

Ask your doctor about  
**LONG-ACTING** AVEED®

## AVEED® TESTOSTERONE INJECTION

**5 SHOTS A YEAR**  
AFTER THE FIRST MONTH OF THERAPY

**AVEED®**  
(testosterone undecanoate) injection   
750 mg/3 mL

Not an actual patient.

AVEED® (testosterone undecanoate) injection is a prescription medicine that contains testosterone, a controlled substance (CIII). AVEED® is used to treat adult males who have low or no testosterone due to certain medical conditions.

### IMPORTANT SAFETY INFORMATION FOR AVEED®

**AVEED® may cause serious side effects, including:**

**A serious lung problem.** AVEED® can cause a serious lung problem called POME. 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

Please see Important Safety Information on pages **14-17**.

Please [click here](#) for full Prescribing Information, including Boxed Warning and patient Medication Guide.

## What Is AVEED®?

AVEED® (testosterone undecanoate) injection is a long-acting prescription medicine that contains testosterone.

AVEED® is used to treat adult males who have a condition called **hypogonadism**.

## What Is Hypogonadism in Men?

Hypogonadism is a term used to describe low testosterone in men, and occurs when the male testes are unable to produce sufficient testosterone (the male sex hormone). This results in **low levels of testosterone**.

### IMPORTANT SAFETY INFORMATION FOR AVEED® (CONT)

**Do not receive AVEED® if you:**

- **have breast cancer, have or might have prostate cancer, are allergic to AVEED® or to any of the ingredients in AVEED® (testosterone undecanoate, castor oil, benzyl benzoate).**
- **are a woman, or are pregnant.** AVEED® may harm your unborn baby.

**AVEED® may cause serious side effects, including:**

- **A serious lung problem.** AVEED® can cause a serious lung problem called POME. 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



Not an actual patient.

**5 SHOTS A YEAR**  
AFTER THE FIRST MONTH OF THERAPY

### IMPORTANT SAFETY INFORMATION FOR AVEED® (CONT)

- **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.

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## Why AVEED®?

If you have hypogonadism, you may be talking with your doctor about controlling your testosterone levels.

TESTOSTERONE LEVELS WITHIN  
THE NORMAL RANGE FOR **10 FULL  
WEEKS**

In a clinical trial, 94% of men who received AVEED® injections maintained average testosterone levels within the normal range for 10 full weeks after the third injection.\* 5.1% of patients had testosterone levels below normal range, and 0.9% of patients had testosterone levels above normal range.



Not an actual patient.

\*AVEED® was studied for 84 weeks in men with hypogonadism aged 18 years or older. Patients received AVEED® 750 mg at baseline, at 4 weeks, and then every 10 weeks thereafter. 110 out of 117 patients (94%) maintained average testosterone concentrations in the normal range (300-1000 ng/dL) for 10 full weeks after the 3rd injection.

## IMPORTANT SAFETY INFORMATION FOR AVEED® (CONT)

**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.**

## Avoid the risk of transference

Since AVEED® is an injection that you receive at your doctor's office, you avoid the risk of transferring the medicine from your body to others.

## How your prescription gets filled

Your physician may either buy AVEED® and bill your health plan or order through a Specialty Pharmacy. The Specialty Pharmacy will contact you to collect your copay, bill your health plan, and deliver the medication to your doctor's office prior to your appointment.

If your physician orders through a Specialty Pharmacy, you should expect to receive a phone call from your Specialty Pharmacy prior to each injection.

## IMPORTANT SAFETY INFORMATION FOR AVEED® (CONT)

- **Serious side effects relating to the heart and blood vessels and mental status are associated with abuse of testosterone and anabolic androgenic steroids.**

**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 heart problems, have liver or kidney problems, have problems breathing while you sleep (sleep apnea), or 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.

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# What to Expect When You Receive AVEED<sup>®</sup>

AVEED<sup>®</sup> is an injection that is always given at the doctor’s office. AVEED<sup>®</sup> is only available through your doctor’s office, clinic, or hospital, and it is not a medicine you will give yourself at home.

When you receive AVEED<sup>®</sup>, here’s what you should expect:

- 1
- Your doctor will inject AVEED<sup>®</sup> into the muscle of your buttock. Receiving the injection itself takes approximately 60 to 90 seconds.
- 2
- Remain at the doctor’s office for 30 minutes to be sure that you are not experiencing any serious injection-related side effects.
- 3
- Return to the doctor’s office for regular injections. **You will get an injection when you start, another injection 4 weeks later, and then an injection every 10 weeks.**

Your doctor will test your blood before you receive and while you are receiving AVEED<sup>®</sup>.

