

MEDICATION GUIDE

AVEED[®] (Uh-Veed)

(testosterone undecanoate)

injection

Read this Medication Guide before you receive AVEED and before each injection. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about AVEED?

AVEED may cause serious side effects, including:

- **A serious lung problem.** AVEED can cause a serious lung problem called a pulmonary oil microembolism (POME) reaction. POME is caused by tiny droplets of oil that have traveled to the lungs. Symptoms of a POME reaction may include:
 - cough or urge to cough
 - difficulty breathing
 - sweating
 - tightening of your throat
 - chest pain
 - dizziness
 - fainting
- **Serious allergic reactions (anaphylaxis).** AVEED can cause a serious allergic reaction right after receiving the injection. Some of these allergic reactions may be life threatening.

These reactions can happen after you receive your first dose of AVEED or may happen after receiving more than 1 dose.

You may need emergency treatment in a hospital, especially if these symptoms get worse over the 24 hours after your AVEED injection.

These side effects may happen during or right after each injection. To be sure that you are not having one of these reactions:

- **You need to stay in the doctor's office, clinic, or hospital for 30 minutes after having your AVEED injection so that your doctor can watch you for symptoms of POME or a serious allergic reaction.**
- **You can only get AVEED at your doctor's office, clinic, or hospital.**

AVEED is only available through a restricted program called the AVEED Risk Evaluation and Mitigation Strategy (REMS) Program. For more information about the AVEED REMS Program go to www.AveedREMS.com or call 1-855-755-0494.

What is AVEED?

AVEED is a prescription medicine that contains testosterone. AVEED is used to treat adult males who have low or no testosterone due to certain medical conditions.

AVEED is only for adult males who need testosterone replacement therapy and when the benefit of receiving AVEED is more than the risk of POME and anaphylaxis.

Your healthcare provider will test your blood before you start and while you are taking AVEED.

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. Improper use of AVEED may affect bone growth in children.

AVEED is a controlled substance (CIII) because it contains testosterone that can be a target for people who abuse prescription medicines.

AVEED is not meant for use in women.

Who should not receive AVEED?

Do not receive AVEED if you:

- have breast cancer
- have or might have prostate cancer
- are pregnant. AVEED may harm your unborn baby.
- are allergic to AVEED or to any of the ingredients in AVEED. See the end of this leaflet for a complete list of ingredients in AVEED.

Talk to your doctor before receiving this medicine if you have any of the above conditions.

What should I tell my doctor before receiving AVEED?

Before receiving AVEED, tell your doctor if you:

- have breast cancer
- have or might have prostate cancer
- have urinary problems due to an enlarged prostate
- have high blood pressure or are being treated for high blood pressure
- have heart problems
- have liver or kidney problems
- have problems breathing while you sleep (sleep apnea)
- have any other medical conditions

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Receiving AVEED with certain other medicines can affect each other. Especially tell your doctor if you take:

- insulin
- medicines that decrease blood clotting
- corticosteroids

Ask your doctor or pharmacist for a list of these medicines, if you are not sure.

Know the medicines you take. Keep a list of your medicines and show them to your doctor and pharmacist when you get a new medicine.

How will I receive AVEED?

See **“What is the most important information I should know about AVEED?”**

Your doctor will inject AVEED deep into the muscle of your buttock. You will get 1 injection when you start, 1 injection 4 weeks later, and then 1 injection every 10 weeks.

Your doctor will test your blood before you receive and while you are receiving AVEED.

What are the possible side effects of AVEED?

AVEED can cause serious side effects including:

- see **“What is the most important information I should know about AVEED?”**
- **if you already have enlargement of your prostate gland, your signs and symptoms can get worse** while receiving AVEED. This can include:
 - increased urination at night
 - trouble starting your urine stream
 - having to pass urine many times during the day
 - having an urge that you have to go to the bathroom right away
 - having a urine accident
 - being unable to pass urine or weak urine flow
- changes in certain blood tests
- **possible increased risk of prostate cancer.** Your doctor should check you for prostate cancer or any other prostate problems before you receive and while you are receiving AVEED.
- **blood clots in the legs or lungs.** Signs and symptoms of a blood clot in your leg can include leg pain, swelling or redness. Signs and symptoms of a blood clot in your lungs can include difficulty breathing or chest pain.
- **Increased blood pressure.** AVEED can increase your blood pressure, which can increase your risk of having a heart attack or stroke over time. Your risk may be greater if you have already had a heart attack or stroke or if you have other risk factors for heart attack or stroke. You may need to start new medicines or have medicines changed for high blood pressure while on AVEED. If your blood pressure

cannot be controlled, AVEED may need to be stopped. Your healthcare provider should check your blood pressure while you use AVEED.

- **in large doses AVEED may lower your sperm count.**
- **liver problems.** Symptoms of liver problems may include:
 - nausea or vomiting
 - yellowing of your skin or whites of your eyes
 - dark urine
 - pain on the right side of your stomach area (abdominal pain)
- **swelling of your ankles, feet, or body, with or without heart failure.** This may cause serious problems for people who have heart, kidney, or liver disease.
- **enlarged or painful breasts.**
- **have problems breathing while you sleep (sleep apnea).**

Call your doctor right away if you have any of the serious side effects listed above.

The most common side effects of AVEED include:

- acne
- pain at the injection site
- increased prostate specific antigen (a test used to screen for prostate cancer)
- increased estradiol level
- low testosterone level
- feeling tired
- irritability
- increased red blood cell count
- difficulty sleeping
- mood swings

Other side effects include more erections than are normal for you or erections that last for a long time.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects with AVEED. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about AVEED

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

This Medication Guide summarizes the most important information about AVEED. If you would like more information, talk with your doctor. You can ask your doctor or nurse for information about AVEED that is written for health professionals. For more information, go to www.AVEEDUSA.com or call 1-800-462-3636.

What are the ingredients in AVEED?

Active ingredient: testosterone undecanoate

Inactive ingredients: benzyl benzoate, refined castor oil

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured for:

Endo USA

Malvern, PA 19355

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