AVEED®—*the only FDA-approved LONG-ACTING* testosterone injection[1,2]

ELEVATE AND CONTROL TESTOSTERONE LEVELS WITH

5 SHOTS A YEAR

AFTER THE FIRST MONTH OF THERAPY

*During the third dosing interval, 94% of men maintained average testosterone levels within the normal range; 5.1% of patients had a C_{avg} <300 ng/dL, and 0.9% of patients had a C_{avg} >1000 ng/dL.[3]**

*Normal range was defined as 300-1000 ng/dL.

INDICATIONS AND USAGE

AVEED® (testosterone undecanoate) is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.

- Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

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 pulmonary oil microembolism and anaphylaxis.

Limitations of use:

- Safety and efficacy of AVEED® in men with "age-related hypogonadism" have not been established.
- Safety and efficacy of AVEED® in males less than 18 years old have not been established.

IMPORTANT SAFETY INFORMATION about AVEED®

WARNING: SERIOUS PULMONARY OIL MICROEMBOLISM (POME) REACTIONS AND ANAPHYLAXIS

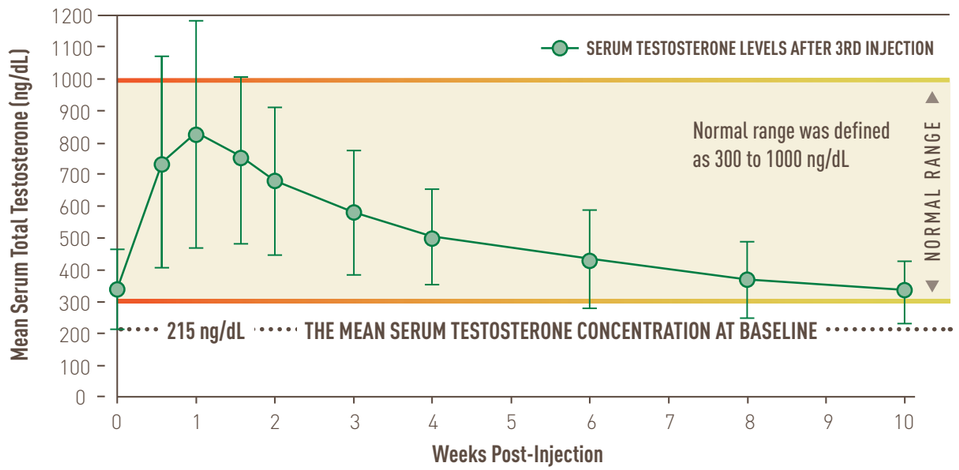
- **Serious POME reactions, involving urge to cough, dyspnea, throat tightening, chest pain, dizziness, and syncope; and episodes of anaphylaxis, including life-threatening reactions, have been reported to occur during or immediately after the administration of testosterone undecanoate injection. These reactions can occur after any injection of testosterone undecanoate during the course of therapy, including after the first dose.**
- **Following each injection of AVEED®, observe patients in the healthcare setting for 30 minutes in order to provide appropriate medical treatment in the event of serious POME reactions or anaphylaxis.**
- **Because of the risks of serious POME reactions and anaphylaxis, AVEED® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the AVEED® REMS Program.**

Please see Important Safety Information throughout. Please see accompanying full Prescribing Information, including Boxed Warning.

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

Elevate and Control Testosterone Levels in Hypogonadal Males

Mean steady-state testosterone concentrations during 3rd dosing interval (N=117)[3-5]*



Over the full 10 weeks at steady state[3,4]:

- The mean C_{min} remained above 300 ng/dL
- 7.7% of patients had a C_{max} >1500 ng/dL
- No patient had a C_{max} >1800 ng/dL

In the Phase 3 US clinical trial[3]:

- Hypogonadal men (morning testosterone level <300 ng/dL) were given 750 mg AVEED® at initiation, at 4 weeks, and every 10 weeks thereafter
- Mean serum testosterone levels at baseline were 215 ng/dL
- Steady-state testosterone levels were achieved with the third injection at 14 weeks

In the US clinical trial, mean testosterone concentrations
remained in the normal range (300-1000 ng/dL) at all measured time points upon achieving steady state.[4]

***STUDY DESIGN[3-5]**

This was an 84-week, single-arm, open-label, multicenter trial of 130 hypogonadal men. All men weighed 65 kg or more and were 18 years of age or older (mean age 54.2 years). Patients who had received prior testosterone treatment completed a washout period and were screened for serum total testosterone concentrations <300 ng/dL.

