INDICATIONS AND USAGE
Testosterone gel 1.62% is indicated for replacement therapy in males with conditions associated with deficiency or absence of endogenous testosterone.

CONTRAINDICATIONS
Testosterone gel 1.62% is contraindicated in patients with a known or suspected diagnosis of prostate cancer, while on a diagnosis of breast cancer, or in those who have an underlying condition that would make use of testosterone inappropriate. Use testosterone with caution in patients with cardiac, hepatic, or renal disease.

WARNINGS AND PRECAUTIONS
Worsening of benign prostatic hyperplasia (BPH) and potential risk of prostate cancer: Use testosterone with caution in patients with BPH symptoms. Monitor patients for signs and symptoms of prostate disease. Testosterone gel 1.62% should be discontinued if prostate enlargement is noted.

POLYCYTHEMIA: Secondary exposure to testosterone may increase the risk of polycythemia. Monitor patients for signs and symptoms of polycythemia.

VENOUS THROMBOEMBOLISM (VTE): Testosterone gel 1.62% may increase the risk of VTE, including deep vein thrombosis (DVT) and pulmonary embolism (PE). Monitor patients for signs and symptoms of VTE.

POTENTIAL FOR SECONDARY EXPOSURE TO TESTOSTERONE: Patients who are secondarily exposed to testosterone gel should be monitored for signs and symptoms of testosterone exposure.

DRUG ABUSE AND DEPENDENCE
Testosterone gel 1.62% may be abused for non-medical purposes. Monitor patients for signs and symptoms of drug abuse and dependence.

ADVERSE REACTIONS
The most common adverse reaction (incidence ≥ 5%) is an increase in prostate specific antigen (PSA). Other adverse reactions may include:

- Hypersensitivity reactions
- Gynecomastia
- Hypercalcemia
- Lipids
- Hepatic adverse effects
- Venous thromboembolism
- Polycythemia
- Potential for secondary exposure to testosterone
- Worsening of benign prostatic hyperplasia (BPH) and potential risk of prostate cancer

DRUG INTERACTIONS
Changes in estradiol levels may be seen with androgens. Meldonium may increase the risk of hematologic malignancy. Use with caution, particularly in patients with cancer, renal, or hepatic disease.

FULL PRESCRIBING INFORMATION: CONTENTS
For full prescribing information, please see the prescribing information for TESTOSTERONE GEL.

PRODUCT COUNTERS
This label highlights the key points of the testosterone gel (Lupin Pharmaceuticals, Inc.) product counter to help patients understand how to use the product safely and effectively.

MISCELLANEOUS
See section 17 for patient counseling information and Medication Guide.
FULL PRESCRIBING INFORMATION

WARNING: SECONDARY EXPOSURE TO TESTOSTERONE

- Vialization has been reported in children who were secondarily exposed to testosterone gel. Warnings and Precautions (5.2) and Adverse Reactions (6.2)
- Children should avoid contact with uncapped or unsealed application sites in men using testosterone gel Dosage and Administration (2.2) and Warnings and Precautions (5.2) and Patient Counseling Information (17).

1 INDICATIONS AND USAGE

Testosterone gel 1.62% is indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired): Testicular failure due to conditions such as cryptorchidism, maternal estrogen, orchitis, vanishing testis syndrome, orchectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) below the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LH-RH) deficiency or pituitary hypoplasia.
- Primary hypogonadism (congenital or acquired): hypogonadotropic hypogonadism (congenital or acquired) is characterized by low serum testosterone concentrations and gonadotropins. These men have low serum testosterone concentrations, but have gonadotropins in the normal or low range.

2 DOSAGE 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 concentrations have been measured in the morning on at least two separate days and that these serum testosterone concentrations are below the normal range.

2.1 Dosing and Dose Adjustment

The recommended starting dose of testosterone gel 1.62% is 40.5 mg (1 pump actuation) applied topically once daily to the shoulders and upper arms.

The dose can be adjusted between a minimum of 20.25 mg of testosterone (1 pump actuation) and a maximum of 60.75 mg of testosterone (3 pump actuations). To ensure proper dosing, the dose should be titrated based on the pre-dose morning serum testosterone concentration from a single blood draw at approximately 14 days and 28 days after starting treatment or following dose adjustment. In addition, serum testosterone concentration should be assessed periodically thereafter. Table 1 describes the dose adjustments required at each titration step.

Table 1: Dose Adjustment Criteria

<table>
<thead>
<tr>
<th>Pre-Dose Morning Total Serum Testosterone Concentration</th>
<th>Dose Titration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greater than 750 ng/dL</td>
<td>Decrease daily dose by 20.25 mg (1 pump actuation)</td>
</tr>
<tr>
<td>Equal to or greater than 350 and equal to or less than 750 ng/dL</td>
<td>No change: continue on current dose</td>
</tr>
<tr>
<td>Less than 350 ng/dL</td>
<td>Increase daily dose by 20.25 mg (1 pump actuation)</td>
</tr>
</tbody>
</table>

The application site and dose of testosterone gel 1.62% are not interchangeable with other topical testosterone products.

2.2 Administration Instructions

Testosterone gel 1.62% should be applied to clean, dry, intact skin of the upper arms and shoulders. Do not apply testosterone gel 1.62% to any other part of the body, including the abdomen, genitals, chest, armpits (axillae), or knees (see CLINICAL PHARMACOLOGY (12.3)). Area of application should be limited to the area that will be covered by the patient's short-sleeve t-shirt. Patients should be instructed to use the patient's hand to apply testosterone gel 1.62% and spread across the maximum surface area as directed in Table 2 (for pump) and in Figure 1.

