**INDICATIONS AND USAGE**

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

- Primary hypogonadism (congenital or acquired)
- Secondary hypogonadism (congenital or acquired)

Limitations of use:

- Safety and efficacy of testosterone gel 1.62% in areas with "age-related hypogonadism" have not been established.
- Safety and efficacy of testosterone gel 1.62% in men older than 65 years have not been established.

**DESCRIPTION**

Testosterone gel 1.62% is flammable until dry (See Full Prescribing Information).

**DRUG ABUSE AND DEPENDENCE**

Warning: Secondary exposure to testosterone gel 1.62% differs from testosterone gel 1%. For dosage and administration of testosterone gel 1% refer to its full prescribing information.

See full prescribing information for complete boxed warning.

**CONTRAINdications**

- Use of testosterone with adrenocorticotrophic hormone (ACTH) or corticosteroids may result in increased fluid retention.
- Exogenous administration of androgens may lead to increased hypertension, cardiac output, and myocardial oxygen demand.
- Venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE) have been identified. Use with caution in patients with coronary artery disease. Use with caution, particularly in patients with cardiac, renal, or hepatic disease.

**WARNINGS AND PRECAUTIONS**

- Monitor patients with benign prostatic hyperplasia (BPH) for worsening of signs and symptoms of BPH (See Cl). Monitor prostate specific antigen (PSA) concentrations periodically (See Cl).
- Monitor serum testosterone, prostate specific antigen (PSA), and a maximum of 81 mg of testosterone (4 pump actuations).
- Monitor patients with benign prostatic hyperplasia (BPH) for worsening of signs and symptoms of BPH (See Cl). Monitor prostate specific antigen (PSA) concentrations periodically (See Cl).
- Monitor serum testosterone, prostate specific antigen (PSA), and a maximum of 81 mg of testosterone (4 pump actuations).
- Monitor patients with benign prostatic hyperplasia (BPH) for worsening of signs and symptoms of BPH (See Cl). Monitor prostate specific antigen (PSA) concentrations periodically (See Cl).
- Monitor serum testosterone, prostate specific antigen (PSA), and a maximum of 81 mg of testosterone (4 pump actuations).
1.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

14 CLINICAL STUDIES
14.1 Clinical Trials in Hypogonadal Males

16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION
17.2 Use in Men with Known or Suspected Prostate or Breast Cancer
17.4 Patients Should Be Advised of the Following Instructions for Use
* Section or subsections cited from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

**WARNING: SECONDARY EXPOSURE TO TESTOSTERONE**

- Administration site and dose of testosterone gel 1.62% are not interchangeable with other topical androgen products.
- Dosage and administration of testosterone gel 1% refer to its full prescribing information. Dosage and Administration for testosterone gel 1.62% differs from testosterone gel 1%.

2.1 Dosing and Dose Adjustment
The recommended starting dose of testosterone gel 1.62% is 40.5 mg of testosterone (2 pump actuations) applied topically once daily in the morning to the shoulders and upper arms.

<table>
<thead>
<tr>
<th>Dose Titration</th>
<th>Dosage and Administration of Testosterone Gel 1% (Less than 350 ng/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gt200 mg/dL</td>
<td>Decrease daily dose by 20.25 mg (1 pump actuation)</td>
</tr>
<tr>
<td>Equal to or greater than 200 and less than 350 mg/dL</td>
<td>No change; continue on current dose</td>
</tr>
<tr>
<td>Less than 200 mg/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, 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, genitalia, chest, armpits (axillae), or knees.

**Figure 1. Application Sites for Testosterone Gel 1.62%**

1. The prescribed daily dose of testosterone gel 1.62% should be applied to the right and left upper arms and shoulders as shown in the shaded areas in Figure 1.
Strict adherence to the following precautions is advised in order to minimize the potential for secondary exposure to testosterone from testosterone gel 1.62%-treated skin:

- Children and women should avoid contact with unwashed or unclothed application site(s) of men using testosterone gel 1.62%.
- Testosterone gel 1.62% should only be applied to the upper arm and shoulders. The area of application should be limited to the axillae that will be covered by a shirt sleeve or vest.
- Patients should wash their hands with soap and water immediately after applying testosterone gel 1.62%.
- Patients should cover the application site(s) with clothing (e.g., a shirt) after the gel has dried.
- Prior to situations in which direct skin-to-skin contact is anticipated, patients should wash the application site(s) thoroughly with soap and water to remove any testosterone residue.
- In the event that unwashed or unclothed skin of a woman being treated with testosterone gel 1.62% has been applied in contact with the skin of another person, the general area of contact to the other person should be washed with soap and water as soon as possible.