In all patients, 750 mg of AVEED® was administered via intramuscular injection at baseline, Week 4, then every 10 weeks thereafter. Blood samples for hormone concentrations were obtained immediately before each injection through the eighth injection (ie, 64-week time point). More frequent samples were drawn for hormones at Days 4, 7, 11, 14, 21, 28, 42, 56, and 70 after the third injection. Safety outcomes were followed during an extension of 20 weeks—2 more injection intervals—through a total of 84 weeks.

IMPORTANT SAFETY INFORMATION about AVEED® (CONT)

CONTRAINDICATIONS

- Men with carcinoma of the breast or known or suspected carcinoma of the prostate.
- Women who are pregnant. Testosterone can cause virilization of the female fetus when administered to a pregnant woman.
- Men with with known hypersensitivity to AVEED® or any of its ingredients (testosterone undecanoate, refined castor oil, benzyl benzoate).

Always Administered by a Healthcare Professional

Because AVEED® is administered in-office, you can:

- Closely monitor treatment progress
- Track patient adherence
- Avoid the risk of transference (secondary exposure to testosterone)

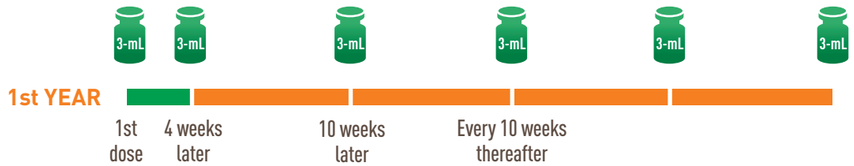
If testosterone abuse is suspected, check serum testosterone concentrations to ensure that they are within therapeutic range. However, testosterone levels may be in the normal or subnormal range in men abusing synthetic testosterone derivatives. Counsel patients concerning the serious adverse reactions associated with abuse of testosterone and anabolic androgenic steroids.[3]

Visit AveedUSA.com for these and other valuable resources:

- Instructional Video/Instructions for proper injection technique
- Patient Scheduling Tool and Reminder Card

No dosage titration necessary[3]

Each 750-mg (3-mL) dose of AVEED® comes in a single-use vial



5 SHOTS A YEAR
AFTER THE FIRST MONTH OF THERAPY

DOSAGE AND ADMINISTRATION

Prior to initiating AVEED®, confirm the diagnosis of hypogonadism by ensuring that serum testosterone concentrations have been measured in the morning on at least two separate days and that these serum testosterone concentrations are below the normal range.[3]

94%
OF MEN MAINTAINED NORMAL LEVELS FOR 10 FULL WEEKS[3]

During the third dosing interval, **94%** of men maintained average testosterone levels within the normal range for the **full 10 weeks**.[3†]

†Normal range was defined as 300-1000 ng/dL.

Over the full 10 weeks at steady state[3]:

- **5.1%** of patients had a C_{avg} <300 ng/dL
- **0.9%** of patients had a C_{avg} >1000 ng/dL

IMPORTANT SAFETY INFORMATION about AVEED® (CONT)

WARNINGS AND PRECAUTIONS

- **Serious Pulmonary Oil Microembolism (POME) Reactions and Anaphylaxis**
  Serious POME reactions, involving cough, urge to cough, dyspnea, hyperhidrosis, throat tightening, chest pain, dizziness, and syncope, have been reported to occur during or immediately after the injection of intramuscular testosterone undecanoate 1000 mg (4 mL). The majority of these events lasted a few minutes and resolved with supportive measures; however, some lasted up to several hours and some required emergency care and/or hospitalization. To minimize the risk of intravascular injection of AVEED®, care should be taken to inject the preparation deeply into the gluteal muscle, being sure to follow the recommended procedure for intramuscular administration.

