

MEDICATION GUIDE
JATENZO® (juh-TEN-zoh)

(testosterone undecanoate) capsules, for oral use CIII

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

JATENZO can cause serious side effects, including:

- JATENZO 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 have already had a heart attack or stroke or if you have other risk factors for heart attack or stroke.
- If your blood pressure increases while on JATENZO, blood pressure medicines may need to be started. If you are 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, JATENZO may need to be stopped.
- Your healthcare provider will monitor your blood pressure while you are being treated with JATENZO.

What is JATENZO?

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

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

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

JATENZO is not meant for use by women.

Do not take JATENZO if you:

- have breast cancer.
- have or might have prostate cancer.
- are a woman who is pregnant. JATENZO may harm your unborn baby.
- are allergic to JATENZO or any ingredients in JATENZO. See the end of this Medication Guide for a complete list of ingredients in JATENZO.
- have low testosterone without certain medical conditions. For example, do not take JATENZO if you have low testosterone due to age.

Before you take JATENZO, tell your healthcare provider about all of your medical conditions, including if you:

- have high blood pressure or are treated for high blood pressure.
- have heart problems.
- have high red blood cell count (hematocrit) or high hemoglobin laboratory value.
- have urinary problems due to an enlarged prostate.
- have liver or kidney 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 over-the-counter medicines, vitamins, and herbal supplements.

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

- insulin

- medicines that decrease blood clotting (blood thinners)
 - corticosteroids.
 - medicines that increase blood pressure such as some cold medicines and pain medicines.
- Know the medicines you take. Ask your healthcare provider or pharmacist for a list of these 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 take JATENZO?

- Take JATENZO exactly as your healthcare provider tells you take it.
- Take JATENZO by mouth two times daily. Take 1 time in the morning and take 1 time in the evening.
- Take JATENZO with food.
- Your healthcare provider may change your JATENZO dose. Do not change your JATENZO dose without talking to your healthcare provider.

What are the possible side effects of JATENZO?

JATENZO may cause serious side effects including:

- See **“What is the most important information I should know about JATENZO?”**
- **Increase in blood pressure.**
 - JATENZO 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 JATENZO.
 - Your healthcare provider should check your blood pressure while you use JATENZO.
- **Increase in red blood cell count (hematocrit) or hemoglobin.**
 - JATENZO increases red blood cell counts in some patients. High red blood cell counts increase the risk of blood clots, strokes, and heart attacks.
 - You may need to stop JATENZO if your red blood cell count increases.
 - Your healthcare provider should check your red blood cell count and hemoglobin while you use JATENZO.
- **If you already have an enlarged prostate, your signs and symptoms may worsen while using JATENZO.**

These may include:

 - increased urination at night
 - trouble starting your urine stream
 - urinating many times during the day
 - urge to go to the bathroom right away
 - a urine accident
 - inability 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 JATENZO.
- **Blood clots in the legs or lungs.** Signs and symptoms of a blood clot in your leg can include 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 JATENZO.
- **In large doses JATENZO 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 (edema), with or without heart failure.**

- **Enlarged or painful breasts.**
- **Breathing problems while you sleep (sleep apnea).**
- **Changes in mood.** Talk to your healthcare provider 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 JATENZO include:

- increased red blood cell count
- burping
- enlarged prostate gland
- diarrhea
- foot, leg and ankle swelling
- high blood pressure
- heart burn
- nausea
- 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. These are not all the possible side effects of JATENZO. 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 JATENZO?

- Store JATENZO at room temperature between 68°F to 77°F (20°C to 25°C).
- Store JATENZO in a dry place.

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

General information about the safe and effective use of JATENZO

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

What are the ingredients in JATENZO?

Active ingredient: testosterone undecanoate

Inactive ingredients: oleic acid, polyoxyl 40 hydrogenated castor oil (Cremophor RH 40), borage seed oil, peppermint oil, and butylated hydroxytoluene. The ingredients of the soft gelatin capsule shells are gelatin, sorbitol, glycerin, purified water, iron oxide red, FD&C Yellow #6, and titanium dioxide.

Distributed by:

Tolmar, Inc. Fort Collins, CO 80526

For more information, go to www.JATENZO.com or call 1-844-4TO-LMAR.

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

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