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 (5.2) and ADVERSE REACTIONS (8.1)].
- Testosterone gel 1.62% is contraindicated in women who are pregnant. Testosterone gel 1.62% can cause virilization of the female fetus from administration to a pregnant woman. Pregnant women need to be aware of the potential for transfer of testosterone from treated with testosterone gel 1.62% to a fetus who is conceived during treatment.
- Testosterone gel 1.62% is contraindicated in women who are nursing. Testosterone gel 1.62% should not be used in women of childbearing potential based on the risk/benefit assessment (see WARNINGS AND PRECAUTIONS (5.2) and USE IN SPECIFIC POPULATIONS (8.1)).

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 of signs and symptoms.
- Patients treated with androgens may be at an 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 product. Signs and symptoms have included enlargement of the penis or clitoris, development of pubic hair, increased erection and libido, aggressive behavior, and advanced bone age. In these cases, signs and symptoms progressed with removal of the exposure to testosterone gel. In a few cases, however, enlarged phallicia did not fully return age-appropriate normal size, and/or age remained markedly greater than chronological age. The risk of transfer was increased in some of these cases by nonadherence to precaution for the appropriate use of the topical testosterone product. Children or women should avoid contact with unwashed or unclothed application sites of men using testosterone gel 1.62% [see DOSAGE AND ADMINISTRATION (2.2), USE IN SPECIFIC POPULATIONS (8.1), and CLINICAL PHARMACOLOGY (12.3)].

5.3 Polycythemia
Increases in hematocrit, reflective of increases in red blood cell mass, may require lowering or discontinuation of testosterone. Check hematocrit prior to initiating treatment. It would also be appropriate to re-evaluate the hematocrit 3 to 6 months after starting treatment, and then annually. If hematocrit becomes elevated, stop therapy until hematocrit decreases to an acceptable concentration. An increase in red blood cell mass may increase the risk of thromboembolic events.

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 swelling 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 (12.2)].

5.5 Cardiovascular Risk
Long-term clinical trials have not been conducted to assess the cardiovascular outcomes of testosterone replacement therapy in men. To date, epidemiologic studies and randomized controlled trials have been inconsistent 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 therapy. Testosterone therapy has been associated with a small increase in total and low-density lipoprotein cholesterol, with a decrease in high-density lipoprotein cholesterol. The clinical significance of these changes is not known. To date, there have been no randomized controlled trials specifically designed to evaluate the impact of testosterone therapy on clinical cardiovascular outcomes. In general, the efficacy of testosterone in the prevention and treatment of cardiovascular disease has not been established.

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

If testosterone abuse is suspected, check serum testosterone concentrations in cases where 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 serious adverse reactions associated with abuse of testosterone and anabolic androgenic steroids. Conversely, consider the possibility of testosterone and anabolic androgenic steroid abuse in patients who present with serious cardiovascular or psychiatric adverse events.

5.7 Use in Women
Due to the lack of controlled evaluations 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 17-alpha-alkylated androgens (e.g., methyltestosterone) has been associated with serious hepatic adverse effects (fulminant hepatic, hepatic necrosis, cholestatic hepatitis, and jaundice). Prolonged use of androgens has been associated with hepatocellular carcinoma in some men. 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 concomitant heart failure, may be a serious complication in patients with preexisting cardiac, renal, or hepatic disease [see ADVERSE REACTIONS (12.2)].

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/lipid 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 concentrations is recommended in these patients.
5.13 Decreased Thyroxine-binding Globulins
Androgens, including testosterone gel 1.62%, may decrease concentrations of thyroxine-binding globulins, resulting in increased total T4 serum concentration and increased resin uptake of T3 and T4. Free thyroid hormone concentrations remain unchanged, however, and there is no clinical evidence of thyroid dysfunction.

