

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use TESTOSTERONE GEL 1.62% safely and effectively. See full prescribing information for TESTOSTERONE GEL.
TESTOSTERONE GEL 1.62% for topical use CHL contains 20.25 mg testosterone. (3)
Packets containing 40.5 mg testosterone. (3)
WARNING: SECONDARY EXPOSURE TO TESTOSTERONE
See full prescribing information for complete boxed warning.
• **Virilization has been reported in children who were secondarily exposed to testosterone gel.** (5.1, 5.2)
• **Children should avoid contact with unwashed or unclothed application sites in men using testosterone gel.** (2.2, 5.2)
• **Healthcare providers should advise patients to strictly adhere to recommended instructions for use.** (2.2, 5.2, 17)

INDICATIONS AND USAGE
Testosterone gel 1.62% is indicated for replacement therapy in males for conditions associated with deficiency or absence of endogenous testosterone:
• Primary hypogonadism (congenital or acquired), (1)
• Hypogonadotropic hypogonadism (congenital or acquired), (1)
Limitations of use:
• Safety and efficacy of testosterone gel 1.62% in men with "age-related hypogonadism" have not been established. (1)
• Safety and efficacy of testosterone gel 1.62% in males less than 18 years old have not been established. (1, 8, 4)
• Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposures. (1, 12, 3)

DOSE AND ADMINISTRATION
• **Dosage and Administration for testosterone gel 1.62% differs from testosterone gel 1%. For dosage and administration of testosterone gel 1% refer to its full prescribing information.** (2)
• Prior to initiating testosterone gel 1.62%, confirm the diagnosis of hypogonadism by ensuring that serum testosterone has been measured in the morning on at least two separate days and that these concentrations are below the normal range (2).
• Starting dose of testosterone gel 1.62% is 40.5 mg of testosterone (2 pump actuations or a single 40.5 mg packet), applied topically once daily in the morning. (2.1)
• Apply to clean, dry, intact skin of the shoulders and upper arms. Do not apply to areas that may be in contact with other parts of the body including the abdomen, chest, armpits (axilla), or knees. (2.2, 2.3)
• Do not apply to areas that may be in contact with other parts of the body including the abdomen, chest, armpits (axilla), or knees. (2.2, 2.3)
• Dose adjustment based on clinical response. The dose should be titrated based on the pre-dose morning serum testosterone concentration at approximately 14 days and 28 days after starting testosterone gel 1.62%.

CONTRAINDICATIONS
• Men with carcinoma of the breast or known or suspected prostate cancer. (4, 5.1)
• Children who are pregnant. Testosterone may cause fetal harm. (5.1)
WARNINGS AND PRECAUTIONS
• Monitor patients with benign prostatic hyperplasia (BPH) for worsening of signs and symptoms of BPH. (5.1)
• Avoid unintentional exposure of women or children to testosterone gel 1.62%. Secondary exposure to testosterone can produce signs of virilization. Testosterone gel 1.62% should be discontinued until the cause of virilization is identified. (5.2)
• Venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients using testosterone products. Evaluate patients with signs or symptoms consistent with DVT or PE. (5.4)
• Some postmarketing studies have shown an increased risk of myocardial infarction and stroke associated with use of testosterone replacement therapy. (5.5)
• Exogenous administration of androgens may lead to azoospermia. (5.3)
• Edema with or without congestive heart failure (CHF) may be a complication in patients with preexisting cardiac, renal, or hepatic disease. (5.10)
• Sleep apnea may occur in those with risk factors. (5.12)
• Monitor serum testosterone, prostate specific antigen (PSA), hemoglobin, hematocrit, liver function tests and lipid concentrations periodically. (5.1, 5.3, 5.9, 5.13)
• Testosterone gel 1.62% is flammable until dry. (5.16)
ADVERSE REACTIONS
• **Common Adverse Reactions** reported in 2% of patients receiving testosterone gel 1.62% treated skin:
• To report SUSPECTED ADVERSE REACTIONS, contact Teva Pharmaceuticals USA, Inc. at 1-888-838-2872 or FDA at 1-800-FDA-1088. www.fda.gov/medwatch.
DRUG INTERACTIONS
• Androgens may decrease blood glucose and therefore may decrease insulin requirements in diabetic patients. (7.1)
• Androgens may potentiate the effects of other drugs on androgens. More frequent monitoring of international Normalized Ratio (INR) and prothrombin time is recommended. (7.2)
• Use of testosterone with adrenocorticotropic hormone (ACTH) or corticosteroids may result in increased fluid retention. Use with caution, particularly in patients with heart failure or congestive heart failure. (7.3)
USE IN SPECIFIC POPULATIONS
There are insufficient long-term safety data in geriatric patients using testosterone gel 1.62% to assess the potential risks of cardiovascular disease and prostate cancer. (8.5)
See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

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Full Prescribing Information: www.tevapharm.com

INDICATIONS AND USAGE

DOSE AND ADMINISTRATION

CONTRAINDICATIONS

WARNINGS AND PRECAUTIONS

ADVERSE REACTIONS

DRUG INTERACTIONS

CLINICAL STUDIES

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

PHARMACOKINETICS

NONCLINICAL TOXICOLOGY

USE IN SPECIFIC POPULATIONS

HOW SUPPLIED/STORAGE AND HANDLING

PATIENT COUNSELING INFORMATION

DESCRIPTION

MECHANISM OF ACTION

PHARMACODYNAMICS

How should I use testosterone gel 1.62%?

