

# AVEED<sup>®</sup> REMS Education Program for Healthcare Providers

## This Education Program Includes Information About:

- AVEED REMS Program requirements
- Serious POME reactions and anaphylaxis with AVEED injection
- Proper administration of AVEED
- Counseling your patient
- Required Knowledge Assessment

# 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 is designed to train healthcare providers (HCPs) who prescribe and/or administer AVEED about these risks.

- **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 primary healthcare setting is enrolled.
- **Healthcare settings** must be certified in the AVEED REMS Program and have one or more associated certified prescribing healthcare providers to be able to order AVEED.
- **Non-Prescribing Healthcare Providers** who will administer AVEED to patients must review the AVEED REMS Education Program for Healthcare Providers before injecting AVEED.

## Steps for Healthcare Provider Certification:

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

The AVEED REMS Education Program, Knowledge Assessment, Healthcare Provider Enrollment Form, and other AVEED REMS Program tools are available online at [www.AveedREMS.com](http://www.AveedREMS.com) or by contacting the AVEED REMS Program at 1-855-755-0494 to request materials.

You can review the educational materials, enroll, and complete the knowledge assessment online at [www.AveedREMS.com](http://www.AveedREMS.com) or review the printed versions and fax your enrollment form and knowledge assessment.

You will not be able to prescribe AVEED without completing your certification in the AVEED REMS Program.

## Healthcare Setting Certification

Each healthcare setting must also be certified in the AVEED REMS Program and have one or more associated certified prescribing healthcare providers to be able to order, dispense, and administer AVEED. Visit [www.AveedREMS.com](http://www.AveedREMS.com) for more information on healthcare setting certification.

## 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.

The safety and efficacy of AVEED in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established. The safety and efficacy of AVEED in males less than 18 years old have not been established.

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

- The majority of these events lasted a few minutes and resolved with supportive measures, e.g., by patient reassurance and/or administration of supplemental oxygen
- 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.

## Strategies That May Mitigate These Risks:

- Take proper precautions and avoid injecting AVEED intravascularly
- Inject AVEED slowly (over 60 to 90 seconds)
- AVEED should not be used or should be discontinued in men with any known hypersensitivity to AVEED or to any of its ingredients (testosterone undecanoate, refined castor oil, benzyl benzoate)

### • 30 Minute Post-Injection Patient Observation

- Observe patients in your healthcare setting for a period of 30 minutes after each AVEED injection to provide appropriate medical treatment in the event of serious POME reactions or anaphylaxis
- The majority of cases reported occurred during or within 30 minutes of the injection

- Your healthcare setting must have immediate access on-site to equipment and personnel trained to manage serious POME reactions and anaphylaxis

## Proper Administration

AVEED is for intramuscular use only. Intravascular injection may lead to POME.

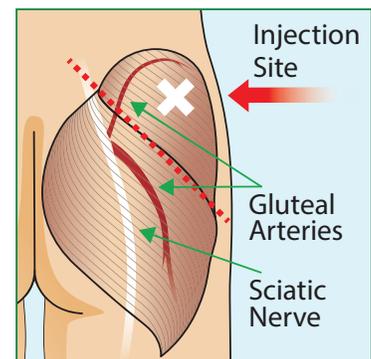
Only healthcare providers trained in the proper injection technique for AVEED should administer AVEED.

## Proper Injection Technique for AVEED Intramuscular Injection

1. The site for injection for AVEED is the gluteus medius muscle site located in the upper outer quadrant of the buttock. Care must be taken to avoid the needle hitting the superior gluteal arteries and sciatic nerve.

2. Following antiseptic skin preparation, enter the muscle and maintain the syringe at a 90° angle with the needle in its deeply imbedded position. Grasp the barrel of the syringe firmly with one hand. With the other hand, pull back on the plunger to aspirate for blood. **IF BLOOD APPEARS IN THE SYRINGE DO NOT PROCEED WITH THE INJECTION**, as this is an indication that a blood vessel may have been punctured. Immediately withdraw the needle completely and replace it.