Table 2: Application Sites for Testosterone Gel 1.62%, Pump

<table>
<thead>
<tr>
<th>Total Dose of Testosterone/Total Pump Actuations</th>
<th>Pump Actuations Per Upper Arm and Shoulder</th>
<th>Upper Arm and Shoulder #1/Upper Arm and Shoulder #2</th>
</tr>
</thead>
<tbody>
<tr>
<td>20.25 mg</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>40.5 mg</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>60.75 mg</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>81 mg</td>
<td>4</td>
<td>2</td>
</tr>
</tbody>
</table>

The prescribed daily dose of testosterone gel 1.62% should be applied to the right and left upper arm and shoulders as shown in the shaded areas in Figure 1.

Figure 1. Application Sites for Testosterone Gel 1.62%

Once the application site is dry, the site should be covered with clothing (see CLINICAL PHARMACOLOGY (12.3)). Wash hands thoroughly with soap and water. Avoid fire, flames or smoking until the gel has dried once alcohol based products, including testosterone gel 1.62%, are flammable.

The patient should avoid swimming or showering or washing the administration site for a minimum of 2 hours after application (see CLINICAL PHARMACOLOGY (12.3)).

To obtain a full first dose, it is necessary to prime the canister pump. To do so, with the canister in the upright position, slowly and fully depress the actuator three times. Safely discard the gel from the first three actuations. It is only necessary to prime the pump before the first dose. After the priming procedure, fully depress the actuator once for every 20.25 mg of testosterone gel 1.62%. Testosterone gel 1.62% should be delivered directly into the palm of the hand and then applied to the application sites. Alternatively, testosterone gel 1.62% can be applied directly to the application sites from the pump.
3 DOSAGE FORMS AND STRENGTHS
Testosterone gel 1.62% for topical use only, is available as follows:

- A metered-dose pump. Each pump actuation delivers 20.25 mg of testosterone in 1.25 g of gel.

4 CONTRAINDICATIONS
- Testosterone gel 1.62% is contraindicated in men with carcinoma of the breast or known or suspected carcinoma of the prostate [see WARNINGS AND PRECAUTIONS (5.1) and ADVERSE REACTIONS (6.1)].
- Testosterone gel 1.62% is contraindicated in women who are pregnant. Testosterone gel 1.62% can cause virilization of the female fetus when administered to a pregnant woman. Pregnant women need to be aware of the potential for transfer of testosterone from treated men to female partners in the household. Pregnant women should also be advised not to handle testosterone gel 1.62% when the application sites are exposed.
- Testosterone gel 1.62% can cause virilization of the female fetus when administered to a pregnant woman. Pregnant women need to be aware of the potential for transfer of testosterone from treated men to female partners in the household. Pregnant women should also be advised not to handle testosterone gel 1.62% when the application sites are exposed.
- Testosterone gel 1.62% is contraindicated in men with carcinoma of the breast or known or suspected carcinoma of the prostate [see WARNINGS AND PRECAUTIONS (5.1) and ADVERSE REACTIONS (6.1)].

5 WARNINGS AND PRECAUTIONS
5.1 Worsening of Benign Prostatic Hyperplasia (BPH) and Potential Risk of Prostate Cancer
- Patients with BPH treated with androgens are at an increased risk for worsening of signs and symptoms of BPH. Monitor patients with BPH for worsening signs and symptoms. Patients treated with androgens may be at increased risk for prostate cancer. Evaluation of patients for prostate cancer prior to initiating and during treatment with androgens is appropriate [see CONTRAINDICATIONS (4)].

5.2 Potential for Secondary Exposure to Testosterone
Cases of secondary exposure resulting in virilization of children have been reported in postmarketing surveillance of testosterone gel products. Signs and symptoms have included enlargement of the penis or clitoris, development of pubic hair, increased erections and libido, aggressive behavior, and advanced bone age. In most cases, these signs and symptoms resolved with removal of the exposure to testosterone gel. In a few cases, however, enlarged genitalia did not fully return to age-appropriate normal size, and bone age remained markedly greater than chronologic age. The risk of virilization is increased in some of these cases by nonadherence to precautions for the appropriate use of the topical testosterone product. Children and women should avoid contact with unwashed or unlabeled application sites in men using testosterone gel 1.62% [see DOSAGE AND ADMINISTRATION (2.2), USE IN SPECIFIC POPULATIONS (8.1) and CLINICAL PHARMACOLOGY (12.3)].

Inappropriate changes in genital size or development of pubic hair or l Harold inclusion, or changes in body hair distribution, significant increase in acne, or other signs of virilization in adult women should be brought to the attention of a physician and the possibility of secondary exposure to testosterone gel should also be brought to the attention of a physician. Testosterone gel should be promptly discontinued until the cause of virilization has been identified.

5.3 Polycythemia
- Increases in hematocrit, reflective of increases in red blood cell mass, may require lowering or discontinuation of testosterone. Evaluate patients for appropriate use of the topical testosterone product. Patients treated with androgens may have an increased risk for polycythemia. Evaluate patients for appropriate use of the topical testosterone product.

5.4 Venous Thromboembolism
- There have been postmarketing reports of venous thromboembolic events, including deep vein thrombosis (DVT) and pulmonary embolism (PE), in patients using testosterone products such as testosterone gel 1.62%. Evaluate patients who report symptoms of pain, edema, warmth, or erythema in the lower extremity for DVT and those who present with acute shortness of breath for PE. If a venous thromboembolic event is suspected, discontinue treatment with testosterone gel 1.62% and initiate appropriate workup and management [see ADVERSE REACTIONS (6.2)].

