

TESTOSTERONE/L-ARGININE/SILDENAFIL COMPOUND

What is this medicine?

Testosterone (tes-TOS-ter-one)

- Testosterone is a sex hormone derived from yams and may be given to patients who no longer produce a sufficient amount on their own.
- Testosterone is an anabolic steroid and a controlled substance.

L-Arginine (L-ARE-gin-een)

- Arginine is an amino acid important for many biological processes.
- L-arginine may impact health conditions related to cardiovascular health, blood pressure, blood sugar, or exercise performance.

Sildenafil Citrate (Sil-DEN-uh-fil SIT rate)

- Sildenafil is a phosphodiesterase type 5 inhibitor.
- It may be used to increase smooth muscle relaxation and blood flow.

This combination may be used prior to intercourse for an augmented sexual response. These medications may also be used for other conditions as determined by your doctor.

Compounded Drug Forms: cream, gel

What should I tell my health care provider before I take this medicine?

- Allergy to testosterone, arginine, or sildenafil
- Have breast or prostate cancer
- Have heart disease, hypotension, kidney disease, or liver disease
- Current bleeding disorder or peptic ulcer disease
- Presence of hereditary degenerative retinal disorders
- Presence of pulmonary veno-occlusive disease
- Presence of QT prolongation
- Pregnant or may become pregnant; are breastfeeding
- Have depression, anxiety, or other mood disorder

How should I use this medicine?

Follow the package directions provided by Belmar Pharma Solutions and by your prescriber. Your dosage is based on your medical condition and response to therapy. Follow the dosing schedule provided carefully.

Topical products can be applied to the inner arm, upper thigh, back of the knee, tops of feet and inner wrists. It is recommended to rotate sites to ensure even retention of the hormone.

Cover treated skin with clothes to avoid contact with people or pets. Wash hands after applying the product. **Significant risk of secondary exposure to people in close contact, specifically children.**

Vaginal preparations should be inserted using your finger or the applicator provided.

What if I miss a dose?

- If you miss a dose, take it as soon as possible.
- If it is almost time for your next dose, skip the missed dose and continue with your regular dosing schedule.
- Do not take double the dose at once.

What should I watch for while using this medicine?

Belmar Pharma Solutions recommends yearly checkups with your provider including, but not limited to, a hormone level test, periodic liver and renal function tests, hemoglobin and hematocrit, and a lipid panel. Monitor heart rate and blood pressure regularly.

What side effects may I notice from receiving this medicine?

Possible side effects that may occur and may go away as your body gets used to the medication include:

- Headache
- Flushing
- Nausea, diarrhea, dyspepsia, or indigestion
- Palpitations
- Muscle pain
- Numbness
- Hypotension
- Changes in hair growth
- Respiratory tract infection or nasal symptoms
- Emotional instability
- Voice deepening
- Changes in taste
- Acne
- Irritation at the site of topical application
- Loss of strength and energy
- Trouble sleeping

Serious Side Effects:

Contact your doctor immediately or seek medical attention if you experience:

- Significant swings in blood pressure (high or low)
- Sudden hearing loss, which may be one-sided and accompanied by tinnitus and dizziness.
- Signs of a blood clot, like chest pain or pressure: coughing up blood, trouble speaking or swallowing, swelling, warmth, numbness, change of color, pain in leg or arm
- Shortness of breath or abnormal heartbeat
- One-sided weakness or difficulty speaking
- Signs of polycythemia/erythrocytosis (increase in hematocrit or hemoglobin)
- Signs of high calcium levels (e.g., weakness, confusion, feeling tired, headache, constipation, bone pain, vomiting, or upset stomach)
- Visual disturbances or sudden vision loss
- Severe headache, nausea, or vomiting
- Bleeding or bruising
- Passing urine more often or trouble passing urine
- Enlarged/painful breasts
- Menstrual changes
- Trouble breathing while sleeping
- Significant shifts in mood or behavior
- Signs of liver problems, such as dark urine, fatigue, decreased appetite, nausea, abdominal pain, light-colored stools, vomiting, or yellow skin
- Excessive weight gain
- Swelling in the arms or legs

You may experience side effects not listed. Contact your doctor with questions.

An allergic reaction to this medication is unlikely but seek medical attention if it occurs. Symptoms of an allergic reaction include rash, itching, swelling, severe dizziness, trouble breathing.

Contraindications

Hypersensitivity to any component of the formulation, breast cancer (in patients born male), known or suspected prostate cancer, pregnancy, serious cardiac, kidney or liver disease. Concomitant use with all forms of nitrates, whether regular or sporadic, due to exaggerated vasodilation risk that may result in an extreme drop in blood pressure.

Where should I keep my medicine?

Store at room temperature between 59 and 86 degrees F, unless otherwise specified on the packaging.

Additional Information:

- Do not share this medication with others.
- Keep out of reach of children and pets.
- **Significant risk of secondary exposure to people in close contact, specifically children.**
- If an overdose is suspected contact your local poison control center at 1-800-222-1222 or go to the nearest emergency room.

If you have any questions concerning this or any of your medications, a pharmacist is available during normal business hours to answer your questions. You may report side effects to the FDA at 1-800-FDA-1088.

Consumer Information Use and Disclaimer: This information should not be used to decide whether or not to take this medication or any other medication. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does not include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. For questions about the source of any of the information provided herein, pharmacists at Belmar Pharma Solutions are available. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of this medicine.

NIOSH Drug: Observe special handling and disposal requirements. Do not flush down a toilet or pour down a drain. Check with your pharmacist if you have questions about the best way to dispose of medications. There may be a drug take-back program in your area.

References:

1. L-Arginine Professional Monograph. Natural Medicines Comprehensive Database. Therapeutic Research Center, LLC. Stockton, CA. Available at: <https://naturalmedicines.therapeuticresearch.com>. Accessed August 2024.
2. Sildenafil Oral. Drug Facts and Comparisons. Facts and Comparisons eAnswers. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com>. Accessed August 2024.

3. Testosterone. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com>. Accessed August 2024.