



- Possible increased risk of heart attack or stroke.
- In large doses testosterone gel 1.62% may lower your sperm count.
- Swelling of your ankles, feet, or body, with or without heart failure.
- Enlarged or painful breasts.
- Have problems breathing while you sleep (sleep apnea).

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

The most common side effects of testosterone gel 1.62% include:

- increased prostate specific antigen (a test used to screen for prostate cancer)
- mood swings
- hypertension
- increased red blood cell count
- skin irritation where testosterone gel 1.62% is applied

**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 testosterone gel 1.62%. 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 testosterone gel 1.62%?**

- Store testosterone gel 1.62% at 59°F to 86°F (15°C to 30°C).
- When it is time to throw away the pump, safely throw away used testosterone gel 1.62% in household trash. Be careful to prevent accidental exposure of children or pets.
- Keep testosterone gel 1.62% away from fire.

**Keep testosterone gel 1.62% and all medicines out of the reach of children.**

**General information about the safe and effective use of testosterone gel 1.62%**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use testosterone gel 1.62% for a condition for which it was not prescribed. Do not give testosterone gel 1.62% to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about testosterone gel 1.62%. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about testosterone gel 1.62% that is written for health professionals.

For more information, contact Teva Pharmaceuticals USA, Inc. at 1-888-838-2872.

**What are the ingredients in testosterone gel 1.62%?**

**Active ingredient:** testosterone, USP

**Inactive ingredients:** carbomer homopolymer type C (carbopol 980), ethyl alcohol, isopropyl myristate, purified water and sodium hydroxide.

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

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The primary endpoint was the percentage of patients with  $C_{min}$  within the normal range of 300 ng/dL to 1000 ng/dL on Day 112. In patients treated with testosterone gel 1.62%, 81.6% (146/179) had  $C_{min}$  within the normal range at Day 112. The secondary endpoint was the percentage of patients, with  $C_{max}$  above three pre-determined limits. The percentages of patients with  $C_{max}$  greater than 1500 ng/dL, and between 1800 and 2499 ng/dL on Day 112 were 11.2% and 5.5%, respectively. Two patients had a  $C_{max}$  greater than 2500 ng/dL on Day 112 (2510 ng/dL and 2350 ng/dL, respectively); neither of these 2 patients demonstrated an abnormal  $C_{max}$  on prior or subsequent assessments at the same dose.

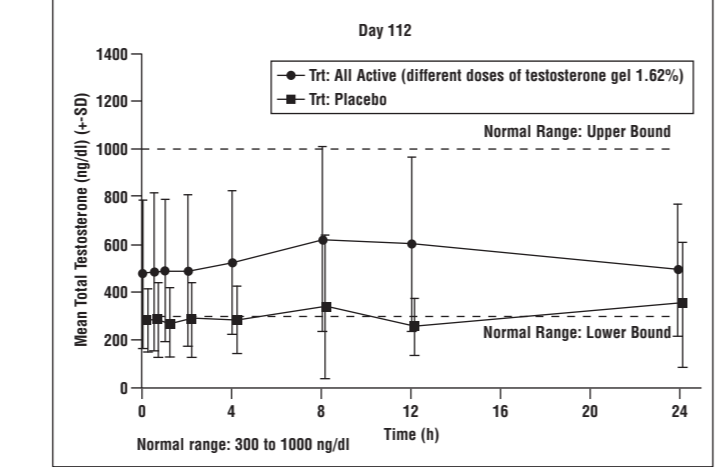
Patients could agree to continue in an open-label, active treatment maintenance period of the study for an additional 182 days.

Dose titrations on Days 14, 28, and 42 resulted in final doses of 20.25 mg to 81 mg on Day 112 as shown in Table 6.

**Table 6: Mean (SD) Testosterone Concentrations ( $C_{min}$  and  $C_{max}$ ) by final dose on Days 112 and 364**

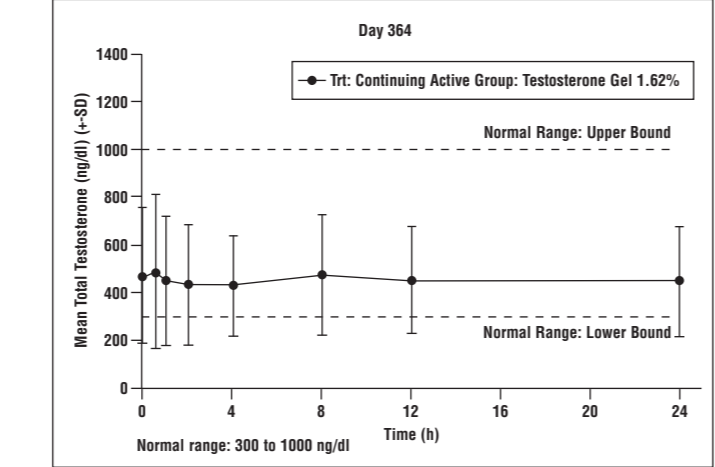
Parameter	Final Dose on Day 112					
	Placebo (n=27)	20.25 mg (n=12)	40.5 mg (n=34)	60.75 mg (n=54)	81 mg (n=79)	All Active (n=179)
$C_{min}$ (ng/dL)	303 (135)	457 (275)	524 (228)	643 (285)	537 (240)	561 (259)
$C_{max}$ (ng/dL)	450 (349)	663 (473)	738 (439)	958 (497)	813 (479)	845 (480)
	Final Dose on Day 364					
	20.25 mg (n=7)	40.5 mg (n=26)	60.75 mg (n=29)	81 mg (n=74)	Continuing Active (n=136)	
$C_{min}$ (ng/dL)	386 (130)	474 (176)	513 (222)	432 (186)	455 (192)	
$C_{max}$ (ng/dL)	562 (187)	715 (306)	839 (568)	649 (329)	697 (389)	

Figure 3 summarizes the pharmacokinetic profile of total testosterone in patients completing 112 days of testosterone gel 1.62% treatment administered as a starting dose of 40.5 mg of testosterone (2 pump actuations) for the initial 14 days followed by possible titration according to the follow-up testosterone measurements.