5.5 Cardiovascular Risk
- Long-term/clinical safety trials have not been conducted to assess the cardiovascular outcomes of testosterone replacement therapy. To date, epidemiologic studies and randomized controlled trials have been inconclusive for determining the risk of major adverse cardiovascular events (MACE), such as non-fatal myocardial infarction, non-fatal stroke, and cardiovascular death, with the use of testosterone products. Some observational studies have suggested that testosterone replacement therapy may be associated with an increased risk of cardiovascular disease in men. Patients should be informed of this possible risk when deciding whether to use or to continue to use testosterone gel 1.62%.

5.6 Abuse of Testosterone and Monitoring of Serum Testosterone Concentration
- Testosterone has been abused, typically at doses higher than recommended for the approved indications and in combination with other anabolic androgenic steroids. Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions [see DRUG ABUSE AND DEPENDENCE (9)].

If testosterone abuse is suspected, check serum testosterone concentration to ensure they are within therapeutic range. However, testosterone levels may be in the normal or subnormal range in men abusing synthetic testosterone derivatives. Counsel patients concerning the serum adverse reactions associated with abuse of testosterone and anabolic androgenic steroids. Concurrently, consider the possibility of testosterone and anabolic androgenic steroid abuse in suspected patients who present with serious cardiovascular or psychiatric adverse events.

5.7 Use in Women
- Due to the lack of controlled evaluation in women and potential virilizing effects, testosterone gel 1.62% is not indicated for use in women [see CONTRAINDICATIONS (4) and USE IN SPECIFIC POPULATIONS (8.1,8.2)].

5.8 Potential for Adverse Effects on Spermatozoa
- With large doses of exogenous androgens, including testosterone gel 1.62%, spermatozoa may be suppressed through feedback inhibition of primary FSH possibly leading to adverse effects on semen parameters including sperm count.

5.9 Hepatic Adverse Effects
- Prolonged use of high doses of orally active 17α-androstenedione (e.g., methyltestosterone) has been associated with serious hepatic adverse effects [potentially hepatitis, hepatic necrosis, cholestatic hepatitis, and jaundice]. Potentially hepatitis can be a life-threatening or fatal complication. Long-term therapy with oral testosterone ester has produced multiple hepatic adenomas. Testosterone gel 1.62% is not known to cause these adverse effects.

5.10 Edema
- Androgens, including testosterone gel 1.62%, may promote retention of sodium and water. Edema, with or without congestive heart failure, may be a serious complication in patients with preexisting cardiac, renal, or hepatic disease [see ADVERSE REACTIONS (6.2)].

5.11 Gynecomastia
- Gynecomastia may develop and persist in patients being treated with androgens, including testosterone gel 1.62%, for hypogonadism.

5.12 Sleep Apnea
- The treatment of hypogonadal men with testosterone may potentiate sleep apnea in some patients, especially those with risk factors such as obesity or chronic lung diseases.

5.13 Lipids
- Changes in serum lipoprotein profile may require dose adjustment or discontinuation of testosterone therapy.

5.14 Hypercalcemia
- Androgens, including testosterone gel 1.62%, should be used with caution in cancer patients at risk of hypercalcemia (and associated hypercalciuria). Regular monitoring of serum calcium concentration is recommended in these patients.
5.15 Decreased Thyroxine-binding Globulins

Androgen, including testosterone gel 1.62%, may decrease concentrations of thyroxine-binding globulins, resulting in increased total T4 serum concentration and increased resin uptakes of T3 and T4. Free thyroid hormone concentrations remain unchanged, however, and there is no clinical evidence of thyroid dysfunction.

5.16 Flammability

Alcohol-based products, including testosterone gel 1.62%, are flammable; therefore, patients should be advised to avoid fire, flame or smoking until the testosterone gel 1.62% has dried.

6 ADVERSE REACTIONS

6.1 Clinical Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug, and may not reflect the rates observed in practice.

Testosterone gel 1.62% was evaluated in a two-phase, 364-day, double-blind clinical study. The first phase was a multi-center, randomized, parallel-group, placebo-controlled period of 182 days, in which 256 hypogonadal men were treated with testosterone gel 1.62% and 80 received placebo. Patients could continue in an open-label, non-comparative, maintenance period for an additional 202 days (see CLINICAL STUDIES (4.1)).

The most common adverse reaction reported in the double-blind period was increased prostatic-specific antigen (PSA) reported in 26 testosterone gel 1.62%-treated patients (11.5%). In 17 patients, increased PSA was considered an adverse event by meeting one of the two pre-specified criteria for abnormal PSA values, defined as (1) average serum PSA >4.0 ng/mL based on two separate determinations, or (2) an average change from baseline in serum PSA of greater than 0.75 ng/mL based on three determinations (see ADVERSE REACTIONS (6.1)).

During the 182-day, double-blind period of the clinical trial, the mean change in serum PSA value was 0.16 ng/mL for patients receiving testosterone gel 1.62% and 0.12 ng/mL for the patients in the placebo group. During the double-blind period, seven patients had a PSA value >4.0 ng/mL, four of these seven patients had PSA levels that equal to or equal to 4.0 ng/mL, upon repeat testing. The other three patients did not undergo repeat PSA testing.

During the 182-day, open-label period of the study, the mean change in serum PSA values was 0.10 ng/mL, for both patients continuing on active therapy and patients transitioning onto active from placebo.