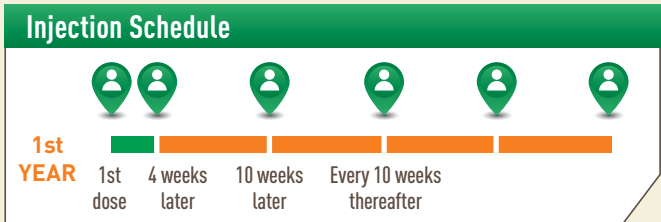
## IMPORTANT SAFETY INFORMATION FOR AVEED<sup>®</sup> (CONT)

Receiving AVEED<sup>®</sup> with certain other medicines can affect each other. Especially tell your doctor if you take insulin, medicines that decrease blood clotting, or corticosteroids. Ask your doctor or pharmacist for a list of these medicines, if you are unsure.

**AVEED<sup>®</sup> can cause serious side effects, including:**

- if you already have enlargement of your prostate gland, your signs and symptoms can get worse while receiving AVEED<sup>®</sup>.
- changes in certain blood tests

# Be Sure to Keep up with Your AVEED<sup>®</sup> Treatments as Prescribed



To keep your testosterone levels in the normal range, it’s important to stay with the recommended dosing schedule and get your treatments **every 10 weeks after the first month of therapy**.

## Appointment Reminder

Keep track of the dates of upcoming appointments:

**NOTE:** If you have not spoken with your Specialty Pharmacy and you are within two weeks of your appointment, please contact the Specialty Pharmacy directly.

Please see Important Safety Information on pages [14-17](#). Please [click here](#) for full Prescribing Information, including Boxed Warning and patient Medication Guide.

## Why a 30-Minute Wait?

Patients must remain at the doctor's office for 30 minutes following each injection with AVEED®, because AVEED® may cause serious side effects. These side effects may occur during or right after an injection.

AVEED® can cause a temporary but potentially serious condition called a pulmonary oil microembolism (POME). POME is **NOT** a blood clot. AVEED® contains castor oil, and POME is believed to be caused by tiny droplets of castor oil that have traveled to the lungs. Castor oil is one of the ingredients that enables AVEED® to be injected every 10 weeks after the first month of therapy.

AVEED® may also cause a severe allergic reaction called anaphylaxis.

Because of these serious potential risks, it's important that you talk to your doctor about whether the benefits of receiving AVEED® outweigh these potential risks. Ask your doctor or nurse if you are unsure about the risks of AVEED®.

### Among 3,556 patients in worldwide clinical trials\*:

- 9 POME events occurred in 8 patients
- 2 events of anaphylaxis occurred

\*Patients treated with intramuscular testosterone undecanoate.

### IMPORTANT SAFETY INFORMATION FOR AVEED® (CONT)

- **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®.
- **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, or 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.

### IMPORTANT SAFETY INFORMATION FOR AVEED® (CONT)

- **enlarged or painful breasts.**
- **have problems breathing while you sleep (sleep apnea).**
- **blood clots in the legs or lungs.** This can include pain, swelling or redness of your legs, difficulty breathing, or chest pain.
- **possible increased risk of heart attack, death, or stroke.**

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

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Not an actual patient.



# Questions and Answers

## Specialty Pharmacies and AVEED®

Ask your doctor’s office if they use a Specialty Pharmacy to order AVEED®. If so, here are answers to some common questions that you will need to know.

### Q. How will my prescription for AVEED® get filled?

A. The Specialty Pharmacy will contact you to collect your copay, bill your health plan, and deliver the medication to your healthcare provider’s office prior to your appointment.

### Q. Are there any forms that I need to complete?

A. Yes, you will need to sign a Patient Authorization Form to authorize a benefits investigation and evaluate your eligibility to receive benefits under the AVEED® Copay Assistance Program.

### Q. How will the Specialty Pharmacy communicate with me?

A. If your doctor orders through a Specialty Pharmacy, you should expect to receive a phone call from your Specialty Pharmacy prior to each injection.

### Q. What should I have ready when I speak with the Specialty Pharmacy?

A. Have your personal information available when you speak with the Specialty Pharmacy, including your insurance information. They will also need payment information, so have a credit or debit card ready to cover the copay or deductible.

### Q. Is there anything else the Specialty Pharmacy needs to know?

A. The Specialty Pharmacy may ask if you have scheduled your appointment at your doctor’s office, clinic, or hospital.

### Q. How can I contact the Specialty Pharmacy?

A. Ask your doctor’s office to circle the Specialty Pharmacy Provider you should contact.

**NOTE:** If you have not spoken with your Specialty Pharmacy and you are within two weeks of your appointment, please contact the Specialty Pharmacy directly at the number below.

Specialty Pharmacies	Phone	Fax
ALLIANCERX WALGREENS PHARMACY	888-347-3416	877-231-8302
CVS CAREMARK	800-237-2767, Ext 103-6990 (Opt 3, 2)	800-323-2445

## IMPORTANT SAFETY INFORMATION FOR AVEED® (CONT)

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, or mood swings.

