HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use FORTESTA® safely and effectively. See full prescribing information for FORTESTA.

FORTESTA® (testosterone) Gel for topical use CIII
Initial U.S. Approval: 1953

WARNING: SECONDARY EXPOSURE TO TESTOSTERONE
See full prescribing information for complete boxed warning.

- **Virilization has been reported in children who were secondarily exposed to testosterone gel. (5.1, 6.2)**
- **Children should avoid contact with unwashed or unclothed application sites in men using FORTESTA. (2.2, 5.1)**
- **Healthcare providers should advise patients to strictly adhere to recommended instructions for use. (2.2, 5.1, 17)**

----------RECENT MAJOR CHANGES----------

Warnings and Precautions, Venous Thromboembolism (5.3)		07/2025
Warnings and Precautions, Blood Pressure Increases (5.5)		07/2025
Warnings and Precautions, Cardiovascular Risk (5.5)	Removed	07/2025

INDICATIONS AND USAGE

FORTESTA is an androgen indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired). (1)
- Hypogonadotropic hypogonadism (congenital or acquired). (1)

Limitations of Use

- Safety and efficacy of FORTESTA in men with "age-related hypogonadism" have not been established. (1)
- Safety and efficacy of FORTESTA in males less than 18 years old have not been established. (8.4)

DOSAGE AND ADMINISTRATION

- Prior to initiating FORTESTA, confirm the diagnosis of hypogonadism by ensuring that serum testosterone has been measured in the morning on at least two separate days and that these concentrations are below the normal range. (2)
- Starting dose of FORTESTA is 40 mg of testosterone (4 pump actuations) applied topically once daily in the morning. (2.1)
- Apply to clean, dry, intact skin of the thighs. Do not apply FORTESTA to the genitals or other parts of the body. (2.2)
- Dose adjustment: FORTESTA can be dose adjusted between a minimum of 10 mg of testosterone (1 pump actuation) and a maximum of 70 mg of testosterone (7 pump actuations) on the basis of total serum testosterone concentrations 2 hours post FORTESTA application. The dose should be titrated based on the serum testosterone concentration from a single blood draw 2 hours after applying FORTESTA at approximately 14 days and 35 days after starting treatment or following dose adjustment. In addition, serum testosterone concentration should be assessed periodically thereafter. (2.1)
- Patients should wash hands immediately with soap and water after applying FORTESTA and cover the application site with clothing after the gel has dried. Wash the application site thoroughly with soap and water prior to any situation where skin-to-skin contact of the application site with another person is anticipated. (2.2)
- FORTESTA is not substitutable with other topical testosterone products. (2.1)

DOSAGE FORMS AND STRENGTHS

- FORTESTA (testosterone) Gel is supplied as a metered-dose pump. One pump actuation delivers 10 mg of testosterone. (3)

CONTRAINDICATIONS

- Men with carcinoma of the breast or known or suspected prostate cancer. (4, 5.4)
- Women who are pregnant. Testosterone may cause fetal harm. (4, 5.7, 8.1, 8.2)

WARNINGS AND PRECAUTIONS

- Avoid unintentional exposure of women or children to FORTESTA. Secondary exposure to testosterone can produce signs of virilization. FORTESTA should be discontinued until the cause of virilization is identified. (5.1)
- Venous thromboembolism (VTE), VTE, including deep vein thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients using testosterone products. Evaluate patients with signs or symptoms consistent with DVT or PE. (5.3)
- Worsening of Benign Prostatic Hyperplasia (BPH) and Potential Risk of Prostate Cancer: Monitor patients with benign prostatic hyperplasia (BPH) for worsening of signs and symptoms of BPH. (5.4)
- Blood Pressure Increases: Testosterone can increase blood pressure, which can increase cardiovascular risk over time. Measure blood pressure periodically. Not recommended for use in men with uncontrolled hypertension (5.5)
- Abuse of Testosterone: Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication and in combination with other anabolic androgenic steroids (5.6).
- Potential for Adverse Effects on Spermatogenesis:
- Exogenous administration of androgens may lead to azoospermia. (5.8)
- Edema with or without congestive heart failure (CHF) may be a complication in patients with pre-existing cardiac, renal, or hepatic disease. (5.10)
- Sleep apnea may occur in those with risk factors. (5.12)
- Monitor serum testosterone, prostate specific antigen (PSA), hemoglobin, hematocrit, liver function tests and lipid concentrations periodically. (5.2, 5.4, 5.9, 5.13)
- FORTESTA is flammable until dry. (5.16)

ADVERSE REACTIONS

The most common adverse reaction (incidence ≥ 3%) is skin reactions at the application site (16.1%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Endo at 1-800-462-3636 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Androgens may decrease blood glucose and therefore may decrease insulin requirements in diabetic patients. (7.1)
- Changes in anticoagulant activity may be seen with androgens. More frequent monitoring of International Normalized Ratio (INR) and prothrombin time is recommended. (7.2)
- Use of testosterone with adrenocorticotropic hormone (ACTH) or corticosteroids may result in increased fluid retention. Use with caution, particularly in patients with cardiac, renal or hepatic disease. (7.3)

