AVEED™ REMS Website

AVEED™ REMS (Risk Evaluation and Mitigation Strategy) Program

What is the AVEED REMS Program?

A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of the drug outweigh its risks. The purpose of the AVEED REMS Program is to inform Healthcare Providers, Healthcare Settings and patients about the risks of:

- Serious pulmonary oil microembolism (POME) reactions
- Anaphylaxis

AVEED REMS Program Requirements

- Training — for Healthcare Providers and authorized representatives of Healthcare Settings on serious POME reactions and anaphylaxis associated with AVEED, safe use strategies, and REMS Program requirements.
- Certification — for Prescribing Healthcare Providers by completing training, Knowledge Assessment and enrollment into the AVEED REMS Program.
- Certification — for Healthcare Settings by completing training and enrollment into the AVEED REMS Program. Each Healthcare Setting must be certified to be able to order AVEED.
- Patient counseling — about the risks of serious POME reactions and anaphylaxis. Healthcare Providers must give patients the Patient Counseling Tool: "What You Need to Know About AVEED Treatment: A Patient Guide."
- Patient observation — patients must remain in Healthcare Setting for 30 minutes after each AVEED injection.

For additional information about the AVEED REMS Program, please call 1-855-755-0494.
AVEED™ REMS Program

Healthcare Provider Certification

Prescribing Healthcare Providers must be certified in the AVEED REMS Program in order to prescribe AVEED. Certification in the AVEED REMS Program includes the following four steps:

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

- You can complete the training and enrollment online by clicking below, or by downloading the print version of the training and taking your Knowledge Assessment and enrollment form into the AVEED REMS Program at 1-866-755-0496.

Click here to complete the AVEED REMS Training and Enrollment online.

- Non-Prescribing Healthcare Providers must also be trained on the AVEED REMS Education Program for Healthcare Providers.

Enrollment is not required for Non-Prescribing Healthcare Providers. Click below to complete the training online.

Click here to complete the AVEED REMS Training online.

- Your Healthcare Setting must also be certified in the AVEED REMS Program in order for you to prescribe AVEED.

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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AVEED™ REMS Program

Healthcare Setting Certification

Healthcare Settings must be certified in the AVEED REMS Program to be able to order AVEED.

To become certified in the AVEED REMS Program, an Authorized Representative of the Healthcare Setting must do the following:

1. Designate an Authorized Representative

2. Review the 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. Implement the necessary staff training and processes to comply with the AVEED REMS Program requirements

- You can complete the training and enrollment online by clicking below, or by downloading the print version of the training and faxing your enrollment form into the AVEED REMS Program at 1-855-755-0495.

Click here to complete the AVEED REMS Training and Enrollment online

- All Prescribing Healthcare providers must be certified in the AVEED REMS Program in order to prescribe AVEED at your Healthcare Setting.
- Non-Prescribing Healthcare Providers who will administer AVEED to patients must review the AVEED REMS Education for Healthcare Providers before injecting AVEED.

For additional information about the AVEED REMS Program, please call 1-855-755-0494.
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