

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 prescriptions, pharmacy will verify:

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

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 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. Up-Dosing and Maintenance may be continued in patients 4 years of age and older.

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)

