

AVEED® REMS Program: An Introduction

What is the AVEED REMS (Risk Evaluation and Mitigation Strategy) Program?

A REMS is a strategy to manage known or potential risks associated with a drug, and is required by the FDA to ensure that the benefits of the drug outweigh its risks. AVEED is available only under a restricted program called the AVEED REMS Program because of the risks of serious pulmonary oil microembolism (POME) reactions and anaphylaxis.

AVEED REMS Program Requirements

Healthcare settings must be certified in the AVEED REMS Program to be able to order AVEED. One representative needs to enroll per healthcare setting (the “Authorized Representative”).

Prescribing Healthcare Providers must be certified in the AVEED REMS Program to be able to prescribe AVEED. Prescribing healthcare providers cannot complete certification until their healthcare setting is enrolled.

Non-Prescribing Healthcare Providers who will administer AVEED to patients must be trained on the *AVEED REMS Education for Healthcare Providers*.

Safe Use Actions You Must Implement for AVEED

- Ensure all healthcare providers who prescribe AVEED at your healthcare setting are certified in the AVEED REMS program
- Ensure all non-prescribing healthcare providers who administer AVEED are trained on:
 - Serious POME reactions and anaphylaxis
 - Proper administration of AVEED
 - Patient counseling
 - 30 minute post-injection patient observation
- Establish a process to ensure all patients are counseled about AVEED and receive *What You Need To Know About AVEED Treatment: A Patient Guide*

• **Establish a process to ensure each patient is observed for 30 minutes at the healthcare setting after each AVEED injection**

- Have the necessary equipment and personnel on-site to manage serious POME reactions or anaphylaxis
- Ensure a patient is NEVER provided AVEED for home or self-injection

Steps for Healthcare Setting Certification

1. Designate an Authorized Representative. This may be a prescribing or non-prescribing healthcare provider, practice manager or any responsible individual in the healthcare setting.
2. Review *AVEED REMS Education Program for Healthcare Settings*, including the Prescribing Information.
3. Complete and sign the Healthcare Setting Enrollment Form. This Enrollment must be renewed every 2 years.
4. Associate certified Prescribing Healthcare Providers to your account. Your healthcare setting is not eligible to receive AVEED until you have associated at least one certified Prescribing Healthcare Provider.
5. Implement the necessary staff training and processes to comply with the AVEED REMS Program requirements.
6. Recertify in the AVEED REMS Program if the healthcare setting designates a new Authorized Representative.

Steps for Healthcare Provider Certification

1. Ensure that your healthcare setting is enrolled. Prescribing healthcare providers will not be able to complete certification until their healthcare setting is enrolled.
Review *AVEED REMS Education Program for Healthcare Providers*, including the Prescribing Information.
2. Successfully complete the 10 question Knowledge Assessment.
3. Complete and sign the one-time Healthcare Provider Enrollment Form.

Where to Find REMS Program Information and Resources

The AVEED REMS Education Program, Healthcare Setting Enrollment Form, and other AVEED REMS Program tools are available online at www.AveedREMS.com or by contacting the AVEED REMS Program at 1-855-755-0494 to request materials.