USE IN SPECIFIC POPULATIONS

There are insufficient long-term safety data in geriatric patients using FORTESTA to assess the potential risks of cardiovascular disease and prostate cancer. (8.5)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 07/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

***Sections or subsections omitted from the full prescribing information are not listed.**

FULL PRESCRIBING INFORMATION

WARNING: SECONDARY EXPOSURE TO TESTOSTERONE

- **Virilization has been reported in children who were secondarily exposed to testosterone gel *[see Warnings and Precautions (5.1) and Adverse Reactions (6.2)]*.**
- **Children should avoid contact with unwashed or unclothed application sites in men using FORTESTA *[see Dosage and Administration (2.2) and Warnings and Precautions (5.1)]*.**
- **Healthcare providers should advise patients to strictly adhere to recommended instructions for use *[see Dosage and Administration (2.2), Warnings and Precautions (5.1), and Patient Counseling Information (17)]*.**

1 INDICATIONS AND USAGE

FORTESTA is indicated for replacement therapy in 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, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol, heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle stimulating hormone [FSH] and luteinizing hormone [LH]) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired) – gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low serum testosterone concentrations but have gonadotropins in the normal or low range.

Limitations of Use

- Safety and efficacy of FORTESTA in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.
- Safety and efficacy of FORTESTA in males <18 years old have not been established *[see Use in Specific Populations (8.4)]*.

2 DOSAGE AND ADMINISTRATION

Prior to initiating, FORTESTA confirm the diagnosis of hypogonadism by ensuring that serum testosterone concentrations have been measured in the morning on at least 2 separate days and that these serum testosterone concentrations are below the normal range.

2.1 Dosing and Dose Adjustment

The recommended starting dose of FORTESTA is 40 mg of testosterone (4 pump actuations) applied once daily to the thighs in the morning. The dose can be adjusted between a minimum of 10 mg of testosterone and a maximum of 70 mg of testosterone. To ensure proper dosing, the dose should be titrated based on the serum testosterone concentration from a single blood draw 2 hours after applying FORTESTA at approximately 14 days and 35 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

Total Serum Testosterone Concentration 2 hours Post FORTESTA Application	Dose Titration
Equal to or greater than 2,500 ng/dL	Decrease daily dose by 20 mg (2 pump actuations)
Equal to or greater than 1,250 and less than 2,500 ng/dL	Decrease daily dose by 10 mg (1 pump actuation)
Equal to or greater than 500 and less than 1,250 ng/dL	No change: continue on current dose
Less than 500 ng/dL	Increase daily dose by 10 mg (1 pump actuation)

The application site and dose of FORTESTA are not substitutable with other topical testosterone products.

2.2 Administration Instructions

FORTESTA should be applied directly to clean, dry, intact skin of the front and inner thighs. Do not apply FORTESTA to the genitals or other parts of the body. Patients should be instructed to use one finger to gently rub FORTESTA evenly onto the front and inner area of each thigh as directed in Table 2.

Table 2: Application of FORTESTA

Total Dose of Testosterone	Total Pump Actuations	Pump Actuations per Thigh	
		Thigh #1	Thigh #2
10 mg	1	1	0
20 mg	2	1	1
30 mg	3	2	1
40 mg	4	2	2
50 mg	5	3	2
60 mg	6	3	3
70 mg	7	4	3

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 applying the gel to the thigh adjacent to the scrotum. Avoid fire, flames, or smoking until the gel has dried since alcohol based products, including FORTESTA, 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 eight times. The first 3 actuations may result in no discharge of gel. Safely discard the gel from the first 8 actuations. It is only necessary to prime the pump before the first dose.

Strict adherence to the following precautions is advised in order to minimize the potential for secondary exposure to testosterone from FORTESTA-treated skin:

- Children and women should avoid contact with unwashed or unclothed application site(s) of men using FORTESTA.
- FORTESTA should only be applied to the front and inner thighs (area of application should be limited to the area that will be covered by the patient's shorts or pants).
- Patients should wash their hands immediately with soap and water after applying FORTESTA.
- Patients should cover the application site(s) with clothing (eg, shorts of sufficient length or pants) after the gel has dried.
- Prior to any situation in which skin-to-skin contact with the application site 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 to which FORTESTA has been applied comes in direct 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.

3 DOSAGE FORMS AND STRENGTHS

FORTESTA (testosterone) Gel for topical use only, is supplied in a metered-dose pump. One (1) pump actuation delivers 10 mg of testosterone.

4 CONTRAINDICATIONS

- FORTESTA is contraindicated in men with carcinoma of the breast or known or suspected carcinoma of the prostate *[see Warnings and Precautions (5.4) and Adverse Reactions (6.1)]*.
- FORTESTA is contraindicated in women who are pregnant. Testosterone can cause virilization of the female fetus when administered to a pregnant woman *[see Use in Specific Populations (8.1, 8.2)]*.

5 WARNINGS AND PRECAUTIONS

5.1 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 regressed 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 modestly greater than chronological age. The risk of transfer was increased in some of these cases by not adhering to precautions for the appropriate use of the topical testosterone product. Children and women should avoid contact with unwashed or unclothed application sites in men using FORTESTA *[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 libido in children, 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.

