I. Administrative Information

Application Number: BLA 125696
Application Holder: Aimmune Therapeutics, Inc.
Initial REMS Approval: 01/2020
Most Recent REMS Update: 05/2021

II. REMS Goal

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:
   a. the risk of anaphylaxis associated with the use of PALFORZIA
   b. 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.

III. REMS Requirements

Aimmune Therapeutics, Inc. must ensure that healthcare providers, patients, healthcare settings, pharmacies, and wholesalers-distributors comply with the following requirements:

1. Healthcare providers who prescribe PALFORZIA must:

   To become certified to prescribe

   1. Review the PALFORZIA Prescribing Information.
   2. Enroll in the REMS by completing the Prescriber Enrollment Form and submitting it to the REMS Program.
Before treatment initiation (first dose)  
3. Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS Program. Provide a completed copy of the form to the patient.  
4. 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.  
5. 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  
6. 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  
7. 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  
8. Verify the patient was monitored and previously tolerated the first dose of the Up-Dosing level.

At all times  
9. Report anaphylaxis including suspected cases managed as anaphylaxis to the REMS Program using the Anaphylaxis Adverse Event Reporting Form.  
10. Report treatment discontinuation or transfer of care to the REMS Program.

2. Patients who are prescribed PALFORZIA:

Before treatment initiation  
1. Enroll in the REMS Program by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the REMS Program.  
2. 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 anaphylaxis.

During treatment, before the first dose of each Up-Dosing level  
3. Receive counseling from a healthcare provider on the need for monitoring for 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  
4. Be monitored for anaphylaxis at the healthcare setting.
At all times

5. Report anaphylaxis to your healthcare provider.
6. Inform your healthcare provider if you need more injectable epinephrine.
7. Have injectable epinephrine available for immediate use.
8. Adhere to the safe use conditions: avoid peanuts and foods that contain peanuts.

### 3. Healthcare settings that dispense PALFORZIA must:

| To become certified to dispense | 1. Have healthcare provider(s) on-site to monitor for and manage anaphylaxis. |
|                               | 2. Have a certified prescriber on-site. |
|                               | 3. Be able to manage anaphylaxis on-site. |
|                               | 4. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the healthcare setting. |
|                               | 5. Have the authorized representative review the Education Program for Healthcare Settings. |
|                               | 6. Have the authorized representative enroll in the REMS Program by completing the Healthcare Setting Enrollment Form and submitting it to the REMS Program. |
|                               | 7. Train all relevant staff involved in dispensing and administering PALFORZIA using the Education Program for Healthcare Settings. |
|                               | 8. Establish processes and procedures to verify the Initial Dose Escalation is prescribed to initiate treatment. |
|                               | 9. Establish processes and procedures to verify the dose, as determined by the certified prescriber, from either the Office Dose Kit or the Daily Dose Pack is dispensed to enrolled patients for the first dose of each Up Dosing level. |
|                               | 10. Establish processes and procedures to verify the patient is monitored by a healthcare provider during and after the Initial Dose Escalation and the first dose of each Up-Dosing level. |
|                               | 11. Establish processes and procedures to verify the patient has injectable epinephrine before the first dose of each Up-Dosing level. |
|                               | 12. Establish processes and procedures to verify the patient was monitored and previously tolerated the first dose of the Up-Dosing level before dispensing a Daily Dose Pack directly to the patient for home use. |
| Before administering (first dose) | 13. Verify the Initial Dose Escalation is for the enrolled patient. |

**During treatment; before the first dose of each Up-Dosing level**

14. Verify that the patient is enrolled in the REMS through the processes and procedures established as a requirement of the REMS Program.
15. Counsel the patient on the need for monitoring for anaphylaxis.
16. Verify that the dose, as determined by the certified prescriber, is dispensed from either the Office Dose Kit or the Daily Dose Pack through the processes and procedures established as a requirement of the REMS Program.
17. Verify that the patient has injectable epinephrine through the processes and procedures established as a requirement of the REMS Program.
During and after administering the Initial Dose Escalation and the first dose of each Up-Dosing level, for at least 60 minutes:

18. Assess the patient for anaphylaxis through the processes and procedures established as a requirement of the REMS Program.

During treatment; before dispensing a Daily Dose Pack directly to the patient for home use:

19. Verify the patient was monitored and previously tolerated the first dose of the Up-Dosing level through processes and procedures established as a requirement of the REMS Program.

To maintain certification to dispense:

20. Have a new Authorized Representative enroll in the REMS Program by completing the Healthcare Setting Enrollment Form if the authorized representative changes.

At all times:

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

22. Not distribute, transfer, lend or sell PALFORZIA.

23. Maintain records of dispensing and that all processes and procedures are in place and are being followed.

24. Only use patient-specific Initial Dose Escalation and Daily Dose Packs for the intended patient.

25. 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.

4. Pharmacies that dispense PALFORZIA must:

To become certified to dispense:

1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the pharmacy.

2. Have the authorized representative review the REMS Program Overview for Pharmacies.

3. Have the Authorized Representative enroll in the REMS Program by completing the Pharmacy Enrollment Form and submitting it to the REMS Program.

4. Train all relevant staff involved in dispensing PALFORZIA using the REMS Program Overview for Pharmacies.

5. For the Initial Dose Escalation: Establish processes and procedures to verify that the prescriber is certified, the patient is enrolled, and the Initial Dose Escalation is only dispensed to certified healthcare settings.

6. For all Up-Dosing (Daily Dose Pack) prescriptions: Establish processes and procedures to verify that the patient is enrolled, the prescriber is certified, and only one dose level is dispensed at a time.

7. For Daily Dose Packs dispensed directly to a patient by shipping it to them for home use: Establish processes and procedures to verify with the prescriber or healthcare setting and document the patient was monitored and previously tolerated the first dose of the Up-Dosing level.

