

MEDICATION GUIDE
XYOSTED™ (ZYE-oh-sted)
(testosterone enanthate) injection, for subcutaneous use CIII

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

- XYOSTED can increase your blood pressure, which can increase your risk of having a heart attack or stroke and can increase your risk of death due to a heart attack or stroke. Your risk may be greater if you already have heart disease or have had a heart attack or stroke.
- If your blood pressure increases while you are on XYOSTED, blood pressure medicines may need to be started. If you are already taking blood pressure medicines, new blood pressure medicines may need to be added or your current blood pressure medicines may need to be changed to control your blood pressure.
- If your blood pressure cannot be controlled, XYOSTED may need to be stopped.
- Your healthcare provider will monitor your blood pressure while you are being treated with XYOSTED.

What is XYOSTED?

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

It is not known if XYOSTED is safe and effective in children younger than 18 years old. Improper use of XYOSTED may affect bone growth in children.

XYOSTED is a controlled substance (CIII) because it contains testosterone that can be a target for people who abuse prescription medicines. Keep your XYOSTED in a safe place to protect it. Never give your XYOSTED to anyone else, even if they have the same symptoms you have. Selling or giving away this medicine may harm others and it is against the law.

XYOSTED is not meant for use by women.

Do not take XYOSTED if you:

- are a man who has breast cancer.
- have or might have prostate cancer.
- are a woman who is pregnant. XYOSTED may harm your unborn baby.
- are allergic to XYOSTED or to any ingredients in XYOSTED including testosterone or sesame oil.
- have low testosterone without certain medical conditions. For example, do not take XYOSTED if you have low testosterone due to age.

Before you use XYOSTED, tell your healthcare provider about all your medical conditions, including, if you:

- have high blood pressure or heart problems.
- have high red blood cell count (hematocrit) or high hemoglobin laboratory value.
- have urinary problems due to an enlarged prostate.
- have kidney or liver problems.
- have a history of mental health illness including suicidal thoughts or actions, depression, anxiety or mood disorder.
- have problems breathing while you sleep (sleep apnea).

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Using XYOSTED with other medicines can affect each other. Especially, tell your healthcare provider if you take:

- insulin
- medicines that decrease blood clotting (blood thinners)
- corticosteroids
- medicines for pain and cold.

Know the medicines you take. Ask your healthcare provider or pharmacist for a list of all your medicines if you are not sure. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I use XYOSTED?

- **See the detailed Instructions for Use for information about how to use XYOSTED.**
- Use XYOSTED exactly as your healthcare provider tells you to take it.
- Your healthcare provider will show you or your caregiver how to inject XYOSTED. You should not inject XYOSTED until you have been trained on the proper way to use it.

What are the possible side effects of XYOSTED?

XYOSTED can cause serious side effects including:

- See “**What is the most important information I should know about XYOSTED?**”
- **Increase in blood pressure.**
 - XYOSTED can increase your blood pressure, which can increase your risk of having a heart attack or stroke and can increase your risk of death due to heart attack or stroke. Your risk may be greater if you already have heart disease or if you have had a heart attack or stroke.
 - You may need to start new medicines or have medicines changed for high blood pressure while on XYOSTED.

- Your healthcare provider should check your blood pressure while you use XYOSTED.
- **Increase in red blood cell count (hematocrit) or hemoglobin.**
 - XYOSTED increases red blood cell counts in some patients. High red blood cell counts increase the risk of clots, strokes, and heart attacks.
 - You may need to stop XYOSTED if your red blood cell count increases.
 - Your healthcare provider should check your red blood cell count and hemoglobin while you use XYOSTED.
- **If you already have an enlarged prostate, your signs and symptoms may get worse while using XYOSTED. 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
- **Increased risk of prostate cancer.** Your healthcare provider should check you for prostate cancer or any other prostate problems before you start and while you use XYOSTED.
- **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.
- **Abuse.** Testosterone can be abused, when taken at higher than prescribed doses and when used with other anabolic androgenic steroids. Abuse can cause serious heart and psychological side effects. Your healthcare provider should check you for signs of abuse before and during treatment with XYOSTED.
- **In large doses XYOSTED 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.**
- **Enlarged or painful breasts.**
- **Problems breathing while you sleep (sleep apnea).**
- **Change in mood.** Talk to your healthcare provide if you have changes in mood or behavior including, new or worsening depression, or suicidal thoughts.

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

The most common side effects of XYOSTED include:

- red blood cell count increase
- prostatic specific antigen (PSA) increase (a test used to screen for prostate cancer)
- high blood pressure
- injection site reactions including:
 - bruising
 - bleeding
 - redness
 - hardness

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

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

These are not all the possible side effects of XYOSTED. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store XYOSTED?

Do not refrigerate or freeze. Use at room temperature.

Store at controlled room temperature, 68°F to 77°F (20°C to 25°C). Protect from light (keep in carton until time of use).

Keep XYOSTED and all medicines out of the reach of children.

General information about the safe and effective use of XYOSTED.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use XYOSTED for a condition for which it was not prescribed. Do not give XYOSTED to other people, even they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about XYOSTED that is written for health professionals.

What are the ingredients in XYOSTED?

Active ingredient: testosterone enanthate

Inactive ingredients: sesame oil

Manufactured by:

Antares Pharma, Inc. Ewing, NJ 08628 XYOSTED is a trademark of Antares Pharma, Inc. ©2018 Antares Pharma, Inc. All rights reserved

For more information, go to www.XYOSTED.com or call 1-844-XYOSTED (1-844-996-7833)

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

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