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

Drug abuse is the intentional use of a drug for its rewarding mental and physical effects. Physical dependence is characterized by withdrawal symptoms after abruptly stopping the drug or significantly reducing the dose. Serious side effects relating to the heart and blood vessels, for instance, heart attack and congestive heart failure, and mental status, including major depression, paranoia, delusions, hallucinations, hostility, and aggression, are associated with abuse of testosterone and anabolic androgenic steroids.

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5 SHOTS A YEAR after the first month of therapy

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## AVEED® Copay Assistance Program

### Speak to your doctor about how you may save on AVEED®

How much you pay for AVEED® will depend on your health benefits or insurance coverage.

- With the AVEED® Copay Assistance Program, eligible patients with commercial insurance plans may pay \$0 copay for AVEED®
- The AVEED® Copay Assistance Program can cover up to \$300 of your out-of-pocket costs for each injection of AVEED®

To find out if you qualify, call 1-800-381-2638.

If your total out-of-pocket expense exceeds these amounts, you are responsible for the additional amounts.

MAJORITY OF ELIGIBLE PATIENTS  
WITH COMMERCIAL INSURANCE PLANS

PAID \$0 OUT-OF-POCKET\*

with the AVEED® Copay Assistance Program

\*January 2016 through May 2020 = 21,188 claims filed.

#### Terms and Conditions apply:

- Offer good only in the USA and void where prohibited or otherwise restricted by law
- Offer is valid for patients with private insurance or paying cash
- Offer not valid for prescriptions that may be reimbursed under a federal or state healthcare program, including Medicare, Medicaid, or any other federal or state healthcare programs, including any state medical pharmaceutical assistance programs

If there are any questions, please call 1-800-381-2638.

Limitations apply. Endo USA, Inc. reserves the right to rescind, revoke, or amend this program without notice.

Patient is responsible for reporting receipt of program rewards to any private insurer that pays for or reimburses any part of the prescriptions filled with this program.

### IMPORTANT SAFETY INFORMATION FOR AVEED® (CONT)

**Side effects associated with abuse or misuse by men include** mini-stroke, convulsions, mild mania (elevation and hyperactivity), irritability, abnormal blood lipids, decrease in size or function of testicles, decreased or absence of fertility; **by women include** unwanted hair growth, development of male characteristics, voice deepening, clitoris enlargement, decrease in size or function of breasts, male pattern baldness, menstrual irregularities; **by male and female adolescents include** halting of growth and early puberty.

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. You may report side effects to FDA at 1-800-FDA-1088.

Please see Important Safety Information on pages 14-17.

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## WHAT IS AVEED®?

AVEED® (testosterone undecanoate) injection is a prescription medicine that contains testosterone, a controlled substance (CIII). 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 pulmonary oil microembolism (POME) and anaphylaxis.

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.

## IMPORTANT SAFETY INFORMATION FOR AVEED®

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- **are a woman, or are pregnant.** AVEED® may harm your unborn baby.

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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, or corticosteroids. Ask your doctor or pharmacist for a list of these medicines, if you are unsure.

**AVEED® can cause serious side effects, including:**

- **if you already have enlargement of your prostate gland, your signs and symptoms can get worse while receiving AVEED®.**
- 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®.
- **in large doses AVEED® may lower your sperm count.**

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## IMPORTANT SAFETY INFORMATION FOR AVEED<sup>®</sup> (CONT)

- **liver problems.** Symptoms of liver problems may include nausea or vomiting, yellowing of your skin or whites of your eyes, dark urine, or 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).**
- **blood clots in the legs or lungs.** This can include pain, swelling or redness of your legs, difficulty breathing, or chest pain.
- **possible increased risk of heart attack, death, or stroke.**

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

**The most common side effects of AVEED<sup>®</sup> 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, or mood swings.

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

Drug abuse is the intentional use of a drug for its rewarding mental and physical effects. Physical dependence is characterized by withdrawal symptoms after abruptly stopping the drug or significantly reducing the dose. Serious side effects relating to the heart and blood vessels, for instance, heart attack and congestive heart failure, and mental status, including major depression, paranoia, delusions, hallucinations, hostility, and aggression, are associated with abuse of testosterone and anabolic androgenic steroids.

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These are not all the possible side effects with AVEED<sup>®</sup>. For more information, ask your doctor or pharmacist. You may report side effects to FDA at 1-800-FDA-1088.

**Geriatric Patients:** There have not been sufficient numbers of geriatric patients in controlled clinical studies with AVEED<sup>®</sup> to determine whether efficacy or safety in those over 65 years of age differs from younger subjects. There are insufficient long-term safety data in geriatric patients to assess the potential risks of cardiovascular disease and prostate cancer

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750 mg/3 mL

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