During the open-label period, three patients had a serum PSA value >4.0 ng/mL, none of whom had a serum PSA less than equal to 4.0 ng/mL upon repeat testing. The other patient did not undergo repeat PSA testing. Among previous placebo patients, 3 of 28 (10.7%), had increased PSA as an adverse event in the open-label period.

Table 3 shows adverse reactions reported by >2% of patients in the 182-day, double-blind period of the testosterone gel 1.62% clinical trial and most frequent in the testosterone gel 1.62% treated group versus placebo.

Table 3: Adverse Reactions Reported in >2% of Patients in the 182-Day, Double-Blind Period of Testosterone Gel 1.62% Clinical Trial

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Testosterone Gel 1.62% N=251</th>
<th>Placebo N=80</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSA increased*</td>
<td>26 (10.3%)</td>
<td>0%</td>
</tr>
<tr>
<td>Emotional lability†</td>
<td>8 (3.2%)</td>
<td>0%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>5 (2.0%)</td>
<td>0%</td>
</tr>
<tr>
<td>Benign prostate hyperplasia (increased)</td>
<td>5 (2.0%)</td>
<td>0%</td>
</tr>
<tr>
<td>Contact dermatitis†</td>
<td>5 (2.0%)</td>
<td>0%</td>
</tr>
</tbody>
</table>
| PSA increased includes PSA values that met pre-specified criteria for abnormal PSA values (an average change from baseline > 0.75 ng/mL, and/or an average PSA value >4.0 ng/mL based on two measurements) as well as those reported as adverse events.
| Emotional lability includes: mood swings, affective disorder, impotence, anger, and aggressiveness.

*Common domain includes: 4 patients with dermatitis at non-application sites.

Other adverse reactions occurring in less than or equal to 2% of testosterone gel 1.62%-treated patients and more frequently than placebo included: Frequent urination, and Hypertension.

In the open-label period of the study (N=195), the most commonly reported adverse reaction (experienced by greater than 2% of patients) was increased PSA (3, 6.2%) and impotence. Other adverse reactions reported in less than or equal to 2% of patients included increased hemoglobin or hematocrit, hyperglycemia, acne, hirsutism decreased, insomnia, and benign prostatic hyperplasia.

During the 182-day, double-blind period of the clinical trial, 25 testosterone gel 1.62%-treated patient (10.7%) discontinued treatment because of adverse reactions. These adverse reactions included 17 patients with PSA increased and 1 report each of: hematuria in increased, blood pressure increased, frequent urination, diabetes, fatigue, pitting edema, tinnitus, dizziness, skin erythema and skin nodule (same patient—without in application site), vasovagal syncope, and diabetes mellitus. During the 182-day, open-label period, 9 patients discontinued treatment because of adverse reactions. These adverse reactions included 6 reports of PSA increased, 2 of hematuria increased, and 1 of triglycerides increased and prostate cancer.

Table 4: Adverse Reactions from Post Approval Experience of testosterone gel 1% by System Organ Class

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Adverse Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular</td>
<td>Impaired urination*</td>
</tr>
<tr>
<td>Blood and lymphatic system disorders</td>
<td>Elevated hematocrit or hemoglobin, polycythemia, anemia</td>
</tr>
<tr>
<td>Endocrine disorders</td>
<td>Hyperglycemia, edema, male infertility</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>Nausea</td>
</tr>
<tr>
<td>General disorders</td>
<td>Anosmia, fatigue, dizziness, headache, insomnia</td>
</tr>
<tr>
<td>Neurological disorders</td>
<td>Abnormal liver function tests</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Fatigue, headache, incontinence, sleep apnea</td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td>Anorexia, anxiety, depression, hostility, emotional lability, decreased libido, nervousness</td>
</tr>
<tr>
<td>Reproductive system and breast disorders</td>
<td>Testicular atrophy or non-palpable testis, varicocele, testicular sensitivity or tenderness</td>
</tr>
<tr>
<td>Respiratory disorders</td>
<td>Dyspnea</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>Acne, eczema, alopecia, vitiligo, psoriasis, rash, pruritus, erythema, flushing</td>
</tr>
<tr>
<td>Vascular disorders</td>
<td>Hypertension, atherosclerosis, thrombosis</td>
</tr>
</tbody>
</table>

**Possible causes include:• hypercalcemia,• hyperthyroidism,• hyperlipidemia,• diabetes mellitus,• psychogenic factors,• other medications**

Secondary Exposure to Testosterone in Children

Causes of secondary exposure to testosterone resulting in civilization of children have been reported in postmarketing surveillance of testosterone gel product. Signs and symptoms of these reported cases have included enlargement of the clinical testicular volume, elevation of the free testosterone, increased axillary and pubic hair, increased excitation and libido, aggressive behavior, and advanced bone age. In some cases, a report was made on the use of testosterone gel on a patient at the age of 12 years. In at least one reported case, the report considered the possibility of secondary exposure from items such as the testosterone gel user's shirts and/or other fabric, such as towels and sheets. [See WARNINGS AND PRECAUTIONS (4.2)].

7 DRUG INTERACTIONS
Changes in insulin sensitivity or glycemic control may occur in patients treated with androgen. In diabetic patients, the metabolic effects of androgens may decrease blood glucose and, therefore, may decrease insulin requirement.

7.2 Oral Anticoagulants
Changes in anticoagulant activity may be seen with androgen, therefore more frequent monitoring of international normalized ratio (INR) and prothrombin time are recommended when taking anticoagulants, especially at the initiation and termination of androgen therapy.

