INDICATIONS AND USAGE
AVEED® 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 continued on next page.
Please click here for full Prescribing Information, including Boxed Warning.
Instructions for Completing the Specialty Pharmacy section of the Benefits Investigation Form

✓ Complete the entire Benefits Investigation Form and fax it to 1-877-488-6701
✓ myAVEED, managed by Endo Advantage™, will provide you with a summary of the patient’s medical health plan and prescription pharmacy drug benefits and the payor-designated specialty pharmacy contact information

PLEASE NOTE: Upon receipt of the benefits results, fax the AVEED® prescription and the Benefits Investigation Form to the designated Specialty Pharmacy associated with the patient’s insurance plan

Fax the form to 1-877-488-6701.

Upon receipt of the benefits results, fax this form to the designated Specialty Pharmacy associated with the patient’s insurance plan.

IMPORTANT SAFETY INFORMATION about AVEED® (CONT)

CONTRAINDICATIONS

- Men with carcinoma of the breast or known or suspected carcinoma of the prostate.
- Women who are or may become pregnant, or who are breastfeeding. Testosterone can cause fetal harm when administered to a pregnant woman. AVEED® may cause serious adverse reactions in nursing infants. Exposure of a fetus or nursing infant to androgens may result in varying degrees of virilization.
- Men with known hypersensitivity to AVEED® or any of its ingredients (testosterone undecanoate, refined castor oil, benzyl benzoate).

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IMPORTANT SAFETY INFORMATION about AVEED®

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• 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.

CONTRAINDICATIONS

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• 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®.

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.

Please see Important Safety Information continued on next page.
Please click here for full Prescribing Information, including Boxed Warning.
Some postmarketing studies have shown an increased risk of major adverse cardiovascular events (MACE) with use of testosterone replacement therapy. 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.

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.

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.

Hypogonadal men with testosterone products may potentiate sleep apnea in some patients, especially those with risk factors such as obesity, chronic lung diseases, and increased resin uptake of T3 and T4. Free thyroid hormone concentrations remain unchanged, however, and there is no clinical evidence of thyroid dysfunction.

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.

Please see Important Safety Information continued on next page.

Please click here for full Prescribing Information, including Boxed Warning.
IMPORTANT SAFETY INFORMATION about AVEED® (CONT)

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.

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.

Please click here for full Prescribing Information, including Boxed Warning.