5.14 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 two 36-week, double-blind, placebo-controlled clinical studies. The first phase was a multi-center, randomized, double-blind, parallel-group, placebo-controlled period of 102 days, in which 238 hypogonadal men were treated with testosterone gel 1.62% and 40 received placebo. Patients could continue in an open-label, non-comparative, maintenance period for an additional 320 days (see CLINICAL STUDIES (4.1)).

The most commonly reported adverse reaction 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 in 1 (average serum PSA > 6 ng/mL based on two separate determinations, or (2) an average change from baseline in serum PSA of greater than 0.75 ng/mL over 12 months; see Clinical Pharmacology (12)).

During the double-blind, double-dummy period of the clinical trial, the mean change in serum PSA value was 0.34 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 less than 4.0 ng/mL at the time of discontinuation of the study. The other three patients did not undergo repeat PSA testing.

During the 320-day, open-label period of the study, the mean change in serum PSA values was 0.30 ng/mL, for both patients continuing on active therapy and patients transitioning from active to placebo. During the open-label period, three patients had a PSA value > 4.0 ng/mL, two of whom had a serum PSA less than 4.0 ng/mL at the time of discontinuation of the study. The other patient did not undergo repeat PSA testing. Among patients with prostate cancer 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 102-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.

6.2 Postmarketing Experience
The following adverse reactions have been identified during post approval use of testosterone gel 1%. Because the reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure (Table 4).

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>
<th>Number (% of Patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular</td>
<td>Hypertension</td>
<td>5 (2.1%)</td>
</tr>
<tr>
<td>Respiratory</td>
<td>Acne</td>
<td>5 (2.1%)</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>Urinary tract</td>
<td>5 (2.1%)</td>
</tr>
<tr>
<td>General disorders</td>
<td>Urinary tract</td>
<td>5 (2.1%)</td>
</tr>
<tr>
<td>Neoplasms</td>
<td>Urinary tract</td>
<td>5 (2.1%)</td>
</tr>
<tr>
<td>Porotic disorders</td>
<td>Urinary tract</td>
<td>5 (2.1%)</td>
</tr>
<tr>
<td>Skin</td>
<td>Urinary tract</td>
<td>5 (2.1%)</td>
</tr>
<tr>
<td>Vascular disorders</td>
<td>Urinary tract</td>
<td>5 (2.1%)</td>
</tr>
</tbody>
</table>

6.3 Pharmacokinetic and Physiological Effects
This section 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.

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 hyperlipidemia. In the open-label period of the study (N=191), the most commonly reported adverse reaction (experienced by greater than 2% of patients) was increased PSA (0.9%, 2.1%) and urticaria. Other adverse reactions reported in less than or equal to 2% of patients included: increased hemoglobin or hematocrit, hypertension, acne, lipids decreased, insomnia, and luteinizing hormone.

During the 102-day, double-blind period of the clinical trial, 25 testosterone gel 1.62%-treated patients (10.7%) discontinued treatment because of adverse reactions. These adverse reactions included 17 patients with PSA increased and 1 report each of: hemorrhage increased, blood pressure increased, frequent urination, diarrhea, fatigue, paresthesia, dizziness, skin rash, and skin nodule (same patient – not in application site), vasomotor syncope, and diarrhea melanoma. During the 102-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 each of triglycerides increased and prostate cancer.

Applications of Testosterone Gel 1.62%
In the 102-day double-blind period of the study, application site reactions were reported in 3 patients (1.6%) and 2 patients (0.9%) in the placebo and testosterone gel 1.62% treatment groups, respectively. None of these subjects were discontinued from the study due to adverse reactions.

Table 2: Adverse Reactions in Patients in the 102-Day, Double-Blind Period of Testosterone Gel 1.62% Clinical Trial

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Number (% of Patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSA increased**</td>
<td>26 (11.5%)</td>
</tr>
<tr>
<td>Emotional lability**</td>
<td>6 (2.6%)</td>
</tr>
<tr>
<td>Hyperuricemia</td>
<td>5 (2.3%)</td>
</tr>
<tr>
<td>Hematuria or hemoglobin (increased)</td>
<td>5 (2.3%)</td>
</tr>
<tr>
<td>Contact dermatitis**</td>
<td>5 (2.3%)</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 2 measurements) as well as those reported as adverse events.