Before dispensing the Initial Dose Escalation:

8. Verify the prescriber is certified, the patient is enrolled, and the Initial Dose Escalation is only dispensed to a certified healthcare setting through the processes and procedures established as a requirement of the REMS Program.
<table>
<thead>
<tr>
<th>Before dispensing all Up-Dosing (Daily Dose Pack) prescriptions</th>
<th>9. Verify that the patient is enrolled, the prescriber is certified, and only one dose level is dispensed at a time through the processes and procedures established as a requirement of the REMS Program.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before dispensing a Daily Dose Pack directly to a patient by shipping it to them for home use</td>
<td>10. Verify with the prescriber or healthcare setting and document that the patient was monitored and previously tolerated the first dose of the Up-Dosing level through the processes and procedures established as a requirement of the REMS Program.</td>
</tr>
<tr>
<td>To maintain certification to dispense</td>
<td>11. Have a new Authorized Representative enroll in the REMS Program by completing the Pharmacy Enrollment Form if the Authorized Representative changes.</td>
</tr>
<tr>
<td>At all times</td>
<td>12. Not dispense the Initial Dose Escalation for use outside a certified healthcare setting.</td>
</tr>
<tr>
<td></td>
<td>13. Not dispense a Daily Dose Pack for the first dose of an Up-Dosing level for use outside a certified healthcare setting.</td>
</tr>
<tr>
<td></td>
<td>14. Not distribute, transfer, loan or sell PALFORZIA.</td>
</tr>
<tr>
<td></td>
<td>15. Maintain records that all processes and procedures are in place and are being followed.</td>
</tr>
<tr>
<td></td>
<td>16. 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.</td>
</tr>
</tbody>
</table>

### 5. Wholesalers-distributors that distribute PALFORZIA must:

#### To be able to distribute

1. Establish processes and procedures to ensure that PALFORZIA is distributed only to certified pharmacies and certified healthcare settings.
2. Train all relevant staff involved in distributing on the REMS Program requirements.

#### At all times

3. Distribute only to certified pharmacies and healthcare settings.
4. Maintain records of PALFORZIA distribution.
5. 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.

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**Aimmune Therapeutics, Inc. must provide training to healthcare settings that dispense PALFORZIA.**

The training includes the following educational material: Education Program for Healthcare Settings. The training must be available online and by hard copy via fax, e-mail and mail.

**Aimmune Therapeutics, Inc. must provide training to pharmacies that dispense PALFORZIA.**

The training includes the following educational materials: REMS Program Overview for Pharmacies. The training must be available online and by hard copy via fax, e-mail and mail.
To support REMS Program operations, Aimmune Therapeutics, Inc. must:

1. Establish and maintain a REMS Program website, www.PALFORZIAREMS.com. The REMS Program website must include the capability to complete prescriber and healthcare setting certification online, the capability to enroll patients online, verify prescriber, healthcare setting certification and patient enrollment online, report anaphylaxis adverse events, and the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website. The REMS program website must not link back to the promotional product website(s).

2. Make the REMS Program website fully operational and all REMS Program materials available through the website and REMS Program Coordinating Center by the date PALFORZIA is first commercially distributed.

3. Establish and maintain a REMS Program Coordinating Center for REMS participants at 1-844-725-3679.

4. Establish and maintain a validated, secure database of all REMS Program participants who are enrolled and/or certified in the PALFORZIA REMS Program.

5. Ensure prescribers and healthcare settings are able to become certified in the REMS Program by fax and online.

6. Ensure pharmacies are able to become certified in the REMS Program by fax.

7. Ensure that prescribers are able to enroll patients in the REMS Program by fax and online.

8. Ensure prescribers and healthcare providers are able to report any adverse events of anaphylaxis by fax and mail using the Anaphylaxis Adverse Event Reporting Form, and online.

9. Ensure pharmacies are able to verify patient enrollment, prescriber and healthcare setting certification by phone and online.

10. Provide the Prescriber Enrollment Form, the Prescribing Information, the Patient Enrollment Form, and the Anaphylaxis Adverse Event Reporting Form to healthcare providers who (1) attempt to prescribe PALFORZIA and are not yet certified or (2) inquire about how to become certified.

11. Provide the Healthcare Setting Enrollment Form, the Education Program for Healthcare Settings, the Patient Enrollment Form, and the Anaphylaxis Adverse Event Reporting Form to healthcare settings that (1) attempt to dispense PALFORZIA and are not yet certified or (2) inquire about how to become certified.

12. Provide the Pharmacy Enrollment Form and the REMS Program Overview for Pharmacies to pharmacies that (1) attempt to dispense PALFORZIA and are not yet certified or (2) inquire about how to become certified.

13. Notify prescribers, healthcare settings and pharmacies within 2 business days after they become certified in the REMS Program.

14. Provide certified pharmacies access to the database of certified prescribers, healthcare settings and enrolled patients.

15. Provide authorized wholesalers-distributors access to the database of certified pharmacies and healthcare settings.

16. Provide certified prescribers and healthcare settings access to the database of certified pharmacies, authorized wholesalers-distributors and enrolled patients.

To ensure REMS participants’ compliance with the REMS Program, Aimmune Therapeutics, Inc. must:

17. Maintain adequate records to demonstrate that REMS Program requirements have been met, including, but not limited to records of: PALFORZIA distribution and dispensing; certification of prescribers, healthcare settings, and pharmacies; enrolled patients; documentation of completed Anaphylaxis Adverse Event Reporting Forms; audits of REMS participants. These records must be readily available for FDA inspections.
18. Establish a plan for addressing noncompliance with REMS Program requirements.

19. Monitor prescribers, healthcare settings, and pharmacies on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, including decertification.

20. Verify annually that the authorized representative’s name and information correspond to the certified healthcare setting.

21. Verify annually that the authorized representative’s name and information correspond to the certified pharmacy.

22. Maintain an ongoing annual audit plan of 10% (but no less than 50) certified healthcare settings and 10% (but no less than 50) certified pharmacies.

23. Audit 10% but no less than 50 certified healthcare settings no later than 120 calendar days after the healthcare setting places its first order for PALFORZIA to ensure that REMS Program processes and procedures are in place, functioning, and support the REMS Program requirements.

24. Audit 10% but no less than 50 certified pharmacies no later than 120 calendar days after the pharmacy dispenses its first prescription of PALFORZIA to ensure that REMS Program processes and procedures are in place, functioning, and support the REMS Program requirements.

25. Audit all wholesalers-distributors no later than 120 calendar days after they become authorized to distribute the drug and annually thereafter, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements.

26. Take reasonable steps to improve implementation of and compliance with the requirements in the PALFORZIA REMS Program based on monitoring and evaluation of the PALFORZIA REMS Program.

IV. REMS Assessment Timetable

Aimmune Therapeutics, Inc. must submit REMS assessments at 6 months and 12 months and annually thereafter from the date of initial approval of the REMS (01/31/2020). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Aimmune Therapeutics, Inc. must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the PALFORZIA REMS:

Enrollment Forms

Prescriber:

1. Prescriber Enrollment Form

Patient:

2. Patient Enrollment Form

Healthcare Settings:

3. Healthcare Setting Enrollment Form

Pharmacy:

4. Pharmacy Enrollment Form
Training and Educational Materials

Healthcare settings:
5. Education Program for Healthcare Settings

Pharmacy:
6. REMS Program Overview for Pharmacies

Patient Care Forms
7. Anaphylaxis Adverse Event Reporting Form

Other Materials
8. REMS Program Website

AIMT-REMS-USA-1000 Version Date 05/21
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 online at www.PALFORZIAREMS.com or by fax to 1-844-285-2013.