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

Adverse Reactions in the 84-Week US Clinical Trial*

Adverse reactions reported in at least 1% of patients in the 84-week clinical study of AVEED® (N=153)[3]

Adverse reaction	Number of patients (%)	Adverse reaction	Number of patients (%)
Acne	8 (5.2)	Mood swings	3 (2.0)
Injection site pain	7 (4.6)	Aggression	2 (1.3)
Prostate specific antigen (PSA) increased†	7 (4.6)	Ejaculation disorder	2 (1.3)
Estradiol increased	4 (2.6)	Injection site erythema	2 (1.3)
Hypogonadism	4 (2.6)	Hematocrit increased	2 (1.3)
Fatigue	3 (2.0)	Hyperhidrosis	2 (1.3)
Irritability	3 (2.0)	Prostate cancer	2 (1.3)
Hemoglobin increased	3 (2.0)	Prostate induration	2 (1.3)
Insomnia	3 (2.0)	Weight increased	2 (1.3)

*AVEED® was evaluated in a single-arm, open-label, 84-week clinical study using 750 mg (3 mL) at initiation, at 4 weeks, and every 10 weeks thereafter in 153 hypogonadal men.

†***Prostate specific antigen increased*** defined as a serum PSA concentration >4 ng/mL.

Among 3,556 patients in worldwide clinical trials[3‡]

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

‡Patients treated with intramuscular testosterone undecanoate.

Pulmonary oil microembolism and anaphylaxis[3]

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In addition to serious POME reactions, episodes of anaphylaxis, including life-threatening reactions, have also been reported to occur following the injection of intramuscular testosterone undecanoate.

IMPORTANT SAFETY INFORMATION about AVEED® (CONT)

WARNINGS AND PRECAUTIONS (CONT)

In addition to serious POME reactions, episodes of anaphylaxis, including life-threatening reactions, have also been reported to occur following the injection of intramuscular testosterone undecanoate.

Both serious POME reactions and anaphylaxis can occur after any injection of testosterone undecanoate during the course of therapy, including after the first dose. Patients with suspected hypersensitivity reactions to AVEED® should not be re-treated with AVEED®.

Following each injection of AVEED®, observe patients in the healthcare setting for 30 minutes in order to provide appropriate medical treatment in the event of serious POME reactions and anaphylaxis.

Support as You Prescribe AVEED®

Start by enrolling in the AVEED® REMS Program

AVEED® is available only through a restricted program called the AVEED® REMS Program because of the risk of serious POME and anaphylaxis.

Further information is available at
www.AveedREMS.com *or*
by calling 1-855-755-0494

Writing a Prescription for AVEED®

Rx

Initial Prescription:

AVEED® 750mg/3mL

Dispense Qty:

4 vials up to 180 days supply with NR

SIGNATURE _____

Inject 750mg IM on day 1, followed by a second injection 4 weeks later. Subsequent injections are given every 10 weeks thereafter.[3]

Rx

Maintenance Prescription:

AVEED® 750mg/3mL

Dispense Qty:

1 vial, with 2 refills

SIGNATURE _____

Inject 750mg IM every 10 weeks.[3]

In-office storage

- No refrigeration required[3]
- 60-month shelf life[6]

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

myAVEED Access and Reimbursement Support

The my**AVEED** hotline provides assistance with benefits verification and information about prior authorization and reimbursement, all by calling 1-855-my**AVEED** (692-8333).

2 convenient ways to order AVEED®:

- Via Specialty Pharmacy with processing by my**AVEED**
- Buy-and-Bill method through a specialty distributor

J Code	
J3145	AVEED® Injection, testosterone undecanoate, 1 mg
CPT Code (Intramuscular Injection of AVEED®)	
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
Diagnosis Code (ICD-10-CM)	
E 29.1	Testicular dysfunction (other testicular hypofunction)—includes testicular hypogonadism
National Drug Code (NDC)	
67979-511-43 (10-digit)	AVEED® 750 mg/3 mL (250 mg/mL)
67979-0511-43 (11-digit)	

The 11-digit billing format is an electronic transaction standard required by many health plans that require NDC codes for billing. Check with the health plan for the requirements specific to your patient.

NOTE: Coding is part of the clinical decision. Please use codes that most accurately reflect the procedures performed. Suggestions by Endo Pharmaceuticals Inc. do not guarantee reimbursement or take the place of professional coding advice.

Download the Buy-and-Bill and Specialty Pharmacy Benefits Investigation Form and patient rebate forms at

AveedUSA.com.

my**AVEED**, managed by Endo Advantage™

IMPORTANT SAFETY INFORMATION about AVEED® (CONT)

WARNINGS AND PRECAUTIONS (CONT)

- **AVEED® Risk Evaluation and Mitigation Strategy (REMS) Program**
  AVEED® is available only through a restricted program called the AVEED® REMS Program because of the risk of serious POME and anaphylaxis.
  Notable requirements of the AVEED® REMS Program include the following:
  - Healthcare providers who prescribe AVEED® must be certified with the REMS Program before ordering or dispensing AVEED®.
  - Healthcare settings must be certified with the REMS Program and have healthcare providers who are certified before ordering or dispensing AVEED®. Healthcare settings must have on-site access to equipment and personnel trained to manage serious POME and anaphylaxis.

