

r 1274 Anna J Stepp Rd. Ypsilanti, MI 48197

855-GOO-BLUE (855-466-2583) Toll Free Phone 855-445-1119 Toll Free Fax info@valiantrx.com www.valiantrx.com

Testosterone/Anastrozole

Benefits

- Testosterone is used primarily to treat hypogonadism, also known as low testosterone, caused by certain medical conditions.
 - In general, testosterone is prescribed to maintain male features such as muscle strength and mass, improve libido and possibly sperm count.
- Anastrozole is primarily used to treat breast cancer in women. It suppresses estrogen production, so it can also be used to reduce female sex hormones in men.
 - When used in this combination, anastrozole can work with testosterone to boost male hormones while lowering female hormones.
 - Talk to your doctor to understand exactly why this drug was prescribed for you and what your expected outcomes should be.
- It is not known if testosterone is safe or effective to treat men who have low testosterone due to aging. Testosterone may not be safe for males under the age of 18.
- Time of onset and the length of time for complete improvement varies among individuals. Follow the recommendations of your prescriber.

Side Effects

- Possible side effects include changes in mood, increased blood pressure, arthritis, backache, headache, insomnia, cough, sore throat, nausea, vomiting, diarrhea, agitation, depression, acne, sustained and painful erection, changes in libido, abnormal hair growth to the face and/or body, voice changes and electrolyte retention.
- Report severe or unusual side effects to your doctor. Severe side effects include rash/ hives/itching, swelling of the face, throat, or neck; trouble breathing, chest pain, or tightness in chest or throat; increased cholesterol or blood clots (stroke or heart attack); decreased bone density; and breast cancer.
- Other side effects not listed above may occur in some patients. If you experience an adverse event, please tell your physician immediately and you may also report your experience to the FDA Med-Watch Program at 1-800-FDA-1088.

Administration

• Always follow the directions on your prescription label on how to take your medication.



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• Topical: clean and dry the designated area, then apply the recommended amount of medication to the area and rub in well for 2 minutes. After administration, wash your hands thoroughly to prevent transferring the medication onto others.

Additional Information/Warnings

Testosterone/Anastrozole can be transferred by skin-to-skin contact. Male doses of topical testosterone/anastrozole can cause negative side effects in women and children who contact skin after the medication has been applied. If exposed to testosterone children may develop aggressive behavior, enlarged genitals, and pubic hair. Women may develop unwanted hair growth or acne. Testosterone transfer is dangerous for pregnant women because it can cause birth defects. Anastrozole is especially dangerous to pregnant women because it can cause serious damage to an unborn child. Use extreme caution with this medication if you have contact with women who are pregnant or could be pregnant.

To prevent these problems, don't allow skin-to-skin contact of the treated area with other people. Keep the treated area covered with loose clothing until the medication is absorbed, about 4 hours. Hand washing does not remove all the drug residue. It is best to apply medication with disposable latex or latex free gloves.

- The FDA has published a warning to patients that testosterone may increase cardiovascular risks such as heart attack and stroke.
- Immediately report new or worsening chest pain or shortness of breath.
- While taking this medication, your cholesterol levels may rise, and your bone mineral density may lower. Speak with your physician to determine your risk of these side effects and the appropriate way to monitor them.
- If you miss a dose of this medication, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once and if you have any questions, contact your physician or pharmacist.
 - Before taking this medication, tell your healthcare provider about all the medicines, herbal supplements, vitamins, and over the counter medications that you are currently taking.



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- Continue to have routine follow-up within order to assess and monitor your medication with your disease state as recommended by your healthcare provider.
- Do not share medication with another person, even if they have the same symptoms you are experiencing.
- The information in this patient advisory leaflet is not intended to cover all possible uses, directions, precautions, drug interactions, or adverse effects. If you have questions about the medicines, you are taking or would like more information, check with your doctor or pharmacist.
- This compound medication is customized for the patient and is exclusively available with the prescription from a prescriber.
- Please refer to your receipt for a list of ingredients in your medication.

Storage

- Refer to the label on your prescription for refrigeration requirements (do not freeze).
 - If refrigeration is NOT required- store medication at room temperature in a cool, dry place. Do not store in the bathroom, a vehicle, or any other location with varying temperatures or humidity.
 - If refrigeration is required, store in the refrigerator out of reach of children.
- Compounded medications are not usually prepared in child resistant containers and should be kept away from children and pets. If you would like to have a lockable zip lock bag for your compounded medications, please call the pharmacy and ask the technician to include child resistant packaging with your refills.
- Unused medications left in the medicine cabinet can be a temptation for children and teenagers. Discard unused medications promptly. Do not flush drugs down the toilet or into the sink drain as they could be hazardous to the environment. Contact your local disposal company for more details about how to safely discard medications when they are expired or no longer needed. Big Red Barrel and Yellow Jug are national drug disposal programs. Visit <u>www.bigredbarrel.com</u>

Expiration of your prescription & Beyond Use Date of the medication

- Refer to the label for the expiration date of your prescription.
 - Your prescription expires in two ways:
 - You have used all the refills prescribed (maximum 5 for controlled substances like testosterone, which is schedule III).



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- The prescription has reached the expiration date of six months (because testosterone is controlled – non-controlled prescriptions expire after one year).
- Allow plenty of time to visit your doctor and for the pharmacist to compound your prescription renewal.
- Refer to the *discard date* or *beyond use date* on your bottle to learn when your medication should be discarded. Compounded medications have a shorter shelf life than those of manufactured drugs. The beyond use date is the longest date we can guarantee full potency of your medication.

Additional Information regarding hormone treatment

- Hormone therapies should be closely monitored. Inform your doctor if you change your medication protocol or add/discontinue over-the-counter products. Do not stop abruptly. Talk to your doctor about a gradual decrease in hormone treatments.
- Certain medical procedures may require you to stop using your medications a week or two prior to your procedure. To reduce the chance of unwanted side effects, discuss medication changes with your prescriber.
- If you have gained or lost more than twenty pounds, your hormone dose may need to be adjusted. Contact your prescriber.
- Hormone therapy medications can interact with other medications. If you started a new medication and are taking hormones, contact your prescriber to determine if there are any possible drug interactions.

Please contact Valiant Compounding Pharmacy at 734-545-1117 or toll free at 855-466-2583 with any questions, concerns, or for prescription refills.