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.

PRESCRIBER INFORMATION (*indicates required field)

<table>
<thead>
<tr>
<th>First Name*</th>
<th>Last Name*</th>
<th>National Provider Identifier (NPI #)*</th>
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<tr>
<th>Credentials* (please select one):</th>
<th>Specialty* (please select one):</th>
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<tr>
<td>MD</td>
<td>DO</td>
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<tr>
<th>Office Phone Number*</th>
<th>Office Fax Number*</th>
<th>Email Address*</th>
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</table>

Practice/Facility Name*:

Address 1*:

Address 2:

City*:

State*:

Zip*:

OFFICE CONTACT INFORMATION

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<th>First Name:</th>
<th>Last Name:</th>
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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 (1-844-725-3679)

PRESCRIBER AGREEMENT

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

- 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

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Prescriber Signature * ______________________ Date* ____________

Phone: 1-844-PALFORZ (1-844-725-3679) www.PALFORZIAREMS.com Fax: 1-844-285-2013
**PRESCRIBER INSTRUCTIONS:**

1. Review the Patient Enrollment Form with the patient or parent/guardian and answer any questions the patient or parent/guardian has about PALFORZIA.

2. Complete and submit the Patient Enrollment Form online at www.PALFORZIAREMS.com or by fax to 1-844-285-2013. Complete all mandatory fields on this form to avoid a delay in the enrollment process. Upon completion of the form, the REMS Program will notify the prescriber of successful patient enrollment within 2 business days.

**PRESCRIBER INFORMATION** (*indicates required field)

<table>
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<tr>
<th>First Name:*</th>
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<th>National Provider Identifier (NPI #)*:</th>
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<td>Practice/Facility Name*:</td>
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<td>Address 1*:</td>
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<td>Address 2:</td>
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<tr>
<td>City*:</td>
<td>State*:</td>
<td>ZIP*:</td>
</tr>
<tr>
<td>Office Phone Number *:</td>
<td>Email Address*:</td>
<td></td>
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</tbody>
</table>

**PATIENT INFORMATION** (*indicates required field)

<table>
<thead>
<tr>
<th>First Name*:</th>
<th>MI:</th>
<th>Last Name*:</th>
<th>Date of Birth* (MM/DD/YYYY)</th>
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<tbody>
<tr>
<td>Address 1*:</td>
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<td>Address 2:</td>
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<tr>
<td>City*:</td>
<td>State*:</td>
<td>ZIP*:</td>
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<td>Phone Number:</td>
<td>Email Address:</td>
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<tr>
<td>Parent/Guardian First Name*:</td>
<td>Parent/Guardian Last Name*:</td>
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<tr>
<td>Relationship to Patient*:</td>
<td>Parent/Guardian Phone Number*:</td>
<td>Same as above</td>
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</table>

**PATIENT AGREEMENT**

By signing this form, the patient/parent/guardian acknowledges the following:

**Before treatment begins:**
- Enroll in the PALFORZIA REMS by completing this Patient Enrollment Form with prescriber
- Receive counseling 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

**Patient/parent/guardian will:**
- 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

**Patient/parent/guardian understands:**
- In order to receive PALFORZIA, patient is required to be enrolled in the REMS, and patient’s information will be stored in a database of all patients who receive PALFORZIA in the United States
- Aimmune Therapeutics, Inc., and its agents, including trusted vendors, may contact patient via phone, mail, fax, or email to support administration of the REMS

☐ Patient or ☐ Parent/Guardian Signature* (please select one and sign):

Printed Parent/Guardian Name (if applicable):
### 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 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 or by fax to 1-844-285-2013.

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 healthcare setting of successful certification within 2 business days.

### HEALTHCARE SETTING INFORMATION

<table>
<thead>
<tr>
<th>Healthcare Setting Name*</th>
<th>National Provider Identifier (NPI #)*</th>
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<tr>
<th>Healthcare Setting Type*</th>
<th>Independent Practice</th>
<th>Private Group Practice</th>
<th>Outpatient Clinic</th>
<th>Hospital Ambulatory Clinic</th>
<th>Other</th>
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Address 1*:

Address 2:

City*:

State*:

ZIP*:

If you are certifying more than one healthcare setting location for which the Authorized Representative is responsible, check this box and provide the information for each site below.

### AUTHORIZED REPRESENTATIVE INFORMATION

<table>
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<tr>
<th>First Name*</th>
<th>Last Name*</th>
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<thead>
<tr>
<th>Role*</th>
<th>Physician</th>
<th>Physician Assistant</th>
<th>Nurse Practitioner</th>
<th>Pharmacist</th>
<th>Practice Manager</th>
<th>Other Responsible Individual Designated by Healthcare Setting</th>
<th>Reason for Form* (please select one):</th>
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<td>New Authorized Representative</td>
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Phone Number*:

Fax Number*:

Email Address*:

Address 1*:

Address 2:

City*:

State*:

ZIP*:

### 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 of and ensure my healthcare setting’s compliance with the PALFORZIA REMS requirements
- Review the Education Program for Healthcare Settings
- 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, and establish processes and procedures to ensure that the following take place 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-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 either the Office Dose Kit or the Daily Dose Pack
- Verify that the patient has injectable epinephrine

CONTINUED ON NEXT PAGE
HEALTHCARE SETTING AUTHORIZED REPRESENTATIVE AGREEMENT (Continued)

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

During treatment before dispensing 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:
- Report anaphylaxis including suspected cases managed as anaphylaxis to the REMS Program using the Anaphylaxis Adverse 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
- Not distribute, transfer, loan, or sell PALFORZIA

Use this section to add all additional Healthcare Setting locations for which the same Authorized Representative will be responsible.