  Further information is available at www.AveedREMS.com or call 1-855-755-0494.
- **Worsening of Benign Prostatic Hyperplasia (BPH) and Potential Risk of Prostate Cancer -** Patients with BPH treated with androgens are at an increased risk of worsening of signs and symptoms of BPH. Monitor patients with BPH for worsening signs and symptoms. Patients treated with androgens may be at an increased risk for prostate cancer. Evaluate patients for prostate cancer prior to initiating and during treatment with androgens.

INDICATIONS AND USAGE

AVEED® (testosterone undecanoate) is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.

- Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
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Limitations of use:

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IMPORTANT SAFETY INFORMATION about AVEED®

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- **Following each injection of AVEED®, observe patients in the healthcare setting for 30 minutes in order to provide appropriate medical treatment in the event of serious POME reactions or anaphylaxis.**
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CONTRAINDICATIONS

- Men with carcinoma of the breast or known or suspected carcinoma of the prostate.
- Women who are pregnant. Testosterone can cause virilization of the female fetus when administered to a pregnant woman.
- Men with known hypersensitivity to AVEED® or any of its ingredients (testosterone undecanoate, refined castor oil, benzyl benzoate).

WARNINGS AND PRECAUTIONS

- **Serious Pulmonary Oil Microembolism (POME) Reactions and Anaphylaxis**
  Serious POME reactions, involving cough, urge to cough, dyspnea, hyperhidrosis, throat tightening, chest pain, dizziness, and syncope, have been reported to occur during or immediately after the injection of intramuscular testosterone undecanoate 1000 mg (4 mL). The majority of these events lasted a few minutes and resolved with supportive measures; however, some lasted up to several hours and some required emergency care and/or hospitalization. To minimize the risk of intravascular injection of AVEED®, care should be taken to inject the preparation deeply into the gluteal muscle, being sure to follow the recommended procedure for intramuscular administration.
  In addition to serious POME reactions, episodes of anaphylaxis, including life-threatening reactions, have also been reported to occur following the injection of intramuscular testosterone undecanoate.
  Both serious POME reactions and anaphylaxis can occur after any injection of testosterone undecanoate during the course of therapy, including after the first dose. Patients with suspected hypersensitivity reactions to AVEED® should not be re-treated with AVEED®.
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Continued on next page.

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

IMPORTANT SAFETY INFORMATION about AVEED® (CONT)