- See the detailed **Instructions for Use** about how to use testosterone gel 1.62% at the end of this Medication Guide.
- It is important that you apply testosterone gel 1.62% exactly as your healthcare provider tells you to.
- Your healthcare provider may change your testosterone gel 1.62% dose. **Do not** change your testosterone gel 1.62% dose without talking to your healthcare provider.
- Apply testosterone gel 1.62% at the same time each morning. Testosterone gel 1.62% should be applied after showering or bathing.

What are the possible side effects of testosterone gel 1.62%? Testosterone gel 1.62% can cause serious side effects including:
See **“What is the most important information I should know about testosterone gel 1.62%?”**

- If you already have enlargement of your prostate gland your signs and symptoms can get worse while using testosterone gel 1.62%.** This can include:
 - increased urination at night.
 - trouble starting your urine stream.
 - having to pass 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 or weak urine flow.
- Possible 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 testosterone gel 1.62%.
- 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.
- 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.

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. You can ask your pharmacist or healthcare provider for information about testosterone gel 1.62% that is written for health professionals.

What are the ingredients in testosterone gel 1.62%?

Active ingredient: testosterone

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

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

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

Teva Pharmaceuticals USA, Inc.

North Wales, PA 19454

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• 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 sleepiness.
- 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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iss. 8/2019

INSTRUCTIONS FOR USE
Testosterone (tes tos’ ter one) Gel 1.62% 

Read this Instructions for Use for testosterone gel 1.62% before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your healthcare provider about your medical condition or treatment.

Applying testosterone gel 1.62%:
Testosterone gel 1.62% comes in a pump or in packets.

- Before applying testosterone gel 1.62% make sure that your shoulders and upper arms are clean, dry, and that there is no broken skin.**

- Testosterone gel 1.62% is to be applied to the area of your shoulders and upper arms that will be covered by a short sleeve t-shirt (See Figure A). Do not** apply testosterone gel 1.62% to any other parts of your body such as your stomach area (abdomen), penis, scrotum, chest, armpits (axillae), or knees.



(Figure A)
If you are using testosterone gel 1.62% pump:

- Before using a new bottle of testosterone gel 1.62% for the first time, you will need to remove the cap and then prime the pump. To prime the testosterone gel 1.62% pump, slowly push the pump all the way down 3 times, over the sink drain. **Do not** use any testosterone gel 1.62% that came out while priming. Wash it down the sink to avoid accidental exposure to others. Your testosterone gel 1.62% pump is now ready to use.
- Remove the cap from the pump. Then, put the spout opening at the top of the pump where the medicine comes out over the palm of your hand and slowly push the pump all the way down. Apply testosterone gel 1.62% to the application site. You may also apply testosterone gel 1.62% directly to the application site. **Your healthcare provider will tell you the number of times to press the pump for each dose.**
- Wash your hands with soap and water right away.**

Find Your Dose as Prescribed by Your Healthcare Provider		Application Method
1 PUMP	20.25 mg	Apply 1 pump of testosterone gel 1.62% to 1 upper arm and shoulder.
2 PUMPS	40.5 mg	Apply 1 pump of testosterone gel 1.62% to 1 upper arm and shoulder and then apply 1 pump of testosterone gel 1.62% to the opposite upper arm and shoulder.
3 PUMPS	60.75 mg	Apply 2 pumps of testosterone gel 1.62% to 1 upper arm and shoulder and then apply 1 pump of testosterone gel 1.62% to the opposite upper arm and shoulder.
4 PUMPS	81 mg	Apply 2 pumps of testosterone gel 1.62% to 1 upper arm and shoulder and then apply 2 pumps of testosterone gel 1.62% to the opposite upper arm and shoulder.

If you are using testosterone gel 1.62% packets:

- Tear open the packet completely at the dotted line. Squeeze from the bottom of the packet to the top.
- Squeeze all of the testosterone gel 1.62% out of the packet into the palm of your hand.
- Apply testosterone gel 1.62% to the application site. You may also apply testosterone gel 1.62% directly to the application site.
- Let the application site dry completely before putting on a t-shirt.
- Testosterone gel 1.62% is flammable until dry.** Let testosterone 1.62% dry before smoking or going near an open flame.
- Avoid showering, swimming or bathing for at least 2 hours after you apply testosterone gel 1.62%. **Wash your hands right away** with soap and water after applying testosterone 1.62%.

Find Your Dose as Prescribed by Your Healthcare Provider		Application Method
One 20.25 mg packet	20.25 mg	Apply 1 packet of testosterone gel 1.62% to 1 upper arm and shoulder.
One 40.5 mg packet	40.5 mg	Apply half of the 40.5 mg packet of testosterone gel 1.62% to 1 upper arm and shoulder and then apply the remaining packet contents to the opposite upper arm and shoulder.
One 40.5 mg packet and one 20.25 mg packet	60.75 mg	Apply one 40.5 mg packet of testosterone gel 1.62% to 1 upper arm and shoulder and then apply one 20.25 mg packet of testosterone gel 1.62% to the opposite upper arm and shoulder.
Two 40.5 mg packets	81 mg	Apply one 40.5 mg packet of testosterone gel 1.62% to 1 upper arm and shoulder and then apply one 40.5 mg packet of testosterone gel 1.62% to the opposite upper arm and shoulder.

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 or packets, safely throw away used testosterone gel 1.62% in the 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.
This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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