What You Need to Know About AVEED® Treatment: A Patient Guide

Patients: Go over this Patient Guide with your healthcare provider.

• Ask any questions you have each time you get an AVEED injection.
• You will be asked to wait 30 minutes after an AVEED injection to make sure you do not have a potential lung reaction or an allergic reaction.

What Is AVEED?

AVEED is a prescription medicine that contains testosterone. AVEED is used to treat adult men who have low or no testosterone due to certain medical conditions. It is not known if AVEED is safe or effective to treat men who have low testosterone due to aging. It is not known if AVEED® is safe and effective for use in children younger than 18 years old.

AVEED contains testosterone in castor oil. Your healthcare provider will inject AVEED in the muscle of your buttocks. AVEED is then slowly released from your muscle into your body. You can only get AVEED in your healthcare provider’s office, clinic, or hospital because of the possible serious risks.

What Are the Most Serious Risks with AVEED Treatment?

• A serious lung reaction. Tiny droplets of the castor oil in AVEED could travel from your muscle to your lungs after you get AVEED treatment, which is called pulmonary oil microembolism (POME). POME is not a blood clot that travels to your lungs.
• Severe or life-threatening allergic reaction (anaphylaxis).

These reactions can occur with any AVEED injection during your treatment, even if you have not had a reaction occur before.

Each time you get AVEED, stay in the office, clinic, or hospital for 30 minutes to be sure you do not have symptoms of a serious lung reaction (POME) or a severe allergic reaction.

What Are the Symptoms of a Serious Lung Reaction (POME)?
POME symptoms can occur within 30 minutes post injection, and may include one or more of the following:

• Trouble breathing
• Tightness in your throat
• Coughing or the urge to cough
• Chest pain
• Excessive sweating
• Feeling dizzy or fainting

What Are the Symptoms of an Allergic Reaction?

Symptoms of an allergic reaction can occur during or right after injection and may include:

• Itching
• Rash
• Stomach pain
• Feeling flush
• Tightness in your throat
• Trouble breathing
• Excessive sweating
• Feeling dizzy or fainting

If you have any symptoms of a serious reaction, get medical help right away.
These are NOT all the possible risks of AVEED. See the AVEED Medication Guide that you were given or talk to your healthcare provider for medical advice about other risks.

What Can I Do to Help Reduce the Risks of AVEED?
1. Tell your healthcare provider if you have ever had an allergic reaction to AVEED or any of its ingredients. The ingredients in AVEED are:
   • Testosterone undecanoate
   • Castor oil
   • Benzyl benzoate

2. Know the symptoms of a serious lung reaction (POME) and a severe allergic reaction.

3. Each time you get AVEED, stay in the office, clinic, or hospital for 30 minutes to be sure you do not have symptoms of a serious lung reaction (POME) or a severe allergic reaction.

How Often Will I Receive an Injection of AVEED?
You will get:
• 1 injection when you start
• 1 injection 4 weeks later
• 1 injection every 10 weeks thereafter

Where Can I Get More Information on AVEED?
• Your healthcare provider will give you the AVEED Medication Guide to read each time you get an AVEED injection.
• You can also find additional information at www.AvededREMS.com or
• Contact the AVEED REMS Program at 1-855-755-0494.

Injection Observation Log
Use this tracking log so you know when 30 minutes have passed since your AVEED injection. If you have no symptoms of a serious lung reaction (POME) or a severe allergic reaction, check with your healthcare provider before you leave.

<table>
<thead>
<tr>
<th>Time I received the Injection</th>
<th>How long I need to wait in the office</th>
<th>Time I can leave the office</th>
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<tbody>
<tr>
<td><em><strong><strong>:</strong></strong></em>__</td>
<td>30 Minutes</td>
<td><em><strong><strong>:</strong></strong></em>__</td>
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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
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 and have at least one certified prescriber associated with the facility to be able to order, receive, or administer AVEED. Healthcare providers are associated to a healthcare setting by:
  - The healthcare provider selecting the healthcare setting during the healthcare provider enrollment process, or
  - Being associated to the healthcare setting by the Authorized Representative via the REMS Call Center
- **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

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<tr>
<th>Step</th>
<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>Designate an Authorized Representative</td>
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<tr>
<td>2</td>
<td>Review the AVEED REMS Education Program for Healthcare Settings, including the Prescribing Information</td>
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<td>3</td>
<td>Verify annually the Authorized Representative on record</td>
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<td>4</td>
<td>Complete and sign the Healthcare Setting Enrollment Form. This Enrollment must be renewed every 2 years</td>
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<tr>
<td>5</td>
<td>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.</td>
</tr>
<tr>
<td>6</td>
<td>Implement the necessary staff training and processes to comply with the AVEED REMS Program requirements</td>
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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. There is at least one prescriber certified in the Aveed REMS Program associated with your healthcare setting

Who Can Be An Authorized Representative?

An Authorized Representative at the healthcare setting can be:

- 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. The chosen Authorized Representative must be verified as current annually.
- Please note, there are no AVEED REMS requirements for staff at a healthcare setting that will not be involved with prescribing or administering AVEED.
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)
• Hypogonadotrophic 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
- urge to cough
- dizziness
- throat tightening
- chest pain
- syncope
- hyperhidrosis
- dyspnea

• 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 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 immediate access on-site to equipment and personnel to manage serious POME reactions or anaphylaxis
- Ensure a patient is NEVER provided AVEED for home or self-injection
- Establish a process to ensure that your healthcare setting recertifies if the Authorized Representative changes

How Do I Order AVEED?

Contact 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.

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