3. If no blood is aspirated, reinforce the current needle position to avoid any movement of the needle and slowly (**over 60 to 90 seconds**) depress the plunger carefully and at a constant rate, until all the medication has been delivered. Be sure to depress the plunger completely with sufficient controlled force. Withdraw the needle.



**4. Observe the patient in the healthcare setting for 30 minutes after the injection in order to provide appropriate medical treatment in the event of a serious POME reaction or anaphylaxis.**

# Patient Counseling

## With each injection of AVEED:

- Review the AVEED Patient Counseling Tool (“What You Need to Know about AVEED Treatment: A Patient Guide”) with patients and caregivers.
- Give the Patient Counseling Tool to the patient to read during their 30-minute wait in your healthcare setting.

## Explain to patients:

- The importance of providing an accurate medical history about any previous allergic reactions to AVEED or its components (testosterone undecanoate, castor oil and benzyl benzoate)
- AVEED can only be administered by a trained HCP in a certified healthcare setting
- The risks of serious POME reactions and anaphylaxis associated with AVEED
- POME is not a blood clot
- How to recognize the symptoms of serious POME reactions and a severe allergic reaction (anaphylaxis)
- Report signs and symptoms to the healthcare setting staff immediately. These include:
 

<ul style="list-style-type: none"> <li>- feeling dizzy or fainting</li> <li>- hoarseness or trouble speaking</li> <li>- trouble breathing</li> <li>- feeling flushed</li> <li>- itching, rash, or hives</li> </ul>	<ul style="list-style-type: none"> <li>- coughing or feeling the need to cough</li> <li>- tightness in your throat</li> <li>- numbness and tingling in your arms</li> <li>- swelling of the face, throat or tongue</li> </ul>	<ul style="list-style-type: none"> <li>- feeling very sweaty</li> <li>- chest pain</li> <li>- feeling unwell</li> <li>- stomach pain or vomiting</li> </ul>
--	---	---

**The importance of waiting in the healthcare setting for 30 minutes post-injection to provide for appropriate medical treatment in the event of a serious POME reaction or anaphylaxis.**

- The AVEED REMS Patient Counseling Tool contains an AVEED Injection Tracking Sheet. The purpose of this sheet is that the patient’s injection time and scheduled departure time – 30 minutes apart – can be recorded by the HCP and given to the patient. The patient will then know when they have waited 30 minutes and can leave the healthcare setting accordingly. Explain the importance of this tool to your patients and encourage them to use it every time.

<i>Healthcare Professional to Complete</i>		
Time I received the Injection	How long I need to wait in the office	Time I can leave the office
	30 minutes	

- Who to contact immediately if they experience any of the above signs or symptoms after leaving the healthcare setting
- Both serious POME reactions and anaphylaxis can occur after any injection of AVEED during the course of therapy, including after the first dose
- Who they should contact with any questions they may have regarding AVEED

## Reporting of Adverse Events

Report suspected adverse events to Endo Pharmaceuticals at 1-800-462-3636. You also may report adverse event information to the FDA MedWatch Reporting System at 1-800-FDA-1088.

All AVEED REMS documents are available at [www.AveedREMS.com](http://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 Prescribing Information and Medication Guide.**

## Other Resources for Healthcare Providers

The AVEED REMS Program does not include training on how to manage POME and anaphylaxis.

HCPs should also be familiar with current standards for the treatment of anaphylaxis. Treatment guidelines are provided by the following organizations:

- The American Academy of Allergy, Asthma and Immunology (AAAAI)  
(<http://www.aaaai.org/home.aspx>)
- National Institute of Allergy and Infectious Diseases (NIAID)  
(<http://www.niaid.nih.gov/Pages/default.aspx>)
- World Allergy Organization (WAO)  
(<http://www.worldallergy.org/anaphylaxis/>)

## Knowledge Assessment

Complete all 10 questions.

To become a certified healthcare provider in the AVEED REMS Program you will need to answer ALL questions correctly.