Healthcare Setting Name*: ___________________________  National Provider Identifier (NPI #)*: ___________________________

Healthcare Setting Type*:
- [ ] Independent Practice
- [ ] Private Group Practice
- [ ] Outpatient Clinic
- [ ] Hospital Ambulatory Clinic
- [ ] Other

Address 1*: ___________________________
Address 2*: ___________________________
City*: ___________________________  State*: ___________________________  ZIP*: ___________________________

Healthcare Setting Name*: ___________________________  National Provider Identifier (NPI #)*: ___________________________

Healthcare Setting Type*:
- [ ] Independent Practice
- [ ] Private Group Practice
- [ ] Outpatient Clinic
- [ ] Hospital Ambulatory Clinic
- [ ] Other

Address 1*: ___________________________
Address 2*: ___________________________
City*: ___________________________  State*: ___________________________  ZIP*: ___________________________

Healthcare Setting Name*: ___________________________  National Provider Identifier (NPI #)*: ___________________________

Healthcare Setting Type*:
- [ ] Independent Practice
- [ ] Private Group Practice
- [ ] Outpatient Clinic
- [ ] Hospital Ambulatory Clinic
- [ ] Other

Address 1*: ___________________________
Address 2*: ___________________________
City*: ___________________________  State*: ___________________________  ZIP*: ___________________________

Authorized Representative: Please PRINT your name and phone number here.

*Name: ___________________________  *Phone Number: ___________________________

Last: ___________________________  First: ___________________________
PALFORZIA REMS Pharmacy 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

To become certified in the PALFORZIA REMS Program and dispense PALFORZIA, a pharmacy must designate an Authorized Representative to:
1. Review the REMS Program Overview for Pharmacies
2. Carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the pharmacy
3. Complete and submit the Pharmacy Enrollment Form by fax to 1-844-285-2013

Upon completion of these steps, the REMS Program will notify the pharmacy of successful certification within 2 business days.

PHARMACY INFORMATION (*indicates required field)

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Name*</td>
<td></td>
</tr>
<tr>
<td>National Council for Prescription Drug Program ID (NCPDP):</td>
<td>Other identifier:</td>
</tr>
<tr>
<td>Address Line 1*:</td>
<td></td>
</tr>
<tr>
<td>Address Line 2:</td>
<td></td>
</tr>
<tr>
<td>City*:</td>
<td>State*:</td>
</tr>
<tr>
<td>State*:</td>
<td>ZIP*:</td>
</tr>
</tbody>
</table>

AUTHORIZED REPRESENTATIVE INFORMATION

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name*:</td>
<td>Last Name*:</td>
</tr>
<tr>
<td>Role* □ RPH □ PharmD □ Other Responsible Individual □ Other</td>
<td>Reason for Form* (please select one):</td>
</tr>
<tr>
<td>Phone Number*:</td>
<td>Fax Number*:</td>
</tr>
<tr>
<td>Email Address*:</td>
<td></td>
</tr>
<tr>
<td>Address 1*:</td>
<td></td>
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<tr>
<td>Address 2:</td>
<td></td>
</tr>
<tr>
<td>City*:</td>
<td>State*:</td>
</tr>
<tr>
<td>State*:</td>
<td>ZIP*:</td>
</tr>
</tbody>
</table>

AUTHORIZED PHARMACY REPRESENTATIVE AGREEMENT

I am the authorized representative designated by my Pharmacy to coordinate the activities of the PALFORZIA REMS. By completing, signing, and submitting this form, I agree, on behalf of myself and my Pharmacy, to comply with the following REMS requirements, I will:
- Oversee implementation of and ensure my pharmacy’s compliance with the PALFORZIA REMS requirements
- Review the REMS Program Overview for Pharmacies and will ensure that all relevant staff involved in the dispensing of PALFORZIA are trained on the PALFORZIA REMS requirements and that a record of training is maintained
- Train all relevant staff involved in dispensing PALFORZIA, and establish processes and procedures to ensure that the following take place in my pharmacy:
  - 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 (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
  - 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
  - At all times:
    - Have any new authorized representative enroll in the REMS by completing the Pharmacy Enrollment Form
    - Maintain records that all processes 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 dispense the Initial Dose Escalation for use outside a certified healthcare setting
    - Not dispense a Daily Dose Pack for the first dose of an Up-Dosing level for use outside a certified healthcare setting.

Authorized Representative Signature * ____________________________________________ Date* ________________________
### INSTRUCTIONS:

Anaphylaxis adverse events (including suspected cases managed as anaphylaxis) must be reported to the REMS. If a patient experienced more than one anaphylaxis event, please complete this form for each unique event. Complete and submit this form to the REMS online at www.PALFORZIAREMS.com or by fax to 1-844-285-2013.

### PATIENT INFORMATION

<table>
<thead>
<tr>
<th>Field</th>
<th>Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name*</td>
<td></td>
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<tr>
<td>MI</td>
<td></td>
</tr>
<tr>
<td>Last Name*</td>
<td></td>
</tr>
<tr>
<td>Date of Birth* (MM/DD/YYYY)</td>
<td></td>
</tr>
<tr>
<td>Sex: Female ☐ Male ☐ Other ☐</td>
<td></td>
</tr>
<tr>
<td>Patient REMS ID:</td>
<td></td>
</tr>
<tr>
<td>Address 1*</td>
<td></td>
</tr>
<tr>
<td>Address 2</td>
<td></td>
</tr>
<tr>
<td>City*</td>
<td></td>
</tr>
<tr>
<td>State*</td>
<td></td>
</tr>
<tr>
<td>ZIP*</td>
<td></td>
</tr>
</tbody>
</table>

### PRESCRIBER INFORMATION

<table>
<thead>
<tr>
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<th>Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name*:</td>
<td></td>
</tr>
<tr>
<td>Last Name*:</td>
<td></td>
</tr>
<tr>
<td>National Provider Identifier (NPI #):</td>
<td></td>
</tr>
<tr>
<td>Prescriber REMS ID:</td>
<td></td>
</tr>
<tr>
<td>Practice/Facility Name:</td>
<td></td>
</tr>
<tr>
<td>Address 1:</td>
<td></td>
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<tr>
<td>Address 2:</td>
<td></td>
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<tr>
<td>City:</td>
<td></td>
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<tr>
<td>State:</td>
<td></td>
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<tr>
<td>ZIP:</td>
<td></td>
</tr>
<tr>
<td>Phone Number:</td>
<td></td>
</tr>
<tr>
<td>Email Address:</td>
<td></td>
</tr>
</tbody>
</table>

### Anaphylaxis Event Characteristics

<table>
<thead>
<tr>
<th>Field</th>
<th>Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Event*:</td>
<td></td>
</tr>
<tr>
<td>Date of start of PALFORZIA:</td>
<td></td>
</tr>
<tr>
<td>Current PALFORZIA Dose*:</td>
<td></td>
</tr>
<tr>
<td>Date of Start of Current PALFORZIA Dose:</td>
<td></td>
</tr>
<tr>
<td>How long after the given dose of PALFORZIA did the symptoms start*:  ___________ hours  ___________ minutes  ☐  Unknown</td>
<td></td>
</tr>
<tr>
<td>Description of clinical course*:</td>
<td></td>
</tr>
</tbody>
</table>
Outcomes:
Did this anaphylaxis event result in any of the following? (check all that apply)
- Emergency Department visit
- Hospitalization
- Intensive Care Unit admission
- Death