6.4 Patients Undergoing Prostate-Specific Antigen Testing
Repeat PSA testing is an essential part of the management of patients on androgens for the treatment of hypogonadal symptoms. Repeat PSA testing is performed at baseline and at regular intervals thereafter (see Dosage and Administration (2.1)).

6.5 Patients Undergoing Bone Density Studies
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.

6.6 Patients Undergoing Hematology Studies
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.

7 DRUG INTERACTIONS

Secondary Exposure to Testosterone in Children
Cases of secondary exposure to testosterone resulting in clinical evidence of childhood have been reported in postmarketing surveillance of testosterone gel products. Signs and symptoms of these reported cases included: enlargement of the clitoris (with surgical intervention) or the penis, development of pubic hair, increased erection and libido, aggressive behavior, and advanced bone age. In most cases, with a reported outcome, these signs and symptoms were reported to have resolved with removal of the testosterone gel exposure. In a few cases, however, enlarged genitalia did not fully return to age-appropriate normal size, and bone age remained moderately greater than chronological age. Because of the cases, direct contact with the sites of application on the skin of menstruating women was reported. In at least one reported case, the operator 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 (5.2)].
7.1 Indications
Changes in insulin sensitivity or glycemic control may occur in patients treated with androgens. In diabetic patients, the metabolic effects of androgens may decrease blood glucose and, therefore, may decrease insulin requirements.

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

7.3 Contraception
The concurrent use of testosterone with contraceptive barrier or systemic hormone (ACTH) or contraceptives 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 (6.1) and CLINICAL PHARMACOLOGY (12)].

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 female offspring. These studies did not meet current standards for nonclinical development toxicity studies.

Use in Animal Data
In developmental studies conducted in rats, rabbits, sheep and rhesus monkeys, pregnant animals received intramuscular injections of testosterone during the period of organogenesis. Testosterone treatment at doses that were compatible with those used for testosterone replacement therapy resulted in structural impairments in both female and male offspring. Structural impairments observed in females included increased ano-genital distance, phallic development, empty scrotum, no external vagina, immature growth retardation, reduced ovulation reserve, and increased ovarian follicular recruitment. Structural impairments seen in male offspring included increased testicular weight, larger seminal tubule luminal diameter, and higher frequency of occluded tubule lumen. Increased primary weight was seen in both sexes.

Testosterone exposure in utero also resulted in hormonal and behavioral changes in offspring. Hyperthymia was observed in pregnant female rats and their offspring exposed to doses approximately twice those used for testosterone replacement therapy.

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, testicular atrophy, and oligospermia have been identified during use of testosterone gel 1.62%.[see ADVERSE REACTIONS (6.2)].

During treatment with large doses of exogenous androgens, including testosterone gel 1.62%, spermatogenesis may be suppressed through feedback inhibition of the hypothalamic-pituitary-testicular axis.[see WARNINGS AND PRECAUTIONS (5.7)]. 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 reversible.

8.4 Pediatric Use

The safety and effectiveness of testosterone gel 1.62% in pediatric patients less than 18 years of age has not been established. Improved use may result in accelerated 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 236 patients enrolled in the clinical trial utilizing testosterone gel 1.62%, 21 were over 65 years of age. Additionally, there is insufficient long-term data in geriatric patients to assess the potentially increased risks of cardiovascular disease and prostate cancer.

Geriatric patients treated with testosterone 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 male and female adults and adolescents. Testosterone, either in combination with other anabolic anabolic steroids (SAS), and not obtained by prescription through a pharmacy, may be abused by athletes and bodybuilders. There have been reports of abuse by men taking 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, hyperglycemia, and very high serum liver failure, cerebrovascular accident, hypokalemia, and serious psychiatric manifestations, including major depression, mania, paranoia, psychosis, delusions, hallucinations, hostility and aggression.

The following adverse reactions have also been reported in men taking testosterone: acne, arrhythmias, headache, hypertension, anemia, thrombosis, and muscle cramps.