5.2 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.

5.3 Venous Thromboembolism (VTE)

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 FORTESTA.

In the Testosterone Replacement therapy for Assessment of long-term Vascular Events and efficacy ResponSE in hypogonadal men (TRAVERSE) Study, a randomized, double-blind, placebo-controlled, cardiovascular (CV) outcomes study, compared to placebo, topical testosterone gel was associated with a numerically higher incidence of VTE (1.7% vs 1.2%) which included DVT (0.6% vs 0.5%) and PE events (0.9% vs 0.5%) *[see Adverse Reactions (6.1)]*.

Evaluate patients who report symptoms of pain, edema, warmth and 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 FORTESTA and initiate appropriate workup and management.

5.4 Worsening of Benign Prostatic Hyperplasia (BPH) and Potential Risk of Prostate Cancer

- Patients with BPH treated with androgens are at an increased risk of 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 the patients for the presence of prostate cancer prior to initiating and during treatment with androgens is appropriate *[see Contraindications (4)]*.

5.5 Blood Pressure Increases

FORTESTA can increase blood pressure. In an ambulatory blood pressure monitoring (ABPM) study, FORTESTA increased the mean systolic/diastolic blood pressure by 3.1/1.2 mm Hg from baseline after 16 weeks of treatment. In patients with hypertension on antihypertensive therapy, FORTESTA increased the mean systolic/diastolic BP by 4.0/1.3 mm Hg from baseline. Blood pressure increases can increase cardiovascular (CV) risk over time.

The CV risk associated with topical testosterone gel was evaluated in TRAVERSE, a randomized, double-blind, placebo-controlled, CV outcomes study in men with a history of CV disease or multiple CV risk factors. In TRAVERSE, topical testosterone gel increased mean systolic blood pressure by 1.0 mm Hg from baseline to 36 months, whereas a mean decrease from baseline of 0.5 mm Hg was observed in the placebo group at this timepoint, for a mean between-group difference of 1.5 mm Hg. However, the incidences of major adverse cardiovascular events (MACE), including cardiovascular death, non-fatal myocardial infarction [MI] and non-fatal stroke, were similar between treatment groups (7% for topical testosterone gel vs 7.3% for placebo) *[See Adverse Reactions (6.1)]*.

Monitor blood pressure periodically in men using FORTESTA, especially men with hypertension. FORTESTA is not recommended for use in patients with hypertension.

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 can lead to serious cardiovascular and psychiatric adverse reactions *[see Drug Abuse and Dependence (9)]*.

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

5.7 Not for Use in Women

Due to the lack of controlled evaluations in women and potential virilizing effects, FORTESTA 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 Spermatogenesis

With large doses of exogenous androgens, including FORTESTA, spermatogenesis may be suppressed through feedback inhibition of pituitary FSH which could possibly lead to adverse effects on semen parameters including sperm count.

5.9 Hepatic Adverse Effects

Prolonged use of high doses of orally active 17-alpha-alkyl androgens (eg, methyltestosterone) has been associated with serious hepatic adverse effects (peliosis hepatis, hepatic neoplasms, cholestatic hepatitis, and jaundice). Peliosis hepatis can be a life-threatening or fatal complication. Long-term therapy with testosterone enanthate has produced multiple hepatic adenomas. FORTESTA is not known to cause these adverse effects.

5.10 Edema

Androgens, including FORTESTA, 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 FORTESTA, 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 Lipid Changes

Changes in serum lipid profile may require dose adjustment or discontinuation of testosterone therapy, such as FORTESTA. Monitor the lipid profile periodically, particularly after starting testosterone therapy.

5.14 Hypercalcemia

Androgens, including FORTESTA, 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.

5.15 Decreased Thyroxine-binding Globulin

Androgens, including FORTESTA, may decrease concentrations of thyroxin-binding globulins, resulting in decreased total T4 serum concentrations and increased resin uptake of T3 and T4. Free thyroid hormone concentrations remain unchanged, however, and there is no clinical evidence of thyroid dysfunction.

5.16 Flammability

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

6 ADVERSE REACTIONS

6.1 Clinical Trial 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 clinical practice.

In a controlled multicenter, open-label, non-comparative 90-day clinical study, 149 hypogonadal patients were treated with FORTESTA *[see Clinical Studies (14.1)]*. Adverse reactions occurred in 22.8% (34/149) of patients. The most common adverse reaction reported in this study was skin reactions associated with the site of application (16.1%; 24/149) of which 79% (19/24) were mild and the remainder were moderate (21%; 5/24) (Table 3).

Table 3: Adverse Reactions Reported in >1% of Patients in the US Phase 3 Clinical Trial of FORTESTA

Adverse Reaction	Number (%) of Patients N = 149
Skin reaction	24 (16.1%)
Prostatic specific antigen increased	2 (1.3%)
Abnormal dreams	2 (1.3%)

During the 90-day trial 5 patients (3.4%) discontinued treatment because of adverse reactions. These reactions were: 1 patient with contact dermatitis (considered probably related to FORTESTA application), 1 with application site reaction (considered probably related to FORTESTA application), 1 with gastrointestinal hypomotility (considered possibly related to FORTESTA application), 1 with severe dyspnea (considered not related to FORTESTA application), and 1 with moderate contusion (considered not related to FORTESTA application).