Reporter Signature (* indicates required field)

I agree to be contacted to provide additional pertinent information regarding reports of anaphylaxis

Printed Name:

Phone Number:

Email Address:

Epinephrine availability:

Was epinephrine available to the patient for immediate use at the time of symptom onset?  Yes  No  Unknown

Treatment of Anaphylaxis Event:
Enter all forms of treatment administered including brand name if known (e.g. epinephrine, antihistamines, steroids, etc.)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Dosing and Route of Administration</th>
<th>Number of Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Outcomes:
Did this anaphylaxis event result in any of the following? (check all that apply)
- Emergency Department visit
- Hospitalization
- Intensive Care Unit admission
- Death

Signs and Symptoms:
(please check all signs and symptoms that were present during the event; for descriptions see Table 1 "Glossary of Terms"):

<table>
<thead>
<tr>
<th>Body System</th>
<th>Major Criteria</th>
<th>Minor Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermatological or mucosal</td>
<td>☐ generalized urticaria (hives) ☐ generalized erythema ☐ angioedema, localized or generalized (not hereditary angioedema) ☐ generalized pruritis with skin rash</td>
<td>☐ generalized pruritis without skin rash ☐ generalized prickle sensation ☐ red, itchy eyes</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>☐ measured hypotension ☐ uncompensated shock as indicated by ≥3 of the following: ☐ tachycardia ☐ capillary refill time &gt; 3 seconds (s) ☐ reduced central pulse volume ☐ decreased level or loss of consciousness</td>
<td>☐ reduced peripheral circulation as indicated by ≥2 of the following: ☐ tachycardia ☐ capillary refill time &gt; 3 s, without hypotension ☐ decreased level of consciousness</td>
</tr>
<tr>
<td>Respiratory</td>
<td>☐ bilateral wheeze (bronchospasm) ☐ stridor ☐ upper airway swelling (lip, tongue, throat, uvula, or larynx) ☐ respiratory distress with ≥2 of the following: ☐ tachypnea ☐ increased use of accessory respiratory muscles (sternocleidomastoid, intercostals, etc.) ☐ recession ☐ cyanosis ☐ grunting</td>
<td>☐ persistent dry cough ☐ hoarse voice ☐ difficulty breathing without wheeze or stridor ☐ sensation of throat closure ☐ sneezing, rhinorrhea</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>Not applicable</td>
<td>☐ diarrhea ☐ abdominal pain ☐ nausea ☐ vomiting</td>
</tr>
<tr>
<td>Laboratory</td>
<td>Not applicable</td>
<td>☐ mast cell tryptase elevated above upper limit of normal</td>
</tr>
<tr>
<td>TERM</td>
<td>DESCRIPTION</td>
<td></td>
</tr>
<tr>
<td>------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>Sensation of discomfort or pain in the abdominal region</td>
<td></td>
</tr>
<tr>
<td>Angioedema</td>
<td>Areas of deeper swelling of the skin and/or mucosal tissues in either single or multiple sites which may not be well circumscribed and is usually not itchy. <em>(Reported symptoms of “swelling of the tongue” or “throat swelling” should not be documented as angioedema unless there is visible skin or mucosal swelling.)</em></td>
<td></td>
</tr>
<tr>
<td>Capillary refill time greater than 3 seconds</td>
<td>The capillary refill time is the time required for the normal skin color to reappear after a blanching pressure is applied for 5 seconds. It is usually performed by pressing on the nail bed to cause blanching and then counting the time it takes for the blood to return to the tissue, indicated by a pink color returning to the nail. Normally it is less than 3 seconds.</td>
<td></td>
</tr>
<tr>
<td>Cyanosis</td>
<td>A dark bluish or purplish discoloration of the skin and/or mucous membranes due to a lack of oxygen in the blood</td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>Loose or watery stools which may occur more frequently than usual</td>
<td></td>
</tr>
<tr>
<td>Dry cough</td>
<td>Rapid expulsion of air from the lungs and not accompanied by expectoration <em>(a non-productive cough)</em></td>
<td></td>
</tr>
<tr>
<td>Erythema</td>
<td>Abnormal redness of the skin without any raised skin lesions</td>
<td></td>
</tr>
<tr>
<td>Generalized</td>
<td>Involving more than one body site—that is each limb is counted separately as is the abdomen, back, head and neck.</td>
<td></td>
</tr>
<tr>
<td>Grunting</td>
<td>A sudden and short noise with each breath when breathing out</td>
<td></td>
</tr>
<tr>
<td>Hoarse voice</td>
<td>An unnaturally harsh cry in an infant or vocalization in a child or adult</td>
<td></td>
</tr>
<tr>
<td>Hypotension (measured)</td>
<td>An abnormally low blood pressure documented by appropriate measurement</td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Infants and children—Age specific systolic blood pressure <em>(BP)</em> of less than the 3rd to 5th percentile or greater than a 30% decrease from that person’s baseline</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Adults—Systolic BP of less than 90 mm Hg or greater than 30% decrease from that person’s baseline</em></td>
<td></td>
</tr>
<tr>
<td>Localized</td>
<td>Involving one body site only</td>
<td></td>
</tr>
<tr>
<td>Loss of consciousness</td>
<td>Total suspension of conscious relationship with the outside world as demonstrated by an inability to perceive and respond to verbal, visual, or painful stimulus</td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>An unpleasant sensation vaguely referred to the upper abdominal region <em>(upper region of the abdomen)</em> and the abdomen, with a tendency to vomit</td>
<td></td>
</tr>
<tr>
<td>Pruritis or prickle sensation</td>
<td>An unpleasant skin sensation that provokes the desire to rub and/or scratch to obtain relief</td>
<td></td>
</tr>
<tr>
<td>Rapid progression</td>
<td>A conventional clinical term without a specific timeframe; as determined by the clinician</td>
<td></td>
</tr>
<tr>
<td>Recession (in-drawing or retractions)</td>
<td>Inward movement of the muscles between the ribs <em>(inter-costal)</em>, in the lower part of the neck <em>(supra-clavicular or tracheal tug)</em> or below the chest <em>(sub-costal)</em>. The movements are usually a sign of difficulty with breathing</td>
<td></td>
</tr>
<tr>
<td>Red and itchy eyes</td>
<td>Redness of the whites of the eyes <em>(sclera)</em> with sensation that provokes the desire to rub and/or scratch to obtain relief.</td>
<td></td>
</tr>
<tr>
<td>Reduced central pulse volume</td>
<td>Absent or decreased pulse in one of the following vessels—carotid, brachial or femoral arteries</td>
<td></td>
</tr>
<tr>
<td>Rhinorrhea</td>
<td>Discharge of thin nasal mucus</td>
<td></td>
</tr>
<tr>
<td>Sensation of throat closure</td>
<td>Feeling or perception of throat closing with a sensation of difficulty breathing</td>
<td></td>
</tr>
<tr>
<td>Sneezing</td>
<td>An involuntary <em>(reflex)</em>, sudden, violent, and audible expulsion of air through the mouth and nose</td>
<td></td>
</tr>
<tr>
<td>Stridor</td>
<td>A harsh and continuous sound made on breathing in</td>
<td></td>
</tr>
<tr>
<td>Sudden onset</td>
<td>An event that occurred unexpectedly and without warning leading to a marked change in a subject’s previously stable condition</td>
<td></td>
</tr>
<tr>
<td>Tachycardia</td>
<td>A heart rate that is abnormally high for age and circumstance</td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Infants and children—A heart rate that is above the upper limit expected for age—see Table 2</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Adults and adolescents—The term is usually applied to a heart rate above 100 beats per minute</em></td>
<td></td>
</tr>
<tr>
<td>TERM DESCRIPTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tachypnea</td>
<td>Abnormally rapid breathing which is abnormally high for age and circumstance. Infants and children—A respiratory rate that is above the upper limit expected for age—see Table 2. Adults—a respiratory rate in excess of 25 breaths per minute.</td>
<td></td>
</tr>
<tr>
<td>Urticaria (hives)</td>
<td>Localized redness of superficial layers of skin that is itchy, raised, sharply demarcated and transient (that is skin changes at any location are usually present for less than 12 hours).</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td>The reflex act of ejecting the contents of the stomach through the mouth.</td>
<td></td>
</tr>
<tr>
<td>Wheezing</td>
<td>A whistling, squeaking, musical, or puffing sound made on breathing out.</td>
<td></td>
</tr>
</tbody>
</table>