The following adverse reactions have been reported in men and female adolescents: premature closure of epiphyses with deleterious effects on bone growth and, therefore, may not be 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 dosages than prescribed
- Continued drug use despite medical and social problems due to drug use
- Spending significant time to obtain the drug and supplies of the drug are interrupted
- Giving a higher priority to drug use than other obligations
- Having difficulty 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 supertherapeutic doses of testosterone may experience withdrawal symptoms lasting for weeks or months which include depressed mood, major depression, fatigue, craving, restlessness, irritability, anorexia, insomnia, decreased libido, and hypogonadotropic hypogonadism.

Drug dependence in individuals using approved doses of testosterone for approved indications has not been documented.
In a randomized, 3-way (3 treatment periods without washout period) crossover study in 24 hypogonadal female subjects, testosterone gel 1.62% was applied once daily to the abdomen of the males. The males had not approved for testosterone gel 1.62%. Two (2) hours after application to the males on each day, female subjects rubbed their abdomens for 15 minutes to the abdomen of the males. The males had not approved for testosterone gel 1.62%. Eighty-one (81) mg when it was applied to abdomen only for 7 days, a site of application concentration. After application, female subjects rubbed their hands, wrists, arms, and shoulders to the site of application. Serum concentrations of testosterone were monitored in female subjects following once daily application to clean, dry, intact skin of the shoulders and upper arms. Two (2) hours after application, female subjects rubbed their hands, wrists, arms, and shoulders to the site of application. Mean testosterone C₅₀, maximal serum testosterone concentration after testosterone gel 1.62% was applied to the upper arms/shoulders were comparable to average serum testosterone concentrations (C₅₀) 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)).

Potential for testosterone transfer:
When testosterone gel 1.62% treatment is discontinued, serum testosterone concentrations return to baseline within 48 to 72 hours after administration of the last dose.

Absorption
Testosterone gel 1.62% provides transdermal delivery of testosterone for 24 hours following once daily application to clean, dry, intact skin of the shoulders and upper arms. Mean testosterone C₅₀, maximal serum testosterone concentration after testosterone gel 1.62% was applied to the upper arms/shoulders were comparable to average serum testosterone concentrations (C₅₀) 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)).

Mechanism of Action
Endogenous androgens, including testosterone and dihydrotestosterone (DHT), are responsible for the normal growth and development of the male sex organs and for maintenance of secondary sex characteristics. These effects include the growth and maturation of prostate, seminal vesicles, penis and scrotum; the development of male hair distribution, such as facial, pubic, chest and axillary hair; laryngeal enlargement; vocal chord thickening; and alterations in body musculature and fat distribution. Testosterone and DHT are necessary for the normal development of secondary sex characteristics.

Male hypogonadism, a clinical syndrome resulting from inadequate secretion of testosterone, has two main etiologies. Primary hypogonadism is caused by defects of the gonads, such as Klinefelter’s syndrome or Leydig cell aplasia, whereas secondary hypogonadism is that of the hypophysis (or pituitary) to produce sufficient gonadotropin (FSH, LH).

Pharmacodynamics
No specific pharmacodynamic studies were conducted using testosterone gel 1.62%.

Pharmacokinetics
Absorption
Testosterone gel 1.62% delivers physiologic amounts of testosterone, producing circulating testosterone concentrations that approximate normal levels (100 to 1000 ng/mL) seen in healthy men. Testosterone gel 1.62% provides continuous transdermal delivery of testosterone for 24 hours following once daily application to clean, dry, intact skin of the shoulders and upper arms. Mean testosterone C₅₀, maximal serum testosterone concentration after testosterone gel 1.62% was applied to the upper arms/shoulders were comparable to average serum testosterone concentrations (C₅₀) 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)).

Figure 2: Mean (SD) Serum Total Testosterone Concentrations on Day 7 in Patients Following Testosterone Gel 1.62% Once-Daily Application of 81 mg of Testosterone (N=35) for 7 Days

Distribution
Circulating testosterone is primarily bound to sex hormone-binding globulin (SHBG) and albumin. Approximately 40% of testosterone in plasma is bound to SHBG, 2% remains unbound (free) and the rest is loosely bound to albumin and other proteins.

Metabolism
Testosterone is metabolized in various 17-lactone steroids, two different pathways. The major active metabolites of testosterone are androstenedione and DHT.