Blood Pressure Increases

In a 4-month clinical study, 24-hour ambulatory blood pressure monitoring (ABPM) was conducted on 223 patients. ABPM was conducted at baseline and at Week 16 of FORTESTA therapy. A total of 92 patients had acceptable ABPM recordings at both baseline and Week 16

and were at least 85% compliant with study drug. In that group, the mean change in 24-hour systolic blood pressure (BP) and diastolic BP from baseline to end-of-treatment at Week 16 (n=92) was 3.1 mm Hg (95% CI 0.9, 5.3) and 1.2 mm Hg (95% CI -0.1, 2.5), respectively. In patients with a history of hypertension who were receiving antihypertensive therapy, the mean ABPM systolic and diastolic BP increased by 4.0 mm Hg [95% CI 0.3, 7.8] and 1.3 mm Hg [95% CI -0.9, 3.4], respectively [n=42]). In patients with no history of hypertension, the mean systolic and diastolic blood pressure increased by 1.5 mm Hg [95% CI -1.1, 4.1] and 0.6 mm Hg [95% CI -1.0, 2.1], respectively [n=45].

One patient (1.1 %) on FORTESTA, who was receiving antihypertensive medications at baseline, either started new antihypertensive medications (n=1) or had their antihypertensive medication regimen adjusted (n=0) during the ABPM study.

Of the 223 patients in the ABPM study who used FORTESTA, 7 patients (3.1%) were reported to have either an adverse reaction of hypertension (5 patients, 2.2%) or increased blood pressure (2 patients, 0.9%).

Cardiovascular Outcomes

TRAVERSE was a randomized, double-blind, cardiovascular outcomes study to assess the cardiovascular (CV) safety of topical testosterone gel compared to placebo in 5198 hypogonadal men aged 45 to 80 years with a history of CV disease or with multiple CV risk factors. The primary outcome was the incidence of the composite endpoint of major adverse cardiovascular events (MACE), consisting of CV death, non-fatal myocardial infarction (MI), and non-fatal stroke.

The mean duration of therapy was approximately 22 months. The mean duration of follow-up was 33 months. Approximately 61% of all patients discontinued topical testosterone gel or placebo therapy.

The mean patient age (±SD) was 63.3 (7.9) years, with 2452 patients aged 65 years or more (47%); 2847 (about 55%) patients had pre-existing cardiovascular disease, whereas 2357 patients (about 45%) had an elevated cardiovascular risk at baseline, and mean BMI was 35kg/m^2. Approximately 80% of patients were White, 17% were Black, and 3% were of other races or ethnic groups. Approximately 69%, 84%, and 93% had diabetes mellitus, hyperlipidemia, and hypertension, respectively.

The mean serum testosterone concentration at baseline in patients receiving topical testosterone gel was 220.4 ng/dL (n=2596). The mean serum testosterone concentrations at 12 months, 24 months, 36 months, and 48 months in patients receiving topical testosterone gel were 440.5 ng/dL (n=1683), 420.9 ng/dl (n=1125), 428.7 ng/dL (n=731), and 365.2 ng/dL (n=220), respectively.

For patients treated with topical testosterone gel, the incidence of MACE was 7.0% (n=182 events) and for those receiving placebo, the incidence of MACE was 7.3% (n=190 events). The study demonstrated non-inferiority of topical testosterone gel versus placebo because the upper bound of 95% CI was less than the pre-specified risk margin, of 1.5 for MACE (Hazard Ratio 0.96 [95% CI: 0.78, 1.17]).

Additional Adverse Reactions Reported in TRAVERSE

Additional adverse reactions reported in TRAVERSE at an incidence rate >2% in either treatment group and greater in topical testosterone gel versus placebo included: nonfatal arrythmias warranting intervention (5.2% vs 3.3%), atrial fibrillation (3.5% vs 2.4%), acute kidney injury (2.3% vs 1.5%) and bone fracture (3.5% vs 2.5%). For the adverse reaction of bone fracture, each event was adjudicated by clinical review.

6.2 Postmarketing Experience

The following adverse reactions have been identified during post approval use of FORTESTA. Because these 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 Drug Reactions from Post Approval Experience of FORTESTA by System Organ Class

System Organ Class	Adverse Reaction
Blood and lymphatic system disorders	Polycythemia
Eye disorders	Vitreous detachment
Gastrointestinal disorders	Abdominal symptoms
General disorders and administrative site conditions	Application site erythema, irritation, pruritus, and swelling; fatigue, influenza like illness, and malaise
Investigations	Decreased serum testosterone, increased hematocrit and hemoglobin
Musculoskeletal and connective tissue disorders	Pain in extremity
Nervous system disorders	Dizziness, headache, and migraine
Reproductive system and breast disorders	Erectile dysfunction and priapism
Skin and subcutaneous tissue disorders	Allergic dermatitis, erythema, rash, and papular rash
Vascular disorders	Venous thromboembolism
Cardiovascular disorders	Myocardial infarction and stroke

Secondary Exposure to Testosterone in Children

Cases of secondary exposure to testosterone resulting in virilization of children have been reported in postmarketing surveillance of testosterone gel products. Signs and symptoms of these reported cases have included enlargement of the clitoris (with surgical intervention) or the penis, development of pubic hair, increased erections and libido, aggressive behavior, and advanced bone age. In most cases with a reported outcome, these signs and symptoms were reported to have regressed 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 modestly greater than chronological age. In some of the cases, direct contact with the sites of application on the skin of men using testosterone gel was reported. In at least 1 reported case, the reporter

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 (5.1)]*.