**Figure 3: Mean (±SD) Steady-State Serum Total Testosterone Concentrations on Day 112**

Efficacy was maintained in the group of men that received testosterone gel 1.62% for one full year. In that group, 78% (116/136) had average serum testosterone concentrations in the normal range at Day 364. Figure 4 summarizes the mean total testosterone profile for these patients on Day 364.



**Figure 4: Mean (±SD) Steady-State Serum Total Testosterone Concentrations on Day 364**

The mean estradiol and DHT concentration profiles paralleled the changes observed in testosterone. The levels of LH and FSH decreased with testosterone treatment. The decreases in levels of LH and FSH are consistent with reports published in the literature of long-term treatment with testosterone.

#### 16 HOW SUPPLIED/STORAGE AND HANDLING

Testosterone gel 1.62% is supplied in non-erosol, metered-dose pumps that deliver 20.25 mg of testosterone per complete pump actuation. The pumps are composed of plastic and stainless steel and an LDPE/aluminum foil inner liner encased in rigid plastic with a polypropylene cap. Each 88 g metered-dose pump is capable of dispensing 75 g of gel or 60-metered pump actuations; each pump actuation dispenses 1.25 g of gel.

NDC Number	Package Size
0591-2924-18	88 g pump (each pump dispenses 60 metered pump actuations with each pump actuation containing 20.25 mg of testosterone in 1.25 g of gel)

Store at controlled room temperature 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Used testosterone gel 1.62% pumps should be discarded in household trash in a manner that prevents accidental application or ingestion by children or pets.

#### 17 PATIENT COUNSELING INFORMATION

##### See FDA-Approved Medication Guide

Patients should be informed of the following:

#### 17.1 Use in Men with Known or Suspected Prostate or Breast Cancer

Men with known or suspected prostate or breast cancer should not use testosterone gel 1.62% [see *Contraindications (4) and Warnings and Precautions (5.1)*].

#### 17.2 Potential for Secondary Exposure to Testosterone and Steps to Prevent Secondary Exposure

Secondary exposure to testosterone in children and women can occur with the use of testosterone gel in men. Cases of secondary exposure to testosterone have been reported in children.

Physicians should advise patients of the reported signs and symptoms of secondary exposure, which may include the following:

- In children: unexpected sexual development including inappropriate enlargement of the penis or clitoris, premature development of pubic hair, increased erections, and aggressive behavior.
- In women: changes in hair distribution, increase in acne, or other signs of testosterone effects.
- The possibility of secondary exposure to testosterone gel should be brought to the attention of a healthcare provider.
- Testosterone gel 1.62% should be promptly discontinued until the cause of virilization is identified.

Strict adherence to the following precautions is advised to minimize the potential for secondary exposure to testosterone from testosterone gel 1.62% in men [see *Medication Guide*].

- **Children and women should avoid contact with unwashed or unclothed application site(s)** of men using testosterone gel 1.62%.

- Patients using testosterone gel 1.62% should apply the product as directed and strictly adhere to the following:

- **Wash hands** with soap and water immediately after application.
- **Cover the application site(s)** with clothing after the gel has dried.
- **Wash the application site(s)** thoroughly with soap and water prior to any situation where skin-to-skin contact of the application site with another person is anticipated.

- In the event that unwashed or unclothed skin to which testosterone gel 1.62% has been applied comes in contact with the skin of another person, the general area of contact on the other person should be washed with soap and water as soon as possible [see *Dosage and Administration (2.2), Warnings and Precautions (5.2) and Clinical Pharmacology (12.3)*].

#### 17.3 Potential Adverse Reactions with Androgens

Patients should be informed that treatment with androgens may lead to adverse reactions which include:

- Changes in urinary habits such as increased urination at night, trouble starting the urine stream, passing urine many times during the day, having an urge to go to the bathroom right away, having a urine accident, being unable to pass urine and weak urine flow.
- Breathing disturbances, including those associated with sleep, or excessive daytime sleeping.
- Too frequent or persistent erections of the penis.
- Nausea, vomiting, changes in skin color, or ankle swelling.

#### 17.4 Patients Should Be Advised of the Following Instructions for Use

- **Read the Medication Guide before starting testosterone gel 1.62% therapy and to reread it each time the prescription is renewed.**

- **Testosterone gel 1.62% should be applied and used appropriately to maximize the benefits and to minimize the risk of secondary exposure in children and women.**

- Keep testosterone gel 1.62% out of the reach of children.

- **Testosterone gel 1.62% is an alcohol based product and is flammable; therefore avoid fire, flame or smoking until the gel has dried.**

- It is important to adhere to all recommended monitoring.
- Report any changes in their state of health, such as changes in urinary habits, breathing, sleep, and mood.
- Testosterone gel 1.62% is prescribed to meet the patient's specific needs; therefore, the patient should never share testosterone gel 1.62% with anyone.
- Wait 2 hours before swimming or washing following application of testosterone gel 1.62%. This will ensure that the greatest amount of testosterone gel 1.62% is absorbed into their system.

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