Excretion
There is considerable variation in the half-life of testosterone concentration as reported in the literature, ranging from 10 to 100 minutes. About 90% of a dose of testosterone given intramuscularly is excreted in the urine as glucuronic acid and sulfuric acid conjugates of testosterone and its metabolites. About 6% of a dose is excreted in the feces, mostly in the unconjugated form. Inactivation is excreted in the urine as glucuronic acid and sulfuric acid conjugates of testosterone and its metabolites. About 6% of a dose is excreted in the feces, mostly in the unconjugated form.
The effect of hand-washing on testosterone exposure was assessed after once daily application of testosterone gel 1.62% in upper arms/shoulders for 7 days (treatment period). On the 7th 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 showing at 2 or 6 hours post-dose on Day 7 resulted in 13% and 12% decreases in Cmax, respectively, compared to Day 6 when shower was taken after drug application. Showering at 10 hours after drug administration had no effect on bioavailability. The amount of testosterone remaining in the outer layers of the stratum at the application site on the 7th day was assessed using a tape stripping procedure and was reduced by at least 10% after showering 2 to 10 hours post-dose compared to on the 6th day when a shower was taken after drug application.

**Effect of hand-washing**

In a randomized, placebo-controlled, single-arm, 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 hour of applying the gel, subjects either washed or did not wash their hands prior to study personnel wiping the subjects' hands with ethanol-damped 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) at 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 with washout period) crossover study in 10 hypogonadal males, the effect of applying a moisturizing lotion or a sunscreen on the absorption of testosterone was evaluated with the upper arms/shoulders as application sites. For 7 days, moisturizing lotions or sunscreens (SPF 30) were applied daily to the testosterone gel 1.62% applied 1 hour after the application of testosterone gel 1.62% 40.5 mg. Application of moisturizing lotion increased mean testosterone Cmax and Cavg by 14% and 13%, respectively, compared to testosterone gel 1.62% administered alone. Application of sunscreen increased mean testosterone Cmax and Cavg by 18% and 13%, respectively, compared to testosterone gel 1.62% administered alone.

12 NONCLINICAL TOXICOLOGY

13.3 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Testosterone has been associated with subcutaneous injection and implantation in mice and rats. In fact, the implant induced cervical-uterine tumors which mimicked in some cases. There is suggestive evidence that injection of testosterone into some strains of female mice increases their susceptibility to hepatomas. Testosterone is also known to increase the number of tumors and decrease the degree of differentiation of chemically induced carcinomas of the liver in rats.

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 was reversible 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 (12-day double-blind period) in 274 hypogonadal men with body mass index (BMI) 18 to 40 kg/m² and 18 to 80 years of age (mean age 53.5 years). The patients had average serum testosterone concentrations of 300 ng/dL, as determined by two morning samples collected on the same visit. Patients were Caucasian 63%, Black 13%, Asian or Native American 6%, 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) for the initial 14 days followed by possible titration according to the follow-up testosterone measurements.

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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Placebo (n=27)</th>
<th>20.25 mg (n=7)</th>
<th>40.5 mg (n=26)</th>
<th>60.75 mg (n=47)</th>
<th>81 mg (n=79)</th>
<th>All Active (n=136)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cavg (ng/mL)</td>
<td>583 (269)</td>
<td>500 (176)</td>
<td>540 (235)</td>
<td>557 (240)</td>
<td>561 (250)</td>
<td>545 (248)</td>
</tr>
<tr>
<td>Cmax (ng/mL)</td>
<td>1650 (849)</td>
<td>1457 (779)</td>
<td>1454 (726)</td>
<td>1455 (720)</td>
<td>1463 (736)</td>
<td>1459 (735)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Placebo (n=27)</th>
<th>20.25 mg (n=7)</th>
<th>40.5 mg (n=26)</th>
<th>60.75 mg (n=47)</th>
<th>81 mg (n=79)</th>
<th>All Active (n=136)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cavg (ng/mL)</td>
<td>386 (180)</td>
<td>474 (176)</td>
<td>513 (222)</td>
<td>542 (218)</td>
<td>565 (218)</td>
<td>542 (218)</td>
</tr>
<tr>
<td>Cmax (ng/mL)</td>
<td>752 (395)</td>
<td>715 (385)</td>
<td>789 (391)</td>
<td>814 (400)</td>
<td>847 (400)</td>
<td>845 (400)</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 45.5 mg of testosterone (2 pump actuations) for the initial 14 days followed by possible titration according to the follow-up testosterone measurements.
Figure 4: Mean (±SD) Steady-State Serum Total Testosterone Concentrations on Day 364

![Image]

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 were consistent with reports published in the literature of long-term treatment with testosterone.