7 DRUG INTERACTIONS

7.1 Insulin

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 Corticosteroids

The concurrent administration 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

FORTESTA is contraindicated in pregnant women. Testosterone is teratogenic and may cause fetal harm 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 female and male offspring. These studies did not meet current standards for nonclinical development toxicity studies.

Data

Animal Data

In developmental studies conducted in rats, rabbits, pigs, sheep, and rhesus monkeys, pregnant animals received intramuscular injection of testosterone during the period of organogenesis. Testosterone treatment at doses that were comparable to those used for testosterone replacement therapy resulted in structural impairments in both female and male offspring. Structural impairments observed in females included increased anogenital distance, phallus development, empty scrotum, no external vagina, intrauterine growth retardation, reduced ovarian reserve, and

increased ovarian follicular recruitment. Structural impairments seen in male offspring included increased testicular weight, larger seminal tubular lumen diameter, and higher frequency of occluded tubule lumen. Increased pituitary weight was seen in both sexes.

Testosterone exposure in utero also resulted in hormonal and behavioral changes in offspring. Hypertension 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

FORTESTA is not indicated for use in females.

8.3 Females and Males of Reproductive Potential

Infertility

During treatment with large doses of exogenous androgens, including FORTESTA, spermatogenesis may be suppressed through feedback inhibition of the hypothalamic-pituitary-testicular axis *[see Warnings and Precautions (5.8)]*, possibly leading to adverse effects on semen parameters including sperm count. Reduced fertility is observed in some 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 efficacy of FORTESTA in pediatric patients <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 FORTESTA to determine whether efficacy in those over 65 years of age differs from younger subjects. Of the 149 patients enrolled in the pivotal clinical study utilizing FORTESTA, 20 were over 65 years of age. Additionally, there are insufficient long-term safety data in geriatric patients to assess the potential risks of cardiovascular disease and prostate cancer.

Geriatric patients treated with androgens may also be at risk for worsening of signs and symptoms of BPH.

8.6 Renal Impairment

No studies were conducted in 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

FORTESTA 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, often in combination with other anabolic androgenic steroids (AAS), and not obtained by prescription through a pharmacy, may be abused by athletes and bodybuilders. There have been reports of misuse of 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, hypertrophic cardiomyopathy, congestive heart failure, cerebrovascular accident, hepatotoxicity, 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: transient ischemic attacks, convulsions, hypomania, irritability, dyslipidemias, testicular atrophy, subfertility, and infertility.

The following additional adverse reactions have been reported in women: hirsutism, virilization, deepening of voice, clitoral enlargement, breast atrophy, male-pattern baldness, and menstrual irregularities.

The following adverse reactions have been reported in male and female adolescents: premature closure of bony epiphyses 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

Continued 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 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, 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.

10 OVERDOSAGE

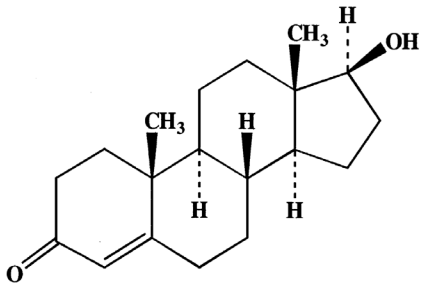
There is a single report of acute overdosage after parenteral administration of an approved testosterone product in the literature. This subject had serum testosterone concentrations of up to 11,400 ng/dL, which were implicated in a cerebrovascular accident. There were no reports of overdose in the FORTESTA clinical trial.

Treatment of overdosage would consist of discontinuation of FORTESTA, washing the application site with soap and water, and appropriate symptomatic and supportive care.

11 DESCRIPTION

FORTESTA is a clear, colorless, odorless, gel containing testosterone. The product may attain slightly yellow color during its shelf-life. FORTESTA is available in a metered-dose pump. Each pump actuation provides 10 mg of testosterone and each container is capable of dispensing 120 pump actuations. One (1) pump actuation dispenses 0.5 g of gel.

The active pharmacologic ingredient in FORTESTA is testosterone. Testosterone USP is a white to almost white powder described chemically as 17-beta hydroxyandrost-4-en-3-one.



Testosterone

$C_{19}H_{28}O_2$ MW 288.42

Pharmacologically inactive ingredients in FORTESTA are: propylene glycol, purified water, ethanol, 2-propanol, oleic acid, carbomer 1382, triethanolamine, and butylated hydroxytoluene.