7.3 Corticosteroids
The concurrent use of testosterone with adrenocorticotropic hormone (ACTH) or corticosteroids may result in increased fluid retention and requires careful monitoring particularly in patients with cardiac, renal or hepatic disease.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary
Testosterone gel 1.62% is contraindicated in pregnant women. Testosterone is teratogenic and may cause fetal harm when administered to a pregnant woman based on data from animal studies and its mechanism of action [see CONTRAINDICATIONS (4) and CLINICAL PHARMACOLOGY (12.1)].

Exposure of a female fetus to androgens may result in varying degrees of virilization. In animal developmental studies, exposure to testosterone in utero resulted in hormonal and behavioral changes in offspring and structural impairments of reproductive tissues in male and male offspring. These studies did not meet current standards for nonclinical development toxicity studies.

8.2 Lactation

Risk Summary
Testosterone gel 1.62% is not indicated for use in women.

8.3 Females and Males of Reproductive Potential

Infertility
Testis disorder, vaginal atrophy, and oligospermia have been identified during use of testosterone gel 1.62% [see ADVERSE REACTIONS (6.1, 6.2)].

During treatment with large doses of exogenous androgens, including testosterone gel 1.62%, spermatogenesis may be suppressed or feedback inhibition of the hypothalamic-pituitary-testicular axis [see WARNINGS AND PRECAUTIONS (5.6)]. Reduced fertility is observed in men taking testosterone replacement therapy. Testicular atrophy, subfertility, and infertility have also been reported in men who abuse anabolic androgenic steroids [see DRUG ABUSE AND DEPENDENCE (9.2)]. With either type of use, the impact on fertility may be irreversible.

8.4 Pediatric Use

The safety and effectiveness of testosterone gel 1.62% in pediatric patients less than 18 years old has not been established. Improper use may result in acceleration of bone age and premature closure of epiphyses.

8.5 Geriatric Use

There have not been sufficient numbers of geriatric patients involved in controlled clinical studies utilizing testosterone gel 1.62% to determine whether efficacy in those over 65 years of age differs from younger subjects. Of the 232 patients enrolled in the clinical trial utilizing testosterone gel 1.62%, 23 were over 65 years of age. Additionally, there is insufficient long-term safety data in geriatric patients to assess the probability increased risks of cardiovascular disease and pressure cancer. Geriatric patients treated with androgen may also be at risk for screening of signs and symptoms of BPH.

8.6 Renal Impairment

No studies were conducted involving patients with renal impairment.

8.7 Hepatic Impairment

No studies were conducted in patients with hepatic impairment.

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

Testosterone gel 1.62% contains testosterone, a Schedule III controlled substance in the Controlled Substances Act.

9.2 Abuse

Drug abuse is intentional non-therapeutic use of a drug, even once, for its rewarding psychological and physiological effects. Abuse and misuse of testosterone are seen in female and male adults and adolescents. Testosterone, either in combination with other anabolic androgenic steroids (AAS), or not obtained by prescription through a pharmacy, may be abused by athletes and bodybuilders. There have been reports of abuse by meta-treating higher doses of legally obtained testosterone than prescribed and continuing testosterone despite adverse events or against medical advice.

Abuse-Related Adverse Reactions

Serious adverse reactions have been reported in individuals who abuse anabolic androgenic steroids and include cardiac arrest, myocardial infarction, hypertensive cardiovascular disease, congestive heart failure, cerebrovascular accident, hematuria, and serious psychiatric manifestations, including major depression, mood, anxiety, psychosis, delusions, hallucinations, hostility and aggression.

The following adverse reactions have also been reported in men taking testosterone: pain, swelling, tenderness, bruising, testicular atrophy, male-pattern baldness, and mental irregularities.

The following adverse reactions have been reported in male and female adolescents following closure of the epiphyses and with termination of growth, and precocious puberty.

Because these reactions are reported voluntarily from a population of uncertain size and may include abuse of other agents, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

9.3 Dependence

Behaviors Associated with Addiction

Continuous abuse of testosterone and other anabolic steroids, leading to addiction is characterized by the following behaviors:

- Taking greater doses than prescribed
- Continued drug use despite medical and social problems due to drug use
- Spending significant time in obtaining the drug when supplies of the drug are interrupted
- Giving a higher priority to drug use than other obligations
- Having difficulty in discontinuing the drug despite desires and attempts to do so
- Experiencing withdrawal symptoms upon abrupt discontinuation of use

Physical dependence is characterized by withdrawal symptoms after abrupt drug discontinuation or a significant dose reduction of a drug. Individuals taking supratherapeutic doses of testosterone may experience withdrawal symptoms lasting for weeks or months which include depressed mood, major depression, fatigue, crying, restlessness, irritability, anxiety, insomnia, decreased libidus and hypogonadotropic hypogonadism.

Drug dependence in individuals using approved doses of testosterone for approved indications has not been documented.
Effect of showering

respectively, compared to mean baseline testosterone concentrations.

The mean testosterone C_{max} on day 1 increased by 43% and 47%, respectively, compared to mean baseline testosterone concentrations.

covered the application area with a T-shirt. The mean testosterone C_{min} on day 1 increased by 6% and 11%, respectively, compared to mean baseline testosterone concentrations.

A separate study was conducted to evaluate the potential for testosterone transfer from 16 males dosed with testosterone gel 1.62% 81 mg to their untreated female partners. In one study, 8 male subjects applied a single dose of testosterone gel 1.62% 81 mg to their shoulders and upper arms. Two (2) hours after application, female subjects rubbed their hands, wrists, arms, and shoulders to the application site of the male subjects for 15 minutes while the site of application was covered by a t-shirt. When a t-shirt was used to cover the site of application, mean testosterone C_{min} on day 1 increased by 43% and 67%, respectively, compared to mean baseline testosterone concentrations.