- **Worsening of Benign Prostatic Hyperplasia (BPH) and Potential Risk of Prostate Cancer -** Patients with BPH treated with androgens are at an increased risk of worsening of signs and symptoms of BPH. Monitor patients with BPH for worsening signs and symptoms. Patients treated with androgens may be at an increased risk for prostate cancer. Evaluate patients for prostate cancer prior to initiating and during treatment with androgens.
- **Polycythemia -** Increases in hematocrit, reflective of increases in red blood cell mass, may require discontinuation of testosterone. Check hematocrit prior to initiating testosterone treatment. It would be appropriate to re-evaluate the hematocrit 3 to 6 months after starting testosterone treatment, and then annually. If hematocrit becomes elevated, stop therapy until hematocrit decreases to an acceptable level. An increase in red blood cell mass may increase the risk of thromboembolic events.
- **Venous Thromboembolism (VTE) -** There have been postmarketing reports of venous thromboembolic events, including deep vein thrombosis (DVT) and pulmonary embolism (PE), in patients using testosterone products, such as AVEED®. Evaluate patients who report symptoms of pain, edema, warmth and erythema in the lower extremity for DVT and those who present with acute shortness of breath for PE. If a venous thromboembolic event is suspected, discontinue treatment with AVEED® and initiate appropriate workup and management.
- **Cardiovascular Risk -** Some postmarketing studies have shown an increased risk of major adverse cardiovascular events (MACE) with use of testosterone replacement therapy. Patients should be informed of this possible risk when deciding to use or to continue to use AVEED®.
- **Abuse of Testosterone and Monitoring of Serum Testosterone Concentrations -** Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication and in combination with other anabolic steroids. Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions. If testosterone abuse is suspected, check serum testosterone concentrations to ensure that they are within therapeutic range. However, testosterone levels may be in the normal or subnormal range in men abusing synthetic testosterone derivatives. Counsel patients concerning the serious adverse reactions associated with abuse of testosterone and anabolic androgenic steroids. Conversely, consider the possibility of testosterone and androgenic steroid abuse in suspected patients who present with serious cardiovascular or psychiatric adverse events.
- **Use in Women -** Due to lack of controlled evaluations in women and potential virilizing effects, AVEED® is not indicated for use in women.
- **Potential for Adverse Effects on Spermatogenesis -** With large doses of exogenous androgens, including AVEED®, spermatogenesis may be suppressed through feedback inhibition of pituitary follicle-stimulating hormone (FSH) which could possibly lead to adverse effects on semen parameters including sperm count.
- **Hepatic Adverse Effects -** Prolonged use of high doses of orally active 17-alpha-alkyl androgens (e.g., methyltestosterone) has been associated with serious hepatic adverse effects (peliosis hepatis, hepatic neoplasms, cholestatic hepatitis, and jaundice). Peliosis hepatis can be a life-threatening or fatal complication. Long-term therapy with intramuscular testosterone enanthate, which elevates blood levels for prolonged periods, has produced multiple hepatic adenomas. AVEED® is not known to produce these adverse effects. Nonetheless, patients should be instructed to report any signs or symptoms of hepatic dysfunction (e.g., jaundice). If these occur, promptly discontinue AVEED® while the cause is evaluated.
- **Edema -** Androgens, including AVEED®, may promote retention of sodium and water. Edema with or without congestive heart failure may be a serious complication in patients with preexisting cardiac, renal, or hepatic disease. In addition to discontinuation of the drug, diuretic therapy may be required.
- **Gynecomastia -** Gynecomastia occasionally develops and occasionally persists in patients being treated for hypogonadism.
- **Sleep Apnea -** The treatment of hypogonadal men with testosterone products may potentiate sleep apnea in some patients, especially those with risk factors such as obesity or chronic lung diseases.
- **Lipids -** Changes in serum lipid profile may require dose adjustment of lipid lowering drugs or discontinuation of testosterone therapy.
- **Hypercalcemia -** Androgens, including AVEED®, should be used with caution in cancer patients at risk of hypercalcemia (and associated hypercalciuria). Regular monitoring of serum calcium concentrations is recommended in these patients.
- **Decreased Thyroxine-binding Globulin -** Androgens, including AVEED®, may decrease concentrations of thyroxine-binding globulin, resulting in decreased total T4 serum concentrations and increased resin uptake of T3 and T4. Free thyroid hormone concentrations remain unchanged, however, and there is no clinical evidence of thyroid dysfunction.
- **Laboratory Monitoring -** Monitor prostatic specific antigen (PSA), hemoglobin, hematocrit, and lipid concentrations at the start of treatment and periodically thereafter.

ADVERSE REACTIONS

AVEED® was evaluated in an 84-week clinical study using a dose regimen of 750 mg (3 mL) at initiation, at 4 weeks, and every 10 weeks thereafter in 153 hypogonadal men. The most commonly reported adverse reactions (≥2%) were: acne, injection site pain, prostate specific antigen increased, hypogonadism, estradiol increased, fatigue, irritability, hemoglobin increased, insomnia, and mood swings.

In the 84-week clinical trial, 7 patients (4.6%) discontinued treatment because of adverse reactions. Adverse reactions leading to discontinuation included: hematocrit increased, estradiol increased, prostatic specific antigen increased, prostate cancer, mood swings, prostatic dysplasia, acne, and deep vein thrombosis.

- **Postmarketing Experience**
  Pulmonary Oil Microembolism (POME) and Anaphylaxis
  Serious pulmonary oil microembolism (POME) reactions, involving cough, urge to cough, dyspnea, hyperhidrosis, throat tightening, chest pain, dizziness, and syncope, have been reported to occur during or immediately after the injection of intramuscular testosterone undecanoate 1000 mg (4 mL) in post-approval use outside the United States.

  In addition to serious POME reactions, episodes of anaphylaxis, including life-threatening reactions, have also been reported to occur following the injection of intramuscular testosterone undecanoate in post-approval use outside of the United States.