**Table 2. Upper limit of heart and respiratory rate in order to define tachycardia and tachypnea²**

<table>
<thead>
<tr>
<th>Age in years</th>
<th>Heart rate upper limit in beats per minute</th>
<th>Respiratory rate upper limit in breaths per minute</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1 year</td>
<td>160</td>
<td>60</td>
</tr>
<tr>
<td>1-2 years</td>
<td>150</td>
<td>40</td>
</tr>
<tr>
<td>2-5 years</td>
<td>140</td>
<td>35</td>
</tr>
<tr>
<td>5-12 years</td>
<td>120</td>
<td>30</td>
</tr>
<tr>
<td>&gt;12 years</td>
<td>100</td>
<td>16</td>
</tr>
</tbody>
</table>

**References**


PALFORZIA® Education Program For Healthcare Settings

Risk Evaluation and Mitigation Strategy (REMS)
What is PALFORZIA®?

- 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)

- 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

• 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
• During treatment, **before prescribing a Daily Dose Pack to be dispensed from a certified pharmacy to a patient for home use:**
  – **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:**
  – **Verify the patient was monitored and previously tolerated** the first dose of the Up-Dosing level
• **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
Overview of PALFORZIA REMS Stakeholder Requirements (continued)

**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 Initial Dose Escalation and 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 either the Office Dose Kit or the Daily Dose Pack
      - 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
    - During treatment before dispensing 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
- Report anaphylaxis including suspected cases managed as anaphylaxis to the REMS Program using the Anaphylaxis Adverse Event Reporting Form
- Have any new Authorized Representative enroll in the REMS by completing the Healthcare Setting Enrollment Form
- Only use patient-specific Initial Dose Escalation and Daily Dose Packs for the intended patient
- 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 (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.
- Prior to dispensing a Daily Dose Pack directly to a patient’s 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.
How to Become a Certified Healthcare Setting

• 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 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

• 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
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 either the Office Dose Kit or the Daily Dose Pack
- 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

During treatment before dispensing 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
Healthcare Setting Requirements

• At All Times:
  – Report anaphylaxis including suspected cases managed as anaphylaxis to the REMS Program using the *Anaphylaxis Adverse Event Reporting Form*
  – Only use patient-specific Initial Dose Escalation and Daily Dose Packs for the intended patient
  – 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

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

• Report any other type of adverse event, by contacting:
  – 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

To order patient-specific PALFORZIA (Initial Dose Escalation, Daily Dose Pack), contact a certified pharmacy.

To order an Office Dose Kit, contact a certified distributor.

Visit the 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

- For more information about the PALFORZIA REMS, visit 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 REMS Program Overview for Pharmacies

What is the PALFORZIA Risk Evaluation and Mitigation Strategy (REMS)?
A REMS is a strategy to manage known or potential risks associated with a drug and is required by the U.S. Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. PALFORZIA® is available only through a restricted program called the PALFORZIA REMS because of the risk of anaphylaxis.

What are the PALFORZIA REMS requirements?

- Healthcare providers who prescribe PALFORZIA must be certified with the program by enrolling
- Only certified pharmacies and healthcare settings may dispense PALFORZIA
- The Initial Dose Escalation and first dose of each Up-Dosing level are only administered to patients in certified healthcare settings
- Patients must be informed 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 peanut avoidance in the diet, and how to recognize the signs and symptoms of anaphylaxis
- Only enrolled patients can receive PALFORZIA

How can a pharmacy become enrolled in the PALFORZIA REMS?
In order to enroll and become certified, the Pharmacy must:

Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the pharmacy, including:

- Overseeing implementation of and ensuring pharmacy’s compliance with the PALFORZIA REMS requirements
- Reviewing the REMS Program Overview for Pharmacies (this document) and ensuring that all relevant staff involved in the dispensing of PALFORZIA are trained on the PALFORZIA REMS requirements and that a record of training is maintained
- Training all relevant staff involved in dispensing PALFORZIA, and establishing processes and procedures to ensure that the following take place in pharmacy:
Prior to dispensing the PALFORZIA Initial Dose Escalation, 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 (Daily Dose Pack) prescriptions, pharmacy will verify:

- The patient is enrolled
- The prescriber is certified
- Only one dose level is dispensed at a time

Prior to dispensing a Daily Dose Pack directly to a patient by shipping it to them for home use, 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

At all times:

- Having any new authorized representative enroll in the REMS by completing the Pharmacy Enrollment Form
- Maintaining records that all processes are in place and are being followed
- Complying 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 dispensing the Initial Dose Escalation for use outside a certified healthcare setting
- Not dispensing a Daily Dose Pack for the first dose of an Up-Dosing level for use outside a certified healthcare setting
- Not distributing, transferring, loaning, or selling PALFORZIA

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 in patients with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients aged 4 through 17 years.

