2. Prior to dispensing all Up-Dosing (Daily Dose Pack) Prescriptions, my pharmacy will verify:
   - The patient is enrolled
   - The prescriber is certified
   - Only one dose level is dispensed at a time

3. Prior to dispensing a Daily Dose Pack directly to a patient by shipping it to them for home use, my pharmacy will verify with the prescriber or healthcare setting and document:
   - The patient was monitored and previously tolerated the first dose of the Up-Dosing level
Patients

PALFORZIA is available only through the PALFORZIA REMS Program. For a patient to receive PALFORZIA the prescriber must enroll the patient in the PALFORZIA REMS Program.

HOW DO I BECOME ENROLLED IN THE PALFORZIA REMS PROGRAM?

1. DISCUSS THE BENEFITS AND RISKS of PALFORZIA with your doctor.

2. ASK YOUR DOCTOR any questions you have about taking PALFORZIA and about the PALFORZIA REMS Program.

3. MAKE SURE you understand:
   - How to enroll and take part in the PALFORZIA REMS
   - The benefits and risks of PALFORZIA
   - That you must have injectable epinephrine available at all times
   - That you must avoid peanuts or peanut containing foods in the diet
   - That you know the signs and symptoms of severe allergic reaction (anaphylaxis) and to tell your doctor if you have any of these signs or symptoms
   - You will need to receive certain doses at your doctor’s office
   - You will need to be monitored after doses received at your doctor’s office for at least 60 minutes

4. TOGETHER WITH YOUR DOCTOR, complete and sign the Patient Enrollment Form.
   - Patient Enrollment Form (English)
   - Patient Enrollment Form (Spanish)

To report side effects please contact Aimmune Therapeutics, Inc. at 1-833-AIM2KNO (1-833-246-2566) or FDA at www.fda.gov/medwatch or call 1-800-FDA-1088 (1-800-332-1088).
Resources

Resources for Healthcare Settings
- Palforzia REMS Education Program for Healthcare Settings
- Palforzia REMS Healthcare Setting Enrollment Form

Resources for Prescribers
- Palforzia REMS Prescriber Enrollment Form
- Palforzia REMS Patient Enrollment Form - English
- Palforzia REMS Patient Enrollment Form - Spanish

Resources for Pharmacies
- Palforzia REMS Program Overview for Pharmacies
- Palforzia REMS Pharmacy Enrollment Form

Resources for Patients
- Medication Guide
- Palforzia REMS Patient Enrollment Form - English
- Palforzia REMS Patient Enrollment Form - Spanish

Patient Care Forms
- Palforzia REMS Anaphylaxis Adverse Event Reporting Form
Certified Participant Locator

For a list of authorized wholesalers-distributors, please contact the PALFORZIA REMS Program at 1-844-PALFORZ (1-844-725-3679).

Please select a certified participant to locate
- Prescriber/Healthcare Setting
- Pharmacy
Certified Participant Locator

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* Please select a certified participant to locate
  - [ ] Prescriber/Healthcare Setting
  - [ ] Pharmacy

* Zip Code: ____________________________

* Search Radius: ____________________________
  -- Please Select --

SEARCH

To report side effects please contact
Aimmune Therapeutics, Inc. at 1-833-AIM2KNO (1-833-246-2566)
or FDA at www.fda.gov/medwatch
or call 1-800-FDA-1088 (1-800-332-1088).

Aimmune Therapeutics, Inc.
Certified Participant Locator

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  - Pharmacy

Certified Prescribers  Certified Healthcare Settings

*Zip Code: 12345  *Search Radius: Within 25 miles

SEARCH

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Certified Prescribers  Certified Healthcare Settings

*Zip Code: 12345  *Search Radius: Within 25 miles

SEARCH

Map  Satellite

HEALTHCARE SETTING NAME
920 Harvest Drive
Blue Bell, PA 19422
555-555-1212
Directions

HEALTHCARE SETTING NAME
920 Harvest Drive
STE 200
Blue Bell, PA 19422
555-555-1212
Directions

HEALTHCARE SETTING NAME
920 Harvest Drive
#200
Blue Bell, PA 19422
555-555-1212
Directions

HEALTHCARE SETTING NAME
2703 Aspen Cir
Blue Bell, PA 19422
555-555-1212
Directions

HEALTHCARE SETTING NAME
eojnibn
AK01Wnp
KwKww, PA 1901
Directions
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- Pharmacy

Certified Pharmacies

<table>
<thead>
<tr>
<th>Pharmacy Name</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC Pharmacy</td>
<td>555 555-1212</td>
</tr>
</tbody>
</table>

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Login is available to certified prescribers to enroll patients, certified healthcare setting users to verify patient enrollment and certified pharmacy users to verify patient, prescriber and healthcare setting enrollment prior to dispensing PALFORZIA.

User Name

LOGIN

Forgot Username
Contact Us

Phone
1-844-PALFORZ (1-844-725-3679)

Fax
1-844-285-2013

Hours of Operation
Monday - Friday
8:00 AM - 8:00 PM
Eastern Time

For more information on PALFORZIA, please read the Medication Guide.

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