**Facts About AVEED™ (testosterone undecanoate) Injection**

**Indication and Usage**
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, including primary hypogonadism (congenital or acquired) and hypogonadotropic 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 pulmonary oil microembolism and severe allergic reaction (anaphylaxis).

**Dosing**
AVEED is available as a single-use vial. Dosage titration is not necessary. Following the first intramuscular injection of 3 mL of AVEED (750 mg), a second 3 mL dose is injected 4 weeks later, and then 3 mL is injected every 10 weeks thereafter.

**Administration**
AVEED is administered as an injection by a trained healthcare professional in a doctor’s office, clinic, or hospital.

**Clinical Development**
AVEED contains testosterone undecanoate, which Endo licensed through its subsidiary Endo Pharmaceuticals Solutions Inc. from Bayer Pharma AG. Outside the U.S., Bayer Pharma AG and its subsidiaries have been marketing testosterone undecanoate injections since 2003. Additional safety data for testosterone undecanoate injections are available from 18 clinical trials conducted worldwide in 3,556 subjects treated outside the U.S.

**Indications and Important Safety Information**

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
What is AVEED?
AVEED is a prescription medicine that contains testosterone. AVEED is used to treat adult males who have low or no testosterone and conditions associated with low or no testosterone.

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.

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 or may become pregnant or are breastfeeding. AVEED may harm your unborn or breastfeeding baby.
- are allergic to AVEED or to any of the ingredients in AVEED. See the active and inactive ingredients at the end 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 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.
- 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).
- blood clots in the legs. This can include pain, swelling or redness of your legs.

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

This Important Safety Information 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.

The active ingredient is testosterone undecanoate.
The inactive ingredients are benzyl benzoate, refined castor oil.

**Please see full Prescribing Information, including Boxed Warning**