16. HOW SUPPLIED AND HANDLING:
Testosterone Gel 1.62% is supplied innon-aerosol, 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 liner (face 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
8818-0944-11 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 25°C (77°F); excursions permitted to 15°C to 30°C (59°F 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 (5.5)).

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 (see WARNINGS AND PRECAUTIONS (5.2)). 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: accelerated 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 action.
- 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 utilization is identified.

Strict adherence to the following precautions is advised to minimize the potential for secondary exposure to testosterone or testosterone gel 1.62% in men (see MEDICATION GUIDE):

- Children and women should avoid contact with unwashed or unclothed skin to which testosterone gel 1.62% has been applied.
- 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.
- Breathtaking difficulties, including those associated with sleep, or excessive daytime sleepiness.
- Tinting or precipitation of the gums.
- Nausea, vomiting, changes in sleep, or restless sleeping.

17.4 Patient 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 alcoholvernacial 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 waiting 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 for:
Lupin Pharmaceuticals, Inc.
Baltimore, Maryland 21202
United States

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

Medication Guide
Testosterone Gel 1.62%, CIII (no TOS see use)

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

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

1. Early signs and symptoms of puberty have happened in young children who were accidentally exposed to testosterone through contact with men using testosterone gel 1.62%.

Signs and symptoms of early puberty in a child may include:
Testosterone gel 1.62% can transfer from your body to others.

2. Women and children should avoid contact with the uncased or unclothed area where testosterone gel 1.62% has been applied in your skin.

Signs and symptoms of exposure to testosterone gel 1.62% in women may include:
- enlarged penis or clitoris
- early development of pubic hair
- increased erections or sex drive
- aggressive behavior

Testosterone gel 1.62% can transfer from your body to others.

To lower the risk of transfer of testosterone gel 1.62% from your body to others, you should follow these important instructions:
- Apply testosterone gel 1.62% only to your shoulders and upper arms that will be covered by a short sleeve t-shirt.
- 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 woman or child makes contact with the testosterone gel 1.62% application area, that area should be washed well with soap and water.

Women and children should avoid contact with the unwashed or unclothed area where testosterone gel 1.62% has been applied.

Do not use testosterone gel 1.62% if you:
- have breast cancer
- have or might have prostate cancer
- are preganant. 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.

Talk to your healthcare provider before using this medicine if you have any of the above conditions.

What should I tell my healthcare provider before using testosterone gel 1.62%?

Before you use testosterone gel 1.62%, tell your healthcare provider if you:
- have breast cancer
- have or might have prostate cancer
- have urinary problem due to over-aged prostate
- have liver problems
- have kidney or liver problems
- have problem breathing while you sleep (sleep apnea)
- have any other medical conditions

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Using testosterone gel 1.62% with certain other medicines can affect each other.

Especially, tell your healthcare provider if you take:
- insulin
- medicines that decrease blood clotting
- corticosteroids

Know the medicines you take. Ask your healthcare provider or pharmacist for a list of all of your medicines, if you are not sure. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I use testosterone gel 1.62%?

It is important that you apply testosterone gel 1.62% exactly as your healthcare provider tells you. Your healthcare provider will tell you how much testosterone gel 1.62% to apply and when to apply it.

Your healthcare provider may change your testosterone gel 1.62% dose. Do not change your testosterone gel 1.62% dose without asking in your healthcare provider.

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. 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 knees.

Apply testosterone gel 1.62% at the same time each morning. Testosterone gel 1.62% should be applied after showering or bathing.

Wash your hands right away with soap and water after applying testosterone gel 1.62%.

Avoid swimming, swimming or bathing for at least 2 hours after you apply testosterone gel 1.62%.