12 CLINICAL PHARMACOLOGY

12.1 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 the maintenance of secondary sex characteristics. These effects include the growth and maturation of the prostate, seminal vesicles, penis, and scrotum; the development of male hair distribution, such as facial, pubic, chest, and axillary hair; laryngeal enlargement; vocal cord 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 insufficient secretion of testosterone, has 2 main etiologies. Primary hypogonadism is caused by defects of the gonads, such as Klinefelter's syndrome or Leydig cell aplasia, whereas secondary hypogonadism is the failure of the hypothalamus or pituitary to produce sufficient gonadotropins (FSH, LH).

12.2 Pharmacodynamics

No specific pharmacodynamic studies were conducted using FORTESTA.

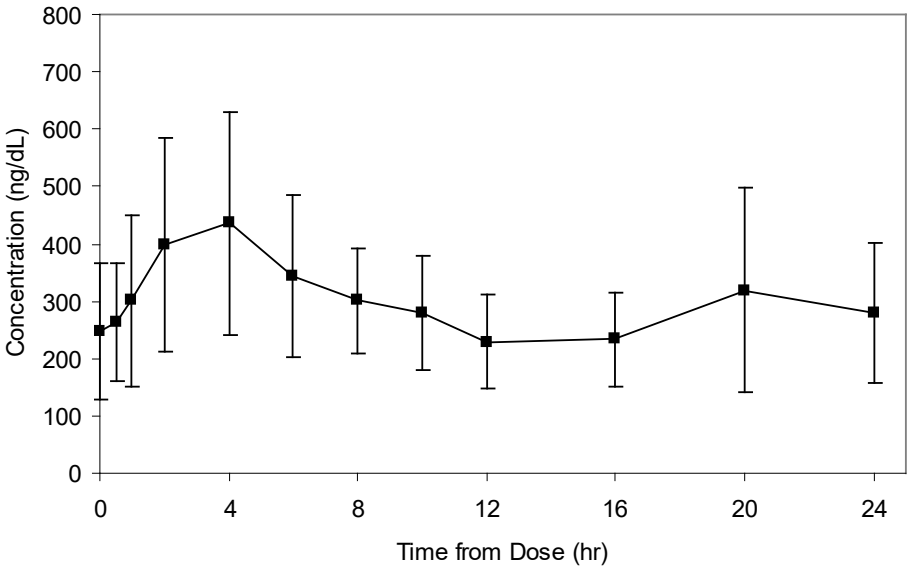
12.3 Pharmacokinetics

Absorption

FORTESTA delivers physiologic amounts of testosterone, producing serum testosterone concentrations that approximate normal concentrations (> 300 ng/dL) seen in healthy men.

FORTESTA provides continuous transdermal delivery of testosterone for 24 hours following a single application to clean, dry, intact skin of the front and inner thighs (Figure 1).

Figure 1: Mean (±SD) Serum Total Testosterone Concentrations on Day 7 in Patients Following FORTESTA Once-Daily Application of 40 mg of Testosterone (N=12)



Distribution

Circulating testosterone is primarily bound in the serum 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 to various 17-keto steroids through 2 different pathways. The major active metabolites of testosterone are estradiol 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% is excreted in the feces, mostly in the unconjugated form. Inactivation of testosterone occurs primarily in the liver.

Potential for Testosterone Transfer

The potential for testosterone transfer from healthy males dosed with FORTESTA to healthy females was evaluated in a placebo-controlled, 3-way crossover study. The washout period was approximately 29 days. Six (6) males were treated with either FORTESTA (30 mg testosterone) or placebo to 1 thigh only. At 2 hours after the application of FORTESTA to males, the females rubbed their forearms for 15 minutes on the thigh of the males. Serum concentrations of testosterone were monitored in females for 24 hours after the transfer procedure. When direct skin-to-skin transfer occurred with FORTESTA mean average concentration (C_{avg}) increased

by 134% and mean maximum concentration (C_{max}) increased by 191%, compared to direct skin-to-skin transfer with placebo. When transfer occurred with FORTESTA while covering a thigh with boxer shorts, mean C_{avg} decreased by 3% and mean C_{max} increased by 2%, compared to direct skin-to-skin transfer with placebo *[see Dosage and Administration (2.2)]*.

Effect of Showering

In a 2-way crossover study, the effects of showering on the pharmacokinetics of total testosterone following application of FORTESTA (30 mg testosterone to each thigh; total 60 mg testosterone) were assessed in 7 hypogonadal males. There were two 7-day treatment phases, with showering 2 hours post FORTESTA application, and without showering on Day 7 of each treatment phase. Showering decreased C_{avg} by 3% and it increased C_{max} by 13% *[see Dosage and Administration (2.2)]*.

Effect of Hand Washing and Application Site (Inner Thigh) Washing

In an open-label, single-dose study, the amount of residual testosterone on the application finger and application site after washing was evaluated in 12 healthy male subjects. Prior to application of FORTESTA, each index finger and each intended application site (left and right front and inner thighs) was wiped using dry sponges to assess baseline skin testosterone. Subjects then used each index finger to rub FORTESTA (40 mg testosterone) onto each inner thigh. On one side, the index finger was immediately wiped using dry sponges to collect residual testosterone. On the other side, each subject washed their hands with liquid soap and warm tap water immediately after drug application, then wipe the index finger using dry sponges to collect residual testosterone. A mean (SD) of 0.002 (0.006) mg of residual testosterone (ie, 99.8% reduction compared to when hand was not washed) was recovered after washing hands with liquid soap and warm tap water.