Visit www.PALFORZIAREMS.com to begin enrollment and for additional information.
You may also contact the PALFORZIA REMS at 1-844-PALFORZ (1-844-725-3679)
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.

**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.

To report side effects please contact
Alimmune Therapeutics, Inc. at 1-833-ALM2KNO (1-833-246-2566)
or FDA at www.fda.gov or call 1-888-INFO-FDA (1-888-466-3322).
Healthcare Setting Overview

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

TO BECOME CERTIFIED IN THE PALFORZIA 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 PALFORZIA

3. COMPLETE AND SUBMIT the Healthcare Setting Enrollment Form to the PALFORZIA REMS Program:
   - Online
   - By fax at 1-844-285-2013

Healthcare settings will be notified of successful certification in the PALFORZIA 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 PALFORZIA 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 (Risk Evaluation and Mitigation Strategy), a risk management 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. REVEW 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 below or by fax to 1-844-280-2013.

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 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

*Gender

- Physician
- Physician Assistant
- Nurse Practitioner
- Pharmacist
- Other Licensed Health Professional
- Administrator

*Telephone Number

*Fax Number

*Address 1

Address 2

*City

*State

- Please select —

*ZIP

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:

- Implement the Education Program for Healthcare Settings.
- Have a certified provider on-site to counsel patients; monitor and manage anaphylaxis.
- Administer and ensure compliance with the PALFORZIA REMS.
- Establish processes and procedures to ensure that the following take place 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-DOSING LEVEL:

- Verify that the dose is determined by the certified provider and is dispensed from the Office Dose Kit or the Daily Dose Pack.
- Verify that the dose is given to the patient in a manner that will avoid anaphylaxis.

DURING AND AFTER ADMINISTERING THE INITIAL Dose ESCALATION AND THE FIRST Dose OF EACH Up-DOSING LEVEL:

- Administer the dose to the patient 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 administered 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/Anaphylactic Event Reporting 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 conducted 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.

- Authorize distribution, 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 (HCS) must designate an Authorized Representative to:

1. REVIEW the Education Program for Healthcare Settings.
2. CARRY OUT THE CERTIFICATION PROCESS and ensure implementation of training and compliance with the REMS Program on behalf of the healthcare setting.
3. COMPLETE AND SUBMIT the Healthcare Setting Enrollment Form before or by fax to 1-866-948-2013.

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 healthcare setting of successful certification within 2 business days.

(*) Indicates required field

HEALTHCARE SETTING INFORMATION

First Name: [Required]
Last Name: [Required]
Address 1: [Required]
City: [Required]
State: [Required]
ZIP: [Required]

Authorized Representative Information

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:

1. I WILL:
   - Once implementation of and ensure my healthcare setting’s compliance with the PALFORZIA REMS requirements.
   - Review the Education Program for healthcare settings.
   - Have a certificate of completion of the training.
   - Have a healthcare provider on site to counsel each patient, and monitor for and manage anaphylaxis.
   - Be able to manage anaphylaxis events.
   - Train all relevant personnel 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):
   - Place the first dose of PALFORZIA at the healthcare setting.
   - Treat the patient for at least 12 hours before the dose.
   - Treat the patient for at least 12 hours before the dose.

   DURING TREATMENT BEFORE DISPENSING THE FIRST DOSE OF EACH UP-DOSE LEVEL:
   - Verify that the patient is receiving the treatment.
   - Verify that the dose is the dose as determined by the REMS program.
   - Verify that the dose is the dose as determined by the REMS program.
   - Verify that the dose is the dose as determined by the REMS program.

   DURING AND AFTER ADMINISTERING THE INITIAL DOSE ESCALATION AND THE FIRST DOSE OF EACH UP-DOSE LEVEL:
   - Assess the patient for any signs of pal or other adverse events.
   - Treat the patient for at least 12 hours before the dose.
   - Treat the patient for at least 12 hours before the dose.
   - Treat the patient for at least 12 hours before the dose.

   DURING TREATMENT BEFORE DISPENSING A SINGLE DOSAGE PACK TO THE PATIENT FOR HOME USE:
   - Verify that the patient’s information is accurate and up-to-date.
   - Verify that the patient’s information is accurate and up-to-date.
   - Verify that the patient’s information is accurate and up-to-date.

   AT ALL TIMES:
   - Report any adverse events including suspected cases managed as anaphylaxis to the REMS program using the appropriate adverse event reporting forms.
   - Have any new authorized representative enroll in the REMS program by completing the Healthcare Setting Enrollment Form.
   - Maintain records of all doses and procedures in place and any being followed.
   - Consult with patients cared for by Immune Therapeutics, Inc. or third party acting on behalf of Immune Therapeutics, Inc. to ensure that all procedures and processes are in place and any being followed.
   - Send NDC transfer codes for each PAN:

   Authorized Representative Signature: [Required]
PALFORZIA REMS Healthcare Setting Enrollment Form

To become certified in the PALFORZIA REMS program and administer PALFORZIA, a healthcare setting (HC) 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 by no later than 4/1/2023

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 certification within 2 business days.

[Submit required field]

**HEALTHCARE SETTING INFORMATION**
- National Provider Identifier (NPI)
- Healthcare Setting Name
- Healthcare Setting Type
- Address
- City
- State
- ZIP Code
- Phone
- [Submit Healthcare Setting]

**AUTHORIZED REPRESENTATIVE INFORMATION**
- First Name
- Last Name
- [Submit 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**
- Oversee implementation and ensure my healthcare setting is in compliance with the PALFORZIA REMS requirements.
- Review the Education Program for healthcare settings.
- Have a verified provider on site.
- Have healthcare professionals on site to counsel each patient, and for and manage anaphylaxis.
- Be able to manage anaphylaxis onsite.
- Train all relevant staff in administering and administering PALFORZIA, and establish procedures and processes to ensure that the following take place in my healthcare setting:

**BEFORE TREATMENT INITIATION (JUVENILE DOSE)**
- Verify the initial Dose Estimations for the enrolled patient.

**DURING TREATMENT BEFORE DISPENSING THE FIRST DOSE OF EACH UPLIFTING LEVEL:**
- Verify that the patient is included in the REMS.
- Have a healthcare provider counsel the patient and/or the need to be monitored for anaphylaxis.
- Verify that the dose, as determined by the Petitioned Dose Tier, is dispensed from either the Junior Dose Kit or the Dose Kit Pack.
- Verify that the patient has a Class 1 anti-IgE medication.