Potential for testosterone transfer:

The potential for testosterone transfer following administration of testosterone gel 1.62% when it was applied only to upper arms/shoulders was evaluated in two clinical studies of males dosed with testosterone gel 1.62% and their untreated female partners. In one study, 8 male subjects applied a single dose of testosterone gel 1.62% 81 mg to their shoulders and upper arms. Two (2) hours after application, female subjects rubbed their hands, wrists, arms, and shoulders to the application site of the male subjects for 15 minutes. Serum concentrations of testosterone were monitored in female subjects for 24 hours after contact occurred. After direct skin-to-skin contact with the site of application, mean testosterone C_{min} and C_{avg} in females increased by 200% and 207%, respectively, compared to mean baseline testosterone concentrations. In a second study evaluating transfer of testosterone, 12 males had testosterone gel 1.62% and their untreated female partners. In one study, 8 male subjects applied a single dose of testosterone gel 1.62% 81 mg to their shoulders and upper arms. Two (2) hours after application, female subjects rubbed their hands, wrists, arms, and shoulders to the application site of the male subjects for 15 minutes while the site of application was covered by a t-shirt. When a t-shirt was used to cover the site of application, mean testosterone C_{min} and C_{avg} in female subjects increased by 6% and 11%, respectively, compared to mean baseline testosterone concentrations.

Effect of showering:

In a randomized, 3-way (3 treatment periods without washout period) crossover study in 24 hypogonadal

Testosterone gel 1.62% provides continuous transdermal delivery of testosterone for 24 hours following one daily application to clean, dry, intact skin of the shoulders and upper arms. Average serum testosterone concentrations over 24 hours (C_{avg}) observed when testosterone gel 1.62% was applied to the upper arms/shoulders were comparable to average serum testosterone concentrations (C_{avg}) when testosterone gel 1.62% was applied using a rotation method utilizing the abdomen and upper arms/shoulders. The rotation of abdomen and upper arms/shoulders was a method used in the pivotal clinical trial [see CLINICAL STUDIES (14.1)].
on the day of each treatment period, hypogonadal men took a shower with soap and water at either 2, 6, or 10 hours after drug application. The effect of showering at 2 or 6 hours post-dose on Day 7 resulted in 10% and 12% decreases in $C_{\text{avg}}$ and $C_{\text{max}}$, respectively, compared to Day 6, whereas showering was taken after drug application. Showering at 10 hours after drug application had no effect on bioavailability. The amount of testosterone remaining in the outer layers of the stratum the application site on the 3rd day was assessed using a tape stripping procedure and was reduced by at least 80% after showering at 2 to 10 hours post-dose compared to the 6th day when no shower was taken after drug application.

**Effect of hand-washing**

In a randomized, open-label, single-dose, 2-way crossover study in 16 healthy male subjects, the effect of hand-washing on the amount of residual testosterone on the hands was evaluated. Subjects used their hands to apply the maximum dose (81 mg testosterone) to their upper arms and shoulders. Within 1 minute of applying the gel, subjects either washed or did not wash their hands prior to study personnel wiping the subjects' hands with ethanol-dipped gauze pads. The gauze pads were then analyzed for residual testosterone content. A mean (SD) of 0.1 (0.04) mg of residual testosterone (0.12% of the actual applied dose of testosterone, and a 96% reduction compared to when hands were not washed) was recovered after washing hands with water and soap.

**Effect of sunscreen or moisturizing lotion on absorption of testosterone:**

In a randomized, 3-way (3 treatment periods without washout period) crossover study in 10 hypogonadal males, the effect of applying a moisturizing lotion or sunscreen on the absorption of testosterone was evaluated with the upper arms as study site. For 7 days, moisturizing lotion or sunscreen (SPF 50) was applied daily to the testosterone gel 1.62% application 1 hour after the application of testosterone gel 1.62% 40.5 mg. Application of moisturizing lotion increased mean testosterone $C_{\text{avg}}$ and $C_{\text{max}}$ by 14% and 17%, respectively, compared to testosterone gel 1.62% administered alone. Application of sunscreen increased mean testosterone $C_{\text{avg}}$ and $C_{\text{max}}$ by 18% and 13%, respectively, compared to testosterone gel 1.62% applied alone.

### 13 NONCLINICAL TOXICOLOGY

#### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

**Carcinogenesis**

Testosterone has been demonstrated to induce tumors in rats when given in high doses or long-term. However, the exact mechanism of this induction is not fully understood. In vitro studies have suggested that testosterone may promote the differentiation of chemically induced carcinomas of the liver in rats. However, these findings have not been consistently reproduced in vivo.

**Mutagenesis**

Testosterone was negative in the in vitro Ames and in vivo mouse micronucleus assays.

**Impairment of Fertility**

The administration of exogenous testosterone has been reported to suppress spermatogenesis in rats, dogs, and non-human primates, which reverses on cessation of the treatment.

### 14 CLINICAL STUDIES

#### 14.1 Clinical Trials in Hypogonadal Males

Testosterone gel 1.62% was evaluated in a multi-center, randomized, double-blind, parallel-group, placebo-controlled study (122-day double-blind period) in 274 hypogonadal men with body mass index (BMI) 18 to 40 kg/m² and 15 to 60 years of age (mean age 53.3 years). The patients had average serum testosterone concentrations <300 ng/dL, as determined by two morning samples collected on the same visit. Patients were Caucasian 83%, Black 13%, Asian or Native American 4%, 7.5% of patients were Hispanic.