Testosterone gel 1.62% is flammable until dry. Let testosterone gel 1.62% dry before smoking or going near an open flame.

Let the application site dry completely before putting on a shirt.

Applying testosterone gel 1.62%:

To use testosterone gel 1.62%:

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

The application sites for testosterone gel 1.62% are the upper arms and shoulders that will be covered by a short sleeve t-shirt (See 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 prime the pump. To prime the testosterone gel 1.62% pump, slowly push the pump all the way down 3 times. Do not use any testosterone gel 1.62% that came out while priming. Wash the device to avoid accidental exposure to others. Your testosterone gel 1.62% pump is now ready to use.
Find Your Dose as Prescribed by Your Healthcare Provider

Application Method

1 PUMP DEPRESSIONS
20.25 mg Apply 1 pump depression of testosterone gel 1.62% to 1 upper arm and shoulder.

2 PUMP DEPRESSIONS
40.50 mg Apply 2 pump depressions of testosterone gel 1.62% to upper arm and shoulder.

3 PUMP DEPRESSIONS
60.75 mg Apply 3 pump depressions of testosterone gel 1.62% to 1 upper arm and shoulder.

4 PUMP DEPRESSIONS
81 mg Apply 4 pump depressions of testosterone gel 1.62% to 1 upper arm and shoulder.

What are the possible side effects of testosterone gel 1.62%?

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

Testosterone gel 1.62% can cause serious side effects including:
• 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:
  o increased urination at night
  o trouble starting your urine stream
  o having to pass urine many times during the day
  o having an urge that you have to go to the bathroom right away
  o having a urine accident
  o 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%.
  • Swelling 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.
  • Edema or painful edema.
  • 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 (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 frequent than normal for you or annoying 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 the pump and the plastic container labeled "DO NOT REUSE" in the trash. Be careful to prevent accidental exposure of children or pets.

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.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Lupin Pharmaceuticals, Inc. at 1-800-399-2561 or visit our website at www.lupinpharmaceuticals.com.

What are the ingredients in testosterone gel 1.62%?

Active ingredient: testosterone USP

Inactive ingredients: carbomer homopolymer type C, dehydrated alcohol, isopropyl myristate, sodium hyaluronate and purified water.

This Medication Guide 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
Pihanpur (M.P.) – 454 775
India
March 2019
ID#: 260032

PACKAGE LABEL,PRINCIPAL DISPLAY PANEL
Testosterone Gel 1.62%, CIII – Carton Label

Testosterone Gel 1.62%, CIII – Carton Label

Testosterone Gel 1.62%, CIII – Container Label

Testosterone Gel 1.62%, CIII – Container Label

Testosterone Gel 1.62%, CIII – Container Label

Testosterone Gel 1.62%, CIII – Multi-dose pump capable of dispensing 60 metered pump actuations.
TESTOSTERONE
gel

Product Information

Product Type: HUMAN PRESCRIPTION DRUG
Item Code (Source): NDC: 68180-941

Route of Administration: TRANSDERMAL
DEA Schedule: CIII

Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>TESTOSTERONE</td>
<td>(UNII: 3XMK78S47O)</td>
<td>16.2 mg in 1 g</td>
</tr>
</tbody>
</table>

Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)</td>
<td></td>
</tr>
<tr>
<td>ALCOHOL (UNII: 3K9958V90M)</td>
<td></td>
</tr>
<tr>
<td>ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)</td>
<td></td>
</tr>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
<tr>
<td>SODIUM HYDROXIDE (UNII: 55X04QC32I)</td>
<td></td>
</tr>
</tbody>
</table>

Packaging

<table>
<thead>
<tr>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDC:68180-941-11</td>
<td>1 CARTON</td>
<td>04/10/2019</td>
<td></td>
</tr>
<tr>
<td>88 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Marketing Information

Marketing Category: ANDA
Application Number or Monograph Citation: ANDA208560
Marketing Start Date: 04/10/2019
Marketing End Date: |

Labeler - Lupin Pharmaceuticals, Inc.
Registrant - Lupin Atlantis Holdings SA
Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUPIN LIMITED</td>
<td>68180-941-11</td>
<td></td>
</tr>
</tbody>
</table>

Revised: 4/2019