DRUG INTERACTIONS

- **Insulin -** Changes in insulin sensitivity or glycemic control may occur in patients treated with androgens. In diabetic patients, the metabolic effects of androgens may decrease blood glucose and, therefore, may necessitate a decrease in the dose of anti-diabetic medication.
- **Oral Anticoagulants -** Changes in anticoagulant activity may be seen with androgens, therefore, more frequent monitoring of international normalized ratio (INR) and prothrombin time are recommended in patients taking warfarin, especially at the initiation and termination of androgen therapy.
- **Corticosteroids -** The concurrent use of testosterone with corticosteroids may result in increased fluid retention and requires careful monitoring, particularly in patients with cardiac, renal or hepatic disease.

USE IN SPECIFIC POPULATIONS

- **Geriatric Use -** There have not been sufficient numbers of geriatric patients in controlled clinical studies with AVEED® 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.
- **Infertility -** Spermatogenesis may be suppressed and reduced fertility is observed in some men taking testosterone replacement therapy.

DRUG ABUSE AND DEPENDENCE

AVEED® contains testosterone undecanoate, a Schedule III controlled substance in the Controlled Substances Act.

- Abuse and misuse of testosterone are seen in male and female adults and adolescents. Testosterone, often in combination with other anabolic androgenic steroids, may be abused by athletes and bodybuilders.
- Serious adverse reactions have been reported in individuals who abuse anabolic androgenic steroids, and include cardiac arrest, myocardial infarction, hypertrophic cardiomyopathy, congestive heart failure, cerebrovascular accident, hepatotoxicity, and serious psychiatric manifestations, including major depression, mania, paranoia, psychosis, delusions, hallucinations, hostility, and aggression.
- The following adverse reactions have been reported in men: transient ischemic attacks, convulsions, hypomania, irritability, dyslipidemia, testicular atrophy, subfertility, and infertility.
- The following adverse reactions have been reported in women: hirsutism, virilization, deepening of voice, clitoral enlargement, breast atrophy, male pattern baldness, and menstrual irregularities.
- The following adverse reactions have been reported in male and female adolescents: premature closure of bony epiphyses with termination of growth, and precocious puberty.
- Withdrawal symptoms can be experienced upon abrupt discontinuation in patients with addiction. Withdrawal symptoms include depressed mood, major depression, fatigue, craving, restlessness, irritability, anorexia, insomnia, decreased libido, and hypogonadotropic hypogonadism. Drug dependence in individuals using approved doses for approved indications have not been documented.

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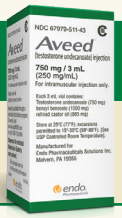
AVEED®
(testosterone undecanoate) injection CIII
750 mg/3 mL

Extended Release Over 10 Weeks



- After establishing steady state*, mean testosterone levels remained within the normal range[3†]

Proven Efficacy

- 94% of men maintained average testosterone levels within the normal range[3†]
- 5.1% of patients had a C_{avg} <300 ng/dL, and 0.9% of patients had a C_{avg} >1000 ng/dL[3]

Controlled In-office Administration

- Healthcare professional control of treatment administration[3]
- Avoids the risk of transference

*After third injection.
†During the third dosing interval; normal range was 300-1000 ng/dL.

INDICATIONS AND USAGE

AVEED® (testosterone undecanoate) is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.

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- **Because of the risks of serious POME reactions and anaphylaxis, AVEED® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the AVEED® REMS Program.**

Please see Important Safety Information throughout. Please see accompanying full Prescribing Information, including Boxed Warning.

References: 1. US Food and Drug Administration. Approved Drug Products with Therapeutic Equivalence Evaluations. 40th ed. https://www.fda.gov/media/71474/download. Accessed March 9, 2020. **2.** Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and management of testosterone deficiency (2018): AUA Guideline. American Urological Association website. https://www.auanet.org/guidelines/testosterone-deficiency-guideline. Accessed March 9, 2020. **3.** AVEED® (Prescribing Information). Malvern, PA: Endo Pharmaceuticals Inc. **4.** Wang C, Harnett M, Dobs AS, Swerdloff RS. Pharmacokinetics and safety of long-acting testosterone undecanoate injections in hypogonadal men: an 84-week phase III clinical trial. *J Androl*. 2010;31(5):457-465. **5.** Data on file. DOF-AV-01. Endo Pharmaceuticals Inc.; 2014. **6.** Data on file. DOF-AV-05. Endo Pharmaceuticals Inc.; 2018.

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