Patients were randomized to receive active treatment or placebo using a rotation method utilizing the abdomen and upper arms/shoulders for 182 days. All patients were started at a daily dose of 40.5 mg (two pump actuations) testosterone gel 1.62% or matching placebo on Day 1 of the study. Patients returned to the clinic on Day 14, Day 28, and Day 42 for periodic serum testosterone assessments. The patients daily dose was titrated up or down to 20.25 mg increments of the previous serum testosterone value was obtained on the previous visit. The study included four active treatment periods: testosterone gel 1.62% doses of 20.25 mg, 40.5 mg, 60.75 mg, and 81 mg daily.

The primary endpoint was the percentage of patients with $C_{\text{avg}}$ within the normal range of 300 to 1000 ng/dL on Day 112. In patients treated with testosterone gel 1.62%, 81.6% (146/179) had $C_{\text{avg}}$ within the normal range of Day 112. The secondary endpoint was the percentage of patients, with $C_{\text{avg}}$ greater than 1500 ng/dL, and between 1000 and 2499 ng/dL on Day 112 were 11.2% and 5.5%, respectively. Two patients had $C_{\text{max}}$'s >2500 ng/dL on Day 112 (2510 ng/dL and 2550 ng/dL, respectively); neither of these 2 patients demonstrated an abnormal $C_{\text{avg}}$ 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. 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 5.

**Table 5: Mean (SD) Testosterone Concentrations (Cavg and Cmax) by final dose on Days 112 and 364**

<table>
<thead>
<tr>
<th>Final Dose on Day 364</th>
<th>Placebo (n=27)</th>
<th>20.25 mg (n=34)</th>
<th>40.5 mg (n=34)</th>
<th>60.75 mg (n=34)</th>
<th>81 mg (n=79)</th>
<th>All Active (n=179)</th>
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<tbody>
<tr>
<td>$C_{\text{avg}}$ (ng/dL)</td>
<td>431 (317)</td>
<td>447 (276)</td>
<td>624 (228)</td>
<td>643 (285)</td>
<td>557 (246)</td>
<td>561 (250)</td>
</tr>
<tr>
<td>$C_{\text{max}}$ (ng/dL)</td>
<td>789 (330)</td>
<td>703 (187)</td>
<td>801 (177)</td>
<td>807 (180)</td>
<td>854 (480)</td>
<td>854 (480)</td>
</tr>
</tbody>
</table>

**Final Dose on Day 112**

<table>
<thead>
<tr>
<th>Placebo (n=27)</th>
<th>20.25 mg (n=7)</th>
<th>40.5 mg (n=20)</th>
<th>60.75 mg (n=20)</th>
<th>81 mg (n=74)</th>
<th>Continuing Active (n=136)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$C_{\text{avg}}$ (ng/dL)</td>
<td>386 (139)</td>
<td>474 (176)</td>
<td>531 (222)</td>
<td>432 (110)</td>
<td>457 (192)</td>
</tr>
<tr>
<td>$C_{\text{max}}$ (ng/dL)</td>
<td>562 (187)</td>
<td>715 (385)</td>
<td>839 (508)</td>
<td>849 (329)</td>
<td>937 (289)</td>
</tr>
</tbody>
</table>

Figure 3 summarizes the pharmacokinetic profile of total testosterone in patients completing 122 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.
Children and women should avoid contact with unwashed or not covered (unclothed) areas where testosterone gel 1.62% has been applied. Men with known or suspected prostate or breast cancer should not use testosterone gel 1.62% [see CONTRAINDICATIONS (4) and WARNINGS AND PRECAUTIONS (5.2)].

17.4 Patients Should Be Advised of the Following Instructions for Use

- 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 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 androgen excess.
- 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].

- 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 (12.5)].

17.5 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, difficulty starting the urine stream, frequency of urination 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.
- Testosterone gel 1.62% is an alcohol-based product and is flammable; therefore avoid fire, flame or smoking until the gel has dried.

18.4 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 not 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 greater amount of testosterone gel 1.62% is absorbed into their system.

Manufactured by:
Lupin Pharmaceuticals, Inc.
Baltimore, Maryland 21202

United States

Manufactured by:
Lupin Limited
Phulbazar (M.P.) – 454 775
India

MEDICATION GUIDE
Testosterone Gel 1.62%, for topical use, CIII

What is the most important information I should know about testosterone gel 1.62%?

Testosterone gel 1.62% can transfer from your body to others including, children and women. Children and women should avoid contact with the unwashed or not covered (unclothed) areas where testosterone gel 1.62% has been applied to your skin. Early signs and symptoms of androgen exposure in young children who have come in direct contact with testosterone by touching areas where men have used testosterone gel 1.62%.

Children
Signs and symptoms of early puberty in a child when they come in direct contact with testosterone gel 1.62% may include:
- Abnormal sexual changes:
  - enlarged penis or breasts
  - early growth of hair near the vagina or around the penis (pubic hair)
- Sleep problems or acting out sexual urges (sex drive)

Behavior problems:
- acting aggressively, behaving in an angry or violent way.

Women
Signs and symptoms in women when they come in direct contact with testosterone gel 1.62% may include:
- changes in body hair.
- an abnormal increase in pimples (acne).

Stop using testosterone gel 1.62% and call your healthcare provider right away if you see any signs and symptoms in a child or a woman that may have happened through accidental touching of the area where you have applied testosterone gel 1.62%.

