

Xyosted (testosterone)

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 for use in children younger than 18 years old. Improper use of XYOSTED may effect 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. 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 use 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 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.

What should I tell my healthcare provider before using XYOSTED?

Before you use XYOSTED, tell your healthcare provider about all of your medical conditions, including, if you any of the following: high blood pressure or heart problems, high red blood cell count, urinary problems due to an enlarged prostate, kidney or liver problems, a history of mental health illness including suicidal thoughts or actions, depression, anxiety or mood disorder, or problems breathing while you sleep (sleep apnea).

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Tell your healthcare provider about all the medicines you take, including prescription and nonprescription 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 or medicines for pain and cold. Know the medicines you take. Ask your pharmacist for a list of all your medicines if you are not sure. Show your list 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?” above.**
- **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 have already had a heart attack or stroke or if you have other risk factors for heart attack or stroke.
- **Increase in red blood cell count, hematocrit or hemoglobin.** 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, hematocrit and hemoglobin while you use XYOSTED.
- **Cardiovascular Risk.** Possible Increase risk of heart attack, death, or stroke.
- **If you already have an enlarged prostate, your signs and symptoms may get worse while using XYOSTED. This can include:** increased nighttime urination, trouble starting urination, more frequent urination,

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feeling an urge to urinate, having a urine accident, and 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.
- **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 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.**
- **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 increase, prostatic specific antigen (PSA) increase (a blood test for prostate cancer), increased blood pressure, and injection site reactions including bruising, bleeding, redness and headache.

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.

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