**DURING AND AFTER ADMINISTERING THE INITIAL DOSE ELEVATION AND EACH LEVEL OF UPLIFTING:**
- 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 that the patient has been monitored and approved for the first dose of the Uplifting level.

At all times:
- Report anaphylaxis including suspected cases managed as anaphylaxis to the REMS Program using the Anaphylaxis Adverse Event Reporting Form
- Have any new Authorized Representative email in the REMS by completing the Healthcare Setting Enrollment Form.
- Maintain records of dispensing instructions at all processes and procedures are in place and are being followed.
- Only dispense specific to Initial Dose Estimation and Daily Dose Packs for the intended patient.
- Comply with all standards set by Allegheny Therapeutics, Inc., or a third-party acting on behalf of Allegheny Therapeutics, Inc., to ensure all processes and procedures are in place and are being followed.

[Submit Authorized Representative Signature]

[CONTINUE]
PALFORZIA REMS Healthcare Setting Enrollment Form

PALFORZIA® is available only through PALFORZIA REMS, a risk assessment and mitigation strategy. It is a biologic product. Only prescribers, healthcare settings, pharmacies, and patients enrolled in the program in accordance with the REMS Program are eligible to treat with PALFORZIA®.

INSTRUCTIONS

1. To become certified in the PALFORZIA REMS Program and administer PALFORZIA, a healthcare setting (HCS) must designate an Authorized Representative to:
   - REVIEW the Education Program for Healthcare Settings.
   - CARRY OUT the Enrollement Process and ensure implementation and compliance with the REMS Program, including all of the Healthcare Setting Health Literacy.

2. COMPLETE AND SUBMIT the Healthcare Setting Enrollment Form before April 30th (2023).

3. Enroll all necessary healthcare provider staff in the REMS Program 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.

Looking for more information on one of the healthcare setting location for which the Authorized Representative is responsible? Click on "Add Healthcare Setting" below and provide the information for each site.

# ADD A HEALTHCARE SETTING

# ADD HEALTHCARE SETTING

AUTHORIZED REPRESENTATIVE INFORMATION

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, Jigen, on behalf of myself and my healthcare setting, agree to comply with all the following REMS requirements:

1. Complete and submit the REMS Program Application for Healthcare Settings;
2. Provide written confirmation to each patient, and monitor and maintain accurate records.
3. Be able to manage emergency situations;
4. Keep all records of all patients enrolled in the program on a timely basis.

Healthcare Setting: Alignment Healthcare

First Name: Jigen
Last Name: Lam
Position: Authorized Representative
Title: Pharmacist, Administration
Phone: 1-844-555-5555
Address 1: 123 Main St.
City: Springfield
State: IL
Zip: 62701

AUTHORIZED REPRESENTATIVE SIGNATURE

Signature

# ADD A HEALTHCARE SETTING

# ADD A HEALTHCARE SETTING

HEALTHCARE SETTING INFORMATION

# Add Healthcare Setting
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 (1-833-246-2566)
or FDA at www.fda.gov/medwatch
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 2 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:
   - 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

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

1. Assess the patient’s tolerance 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)

OFFICE CONTACT INFORMATION

- First Name
- Last Name
- Office Phone Number
- Office Fax Number
- Email Address

To provide additional Office Contacts please contact the PALFORZIA REMS Coordinating Center at 1-844-PALFORZ (1-844-725-3079)

PRESCRIBER AGREEMENT

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

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.
- Assure 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

To report side effects please contact Aimmune Therapeutics, Inc. at 1-833-AIMMEHD (1-833-246-3443) or FDA at 1-888-FDA-1088 (1-888-332-1088).

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PALFORZIA REMS Prescriber Enrollment Form

PALFORZIA® is available only through the PALFORZIA REMS (Risk Evaluation and Mitigation Strategy), a restricted program. Only prescribers, health care 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 1-844-385-2013.

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's name/address does not match what is displayed below, please contact the PALFORZIA REMS Call Center at 1-844-PALFORZIA (1-844-725-3979)

*First Name

*Last Name

*Credential (please select one)

*Specialty (please select one)

*Office Phone Number

*Office Fax Number

*Email Address

OFFICE CONTACT INFORMATION

First Name

Last Name

Office Phone Number - Same as above

Office Phone Number

To provide additional Office Contacts please contact the PALFORZIA REMS Coordinating Center at 1-844-PALFORZIA (1-844-725-3979)

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.
- Cover 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:
- Access the patient's enrollment in the previous dosing level and appropriateness of continuing the Up-Dosing level.

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

CANCANCEL CONTINUE

To report side effects please contact Aimmune Therapeutics, Inc. 413-680-JD17228 (1-866-484-2288) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch
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-AIM2XNO (1-833-246-2566)
or FDA at www.fda.gov/medwatch
or call 1-800-FDA-1088 (1-800-332-1088).
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

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).
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)
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

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

* 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

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

*Zip Code: 

*Search Radius:
- Please Select
- Within 25 miles
- Within 50 miles
- Within 100 miles

SEARCH
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 Prescribers
Certified Healthcare Settings

*Zip Code: 12345

*Search Radius: Within 25 miles

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

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 Prescribers
Certified Healthcare Settings

*Zip Code:
12345

*Search Radius:
Within 25 miles

SEARCH

Healthcare Setting Name
920 Harvest Drive
Blue Bell, PA 19422
555-555-1212

Healthcare Setting Name
920 Harvest Drive
STE 200
Blue Bell, PA 19422
555-555-1212

Healthcare Setting Name
920 Harvest Drive
#200
Blue Bell, PA 19422
555-555-1212

Healthcare Setting Name
2703 Aspen Cir
Blue Bell, PA 19422
555-555-1212

Healthcare Setting Name
eolmynjbn
AKU1WpR
KwKxxw, PA 1901

To report side effects please contact:
Aimmune Therapeutics, Inc. at 1-833-AI2MKN (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

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 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>

To report side effects please contact
Aimmune Therapeutics, Inc. at 1-833-AIM2KNO (1-833-246-2568)
or FDA at www.fda.gov/medwatch
or call 1-800-FDA-1088 (1 800-332-1088).
Login

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

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.

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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.

To report side effects please contact
Aimmune Therapeutics, Inc. at 1-833-AIMUM2KNO (1-833-246-2566)
or FDA at www.fda.gov/medwatch
or call 1-800-FDA-1088 (1-800-332-1088).

Aimmune Therapeutics, Inc.

AIMT-REMS-USA-1007 Version Date 05/21