2. To lower the risk of transfer of testosterone gel 1.62% from your body to others, follow these important instructions:
- Apply testosterone gel 1.62% only to your shoulders and upper arms that will be covered by a short sleeve vest.
- Wash your hands right away with soap and water after applying testosterone gel 1.62%.
- After the gel has dried, cover the application area with clothing. Keep the area covered until you have washed the application area well or have showered.
- If you expect to have skin-to-skin contact with another person, first wash the application area well with soap and water.
- If a child or someone touches the area where you have applied testosterone gel 1.62%, that area on the child or someone should be washed well with soap and water right away.

What is testosterone gel 1.62%?
Testosterone gel 1.62% is a prescription medicine that contains testosterone. Testosterone gel 1.62% is used to treat adult males who have low or no testosterone due to certain medical conditions.
- Your healthcare provider will tell you how much testosterone gel 1.62% to apply to your skin each day.

It is not known if testosterone gel 1.62% is safe or effective to treat men who have low testosterone due to aging.
- It is not known if testosterone gel 1.62% is safe or effective in children younger than 18 years old. Improper use of testosterone gel 1.62% may affect bone growth in children.

Testosterone gel 1.62% is a controlled substance (CIII) because it contains testosterone that can be a target for people who abuse prescription medicines. Keep your testosterone gel 1.62% in a safe place to protect it. Never give your testosterone gel 1.62% 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.

Testosterone gel 1.62% is not meant for use in women.

Do not use testosterone gel 1.62% if you:
- have breast cancer.
- have or might have prostate cancer.
- are pregnant. Testosterone gel 1.62% may harm your unborn baby.
- Women who are pregnant should avoid contact with the area of skin where testosterone gel 1.62% has been applied.

Before using testosterone gel 1.62%, tell your healthcare provider about all of your medical conditions, including if you:
- have breast cancer.
- have or might have prostate cancer.
- have or have had decreased urination at night.
- have or have had an abnormal increase in urination at night.
- have or have had increased urination at night from prostatic hyperplasia.
- have or have had urinary problems due to an enlarged prostate.
- have or have had breast problems.
- have or have had urinary problems due to an enlarged prostate.
- have or have had urinary problems due to an enlarged prostate.
- have or have had 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 testosterone gel 1.62% with other medicines can affect each other.

Especially, tell your healthcare provider if you take:
- medicines that decrease blood clotting (blood thinners)
- corticosteroids
- androgens (testosterone derivatives)

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 shaving 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 or your signs and symptoms can get worse while using testosterone gel 1.62%.
- This can include:
  - increased urination at night.
  - trouble emptying 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 wash your lower body.
- Possible increased risks 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 arms. Signs and symptoms of a blood clot include leg pain, swelling, or bruising. Signs and symptoms of a blood clot in your lungs include difficulty breathing or chest pain.
- Possible increased risks of heart attack or stroke.
- In large doses testosterone gel 1.62% may lower your sperm count.
- Swelling of your ankles, feet, or body. Swelling can be a sign of heart failure.
- Enlarged or painful breasts.
- These 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 presence of specific antigens in your body for prostate cancer)
- shortness of breath.
- increased red blood cell count
- skin irritation where testosterone gel 1.62% is applied

Other side effects may occur and are not listed above. These are 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 ingredients: testosterone USP
Inactive ingredients: carbomer homopolymer type C, dehydrated alcohol (USP), isoamyl alcohol, propylene glycol.
myristate, sodium hydroxide and purified water.
For more information, call 1-800-399-2561.
This Medication Guide has been approved by the U.S. Food and Drug Administration.

INSTRUCTIONS FOR USE
Testosterone Gel 1.62%, for topical use, CIII
(ne TOS ter one)
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.
- 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 part of your body such as your stomach area (abdomen), penis, scrotum, chest, armpits (axillae), or lower.

(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 depression 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

<table>
<thead>
<tr>
<th>Application Method</th>
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</thead>
<tbody>
<tr>
<td>1 pump</td>
</tr>
<tr>
<td>2 pumps</td>
</tr>
<tr>
<td>3 pumps</td>
</tr>
<tr>
<td>4 pumps</td>
</tr>
</tbody>
</table>

How should I store testosterone gel 1.62%?
- Store testosterone gel 1.62% at room temperature between 68ºF to 77ºF (20ºC to 25ºC).
- When it is time to throw away the pump, 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.
Manufactured for:
Lupin Pharmaceuticals, Inc.
Baltimore, Maryland 21202
United States
Manufactured by:
Lupin Limited
Phanapur (M.P.) – 454 775
India
August 2019
ID#: 261052

PACKAGE LABEL:PRINCIPAL DISPLAY PANEL
Testosterone Gel 1.62%, CIII – Container Label
NDC 68180-941-11
20.25 mg of testosterone per pump actuation*
*Each actuation delivers 1.25 mg of gel
For Topical Use Only
Rx only
Multi-dose pump capable of dispensing 60 metered pump actuations.

Testosterone Gel 1.62%, CIII – Carton Label
NDC 68180-941-11
20.25 mg of testosterone per pump actuation*
*Each actuation delivers 1.25 mg of gel
For Topical Use Only
Rx only
Multi-dose pump capable of dispensing 60 metered pump actuations.
**Product Information**

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**Route of Administration**

- **TRANSDERMAL**

**DEA Schedule**

- **CIII**

**Active Ingredient/Active Moiety**

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<th>Ingredient/Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>TESTOSTERONE</td>
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**Inactive Ingredients**

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<tr>
<td>ISOPROPYL MYRISTATE</td>
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</tr>
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**Packaging**

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**Labeler**

- **Lupin Pharmaceuticals, Inc.**

**Registrant**

- **Lupin Atlantis Holding SA**

**Establishment**

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**Revised:** 8/2019