AVEED™
(testosterone undecanoate) injection 750mg/3mL CIII

AVEED™ REMS Education Program for Healthcare Settings

This Educational Piece Includes Information About:

- Serious POME reactions and anaphylaxis with AVEED Injection
- AVEED REMS Program requirements to implement in your healthcare setting
- Ordering AVEED

The REMS Education Program for Healthcare Providers Includes Additional Information About:

- Steps for healthcare PROVIDER certification
- Proper administration of AVEED
- Patient counseling

Reference ID: 3465380

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. The AVEED REMS Education Program for Healthcare Settings is designed to train healthcare setting Authorized Representatives on these serious risks, and AVEED REMS Program requirements to order AVEED for their healthcare setting.

- **Healthcare settings** must be certified in the AVEED REMS Program to be able to order AVEED.
- **Prescribing Healthcare Providers** must be certified in the AVEED REMS Program to be able to prescribe AVEED.
- **Non-Prescribing Healthcare Providers** who will administer AVEED to patients must review the AVEED REMS Education for Healthcare Providers before injecting AVEED.

Steps for Healthcare Setting Certification

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

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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.

You can review the educational materials and enroll online at **www.AveedREMS.com**, or review the printed versions and fax your enrollment form to the AVEED REMS Program at 1-855-755-0495.

Your healthcare setting will not be able to order AVEED unless you meet these two requirements:

1. Your healthcare setting is certified
2. Healthcare providers who prescribe AVEED at your healthcare setting are certified in the AVEED REMS Program

Who Can Be An Authorized Representative?

An Authorized Representative at the healthcare setting can be a:

- Prescribing healthcare providers
- Non-prescribing healthcare providers
- Practice manager
- Or, any responsible individual in the healthcare setting

Please check with your manager to ensure the appropriate person represents the healthcare setting and attests to the enrollment requirements as stated on the Healthcare Setting Enrollment Form.

- One representative needs to enroll per healthcare setting (the "Authorized Representative"). One Authorized Representative can manage more than one healthcare setting.
- Please note, there are no AVEED REMS requirements for staff at a healthcare setting that will not be involved with prescribing or administering AVEED.

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Indication

AVEED™ (testosterone undecanoate) injection is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired)
- Hypogonadotropic hypogonadism (congenital or acquired)

AVEED should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of POME and anaphylaxis.

Serious Risks of POME and Anaphylaxis

With each AVEED injection, there is a potential for serious POME reactions or anaphylaxis to occur. These reactions can occur after any injection of AVEED during the course of therapy, including after the first dose.

The signs and symptoms of serious POME reactions and anaphylaxis overlap. It is important to observe patients in your healthcare setting for 30 minutes after each AVEED injection to determine whether medical intervention is necessary.

Serious POME reactions

POME occurring after an AVEED injection is believed to be caused by tiny droplets of oil, in which the testosterone undecanoate has been dissolved, that have traveled to the lungs.

- POME is **not** a blood clot
- There is a risk of POME occurring with each injection of AVEED

Symptoms of POME

The following symptoms of POME have been reported with AVEED:

- cough
- urge to cough
- dyspnea
- hyperhidrosis
- throat tightening
- chest pain
- dizziness
- syncope

- The majority of these events lasted a few minutes and resolved with supportive measures
- Some of the events lasted up to several hours and in some cases, emergency care and/or hospitalization were required

Anaphylaxis

Episodes of anaphylaxis, including life-threatening reactions, have been reported to occur following AVEED injection.

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Strategies to implement in your healthcare setting to mitigate these risks:

- Ensure all healthcare providers who prescribe AVEED are certified in the AVEED REMS program
  - Maintain up-to-date records
- Ensure all non-prescribing healthcare providers who administer AVEED are trained on:
  - Serious POME reactions and anaphylaxis
  - Patient counseling
  - 30 minute post-injection patient observation
  - Proper administration of AVEED
- Maintain an up-to-date record of training
- 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 your 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

How Do I Order AVEED?

Contact the AVEED REMS Program at 1-855-755-0494.

All AVEED REMS documents are available at www.AveedREMS.com, or call the AVEED REMS Program at 1-855-755-0494.

The completion of the AVEED REMS Education Program and enrollment process is NOT a substitute for reading the AVEED Full Prescribing Information and AVEED Medication Guide.

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