Two (2) hours after the application of FORTESTA onto each inner thigh, one thigh was wiped using dry sponges. On the other thigh, the application site was washed with liquid soap and warm tap water, dried, and then wiped using dry sponges. The sponges were assayed for testosterone. A mean (SD) of 0.24 (0.009) mg of residual testosterone (ie, 94.3% reduction compared to when application site was not washed) was recovered after application site washing.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Testosterone has been tested by subcutaneous injection and implantation in mice and rats. In mice, implant-induced cervical-uterine tumors metastasized in some cases. There is suggestive evidence that injection of testosterone into some strains of female mice increases their susceptibility to hepatoma. 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 the in vivo mouse micronucleus assays.

Impairment of Fertility

The administration of exogenous testosterone has been reported to suppress spermatogenesis in the rat, dog, and non-human primates, which was reversible on cessation of the treatment.

14 CLINICAL STUDIES

14.1 Clinical Study in Hypogonadal Males

FORTESTA was evaluated in a multicenter, 90-day open-label, non-comparative trial of 149 hypogonadal males with body mass index (BMI) ≥ 22 kg/m^2 and < 35 kg/m^2 and 18 to 75 years of age (mean age 54.5 years). The patients were screened for a single serum total testosterone concentration < 250 ng/dL, or 2 consecutive serum total testosterone concentrations < 300 ng/dL. Patients were Caucasian (80.5%), black (10.1%), Hispanic (7.4%), and other (2.0%).

FORTESTA was applied once each morning to the thighs at a starting dose of 40 mg of testosterone (4 pump actuations) per day. The dose was adjusted between a minimum of 10 mg and a maximum of 70 mg testosterone on the basis of total serum testosterone concentration obtained 2 hours post FORTESTA application on Days 14, 35, and 60 (± 3 days).

The primary endpoint was the percentage of patients with C_{avg} within the normal range (greater than or equal to 300 ng/dL and less than or equal to 1140 ng/dL) on Day 90. In patients treated with FORTESTA, 77.5% (100/129) had C_{avg} within the normal range on Day 90. The secondary endpoint was the percentage of patients with C_{max} above 3 pre-determined limits. The percentages of patients with C_{max} greater than 1500 ng/dL, and between 1800 and 2499 ng/dL on Day 90 were 5.4% and 1.6%, respectively. No patient had a C_{max} greater than or equal to 2500 ng/dL on Day 90.

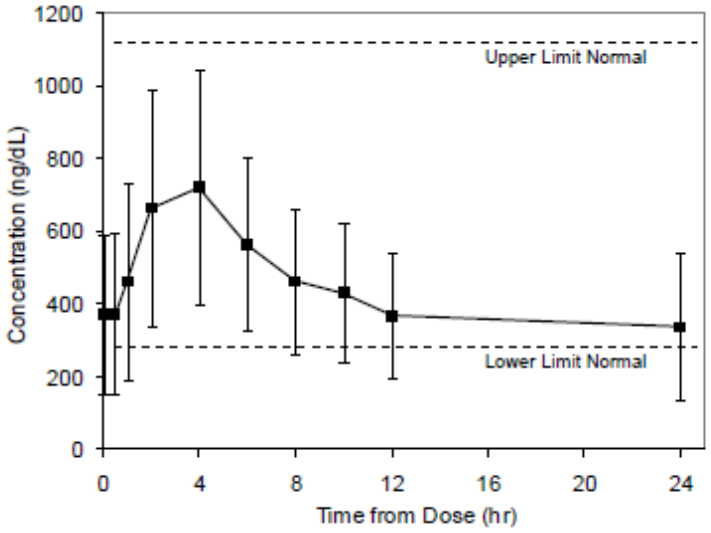
Dose titrations on Days 14, 35, and 60 resulted in mean (SD) C_{avg} and C_{max} for final doses of 10 mg to 70 mg on Day 90 shown in Table 5.

Table 5: Mean (±SD) Steady-State Testosterone Concentrations (C_{avg} and C_{max}) by Final Dose on Day 90

		Final Dose						
		10mg (n=1)	**20mg (n=6)**	**30mg (n=16)**	**40mg (n=30)**	**50mg (n=26)**	**60mg (n=27)**	**70mg (n=23)**
C_{avg} (ng/dL)	Mean	196	464	392	444	483	441	415
	SD		205	164	176	156	163	136
C_{max} (ng/dL)	Mean	503	971	775	855	964	766	724
	SD		399	278	417	389	292	313

Figure 2 summarizes the pharmacokinetic profiles of total testosterone in patients completing 90 days of FORTESTA treatment administered as 40 mg of testosterone once-daily for the initial 14 days followed by possible titration according to follow-up testosterone measurements.