- Complete the Knowledge Assessment, populate and sign the one-time Healthcare Provider Enrollment Form online at [www.AveedREMS.com](http://www.AveedREMS.com)

**OR**

- Fax your responses to all 10 Knowledge Assessment questions and a completed and signed one-time Healthcare Provider Enrollment Form to 1-855-755-0495

**If you complete the Knowledge Assessment and Enrollment Form online**, correspondence from the AVEED REMS Program confirming your enrollment and certification in the AVEED REMS Program will be sent via the preferred communication method (email or fax) selected on your enrollment.

**If you return the Knowledge Assessment and Enrollment Form via fax**, you will receive correspondence from the AVEED REMS Program via the preferred communication method (email or fax) selected on your enrollment form within two business days. Correspondence may include:

- How to retake the Knowledge Assessment, if necessary
- How to correct missing or invalid information provided on the Enrollment Form and resubmit to the AVEED REMS Program for re-processing, if necessary
- A confirmation of your enrollment and certification in the AVEED REMS Program (which requires no further action)

**Questions 1-5 Multiple Choice.** Select only **one** answer for each question.

### QUESTION 1

Which of the following would be an appropriate patient for AVEED?

- A. 45-year-old female with a history of androgen insensitivity syndrome
- B. 16-year-old male with symptoms of delayed puberty and hypogonadism
- C. 40-year-old male with history of congenital hypogonadism complaining of fatigue and decreased libido
- D. 54-year-old male with a family history of prostate cancer and complaining of decreased urine output

### QUESTION 2

Which of the following symptoms most accurately describes a patient experiencing an episode of post-injection pulmonary oil microembolism (POME)?

- A. Severe palpitations and diaphoresis one week post AVEED injection
- B. Headache, nausea, or vomiting prior to AVEED injection
- C. Rash, skin irritation, and erythema surrounding the injection site
- D. Cough, dyspnea, chest pain, and dizziness 5 minutes post-injection

### QUESTION 3

Why should a patient wait in the healthcare setting for 30 minutes following each AVEED injection?

- A. To make sure their insurance information is accurate
- B. To provide them with follow-up appointment information
- C. To provide appropriate medical treatment in the event of a serious POME reaction or anaphylaxis
- D. To ensure that they do not eat for 30 minutes after an injection

### QUESTION 4

What is the proper injection route and injection site for AVEED?

- A. Intramuscular injection in the gluteus muscle
- B. Intramuscular injection in the deltoid
- C. Intravascular injection in the gluteus muscle
- D. None of the above

If you plan on faxing this Knowledge Assessment to the Program please provide your Prescriber NPI so we can associate your progress with your stakeholder record. You can provide this information below.

Prescriber NPI: \_\_\_\_\_

## QUESTION 5

Prior to administering an AVEED injection, you must counsel the patient using the Patient Counseling Tool “What You Need to Know about AVEED Treatment: A Patient Guide” and the AVEED Medication Guide on all of the following EXCEPT:

- A. The risks of serious POME and anaphylaxis associated with AVEED
- B. Techniques for aseptic self-injection of AVEED
- C. The importance of waiting 30 minutes post-injection in the healthcare setting in order to provide appropriate medical treatment in the event of a serious POME reaction or anaphylaxis
- D. Signs and symptoms of an adverse reaction and how to report them

### Questions 6-10 (True or False)

## QUESTION 6

In order to administer AVEED, my healthcare setting must also be certified.

T F

## QUESTION 7

As a patient continues receiving AVEED injections, their risk of experiencing pulmonary oil microembolism (POME) or anaphylaxis decreases.

T F

## QUESTION 8

If a patient experiences a hypersensitivity reaction (e.g., angioedema and/or hives) following an AVEED injection, it is appropriate to continue therapy with AVEED.

T F

## QUESTION 9

Patients who feel comfortable with self-administering AVEED may do so after receiving their initial injection in the healthcare setting.

T F

## QUESTION 10

It is a requirement of the AVEED REMS to review the Patient Counseling Tool “What you need to know about AVEED Treatment: A Patient Guide” with patients and provide them with a copy prior to each injection of AVEED.

T F

If you plan on faxing this Knowledge Assessment to the Program please provide your Prescriber NPI so we can associate your progress with your stakeholder record. You can provide this information below.

Prescriber NPI: \_\_\_\_\_