Figure 2: Mean (±SD) Steady-State Serum Total Testosterone Concentrations on Day 90 (N=129)



Additionally, there were no clinically significant changes from baseline for SHBG (slight decrease), estradiol (slight increase), and ratio of DHT to total testosterone (slight increase) at Day 90.

16 HOW SUPPLIED/STORAGE AND HANDLING

FORTESTA is supplied in 60 g canisters with a metered dose pump that delivers 10 mg of testosterone per complete pump actuation. The metered dose pump is capable of dispensing 120 metered pump actuations. One (1) pump actuation dispenses 0.5 g of gel.

FORTESTA is available in packages of 1, 2, and 3 canisters (NDC 63481-183-16, NDC 63481-183-17, and NDC 63481-183-18, respectively).

Store at controlled room temperature 20°C-25°C (68°F-77°F); excursions permitted to 15°C to 30°C (59°Fto 86°F). [See USP]. Do Not Freeze.

Used FORTESTA canisters should be discarded in household trash in a manner that prevents accidental application or ingestion by children or pets.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Patients should be informed of the following information:

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 FORTESTA *[see Contraindications (4) and Warnings and Precautions (5.4)]*.

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

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

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

- In children; unexpected sexual development including inappropriate enlargement of the penis or clitoris, premature development of pubic hair, increased erections, and aggressive behavior.
- In women; changes in hair distribution, increase in acne, or other signs of testosterone effects.
- The possibility of secondary exposure to FORTESTA should be brought to the attention of a healthcare provider.
- FORTESTA 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 FORTESTA in men *[see Medication Guide]*:

- **Children and women should avoid contact with unwashed or unclothed application site(s)** of men using FORTESTA.
- Patients using FORTESTA should apply the product as directed and strictly adhere to the following:
  - **Wash hands** with soap and water 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 FORTESTA 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 (5.1), 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 your urine stream, passing urine many times during the day, having an urge that you have to go to the bathroom right away, having a urine accident, being unable to pass urine, and weak urine flow.

- Breathing disturbances, including those associated with sleep, or excessive daytime sleepiness.
- Too frequent or persistent erections of the penis.
- Nausea, vomiting, changes in skin color, or ankle swelling.
- Venous thromboembolism, the signs and symptoms of which may include lower limb pain, edema, or erythema; dyspnea; or chest pain.
- Increased blood pressure that can increase cardiovascular risk over time.

17.4 Patients Should Be Advised of the Following Instructions for Use

- **Read the Medication Guide before starting FORTESTA therapy and reread it each time the prescription is renewed.**
- **FORTESTA should be applied and used appropriately to maximize the benefits and to minimize the risk of secondary exposure in children and women.**
- Keep FORTESTA out of the reach of children.
- **FORTESTA 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 signs and symptoms of venous thromboembolism, changes in urinary habits, breathing, sleep, and mood.
- Be aware of the importance of monitoring BP periodically while on FORTESTA. If BP increases while on FORTESTA, antihypertensive medications may need to be started, added, or adjusted, or FORTESTA may need to be discontinued.
- FORTESTA is prescribed to meet the patient's specific needs, therefore, the patient should never share FORTESTA with anyone.
- Wait 2 hours before swimming or washing following application of FORTESTA. This will ensure that the greatest amount of FORTESTA is absorbed into their system.

Manufactured by: Pharbil Waltrop GmbH, Im Wirrigen 25, 45731 Waltrop, Germany

Manufactured for: Endo USA, Malvern, PA 19355

Revised: 07/2025

MEDICATION GUIDE

FORTESTA® (FOR-tes-ta) CIII

(testosterone)

Gel for topical use

What is the most important information I should know about FORTESTA?

1. **FORTESTA 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 FORTESTA has been applied to your skin. Early signs and symptoms of puberty have occurred in young children who have come in direct contact with testosterone by touching areas where men have used FORTESTA.

   Children

   Signs and symptoms of early puberty in a child when they come in direct contact with FORTESTA may include:

   Abnormal sexual changes:

   - enlarged penis or clitoris.
   - early growth of hair near the vagina or around the penis (pubic hair).
   - erections 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 FORTESTA may include:

   - changes in body hair.
   - an abnormal increase in pimples (acne).

Stop using FORTESTA 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 FORTESTA.

2. **To lower the risk of transfer of FORTESTA from your body to others, follow these important instructions:**
   - Apply FORTESTA only to the front and inside area of your thighs that will be covered by clothing.
   - Wash your hands right away with soap and water after applying FORTESTA.
   - 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 woman touches the area where you have applied FORTESTA, that area on the child or woman should be washed well with soap and water right away.

What is FORTESTA?

FORTESTA is a prescription medicine that contains testosterone. FORTESTA is used to treat adult males who have low or no testosterone due to certain medical conditions.

- Your healthcare provider will test your blood before you start and while you are using FORTESTA.

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

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

FORTESTA is not meant for use in women.

Do not use FORTESTA if you:

- have breast cancer.
- have or might have prostate cancer.
- are pregnant. FORTESTA may harm your unborn baby.
- Women who are pregnant should avoid contact with the area of skin where FORTESTA has been applied.

Before using FORTESTA, tell your healthcare provider about all of your medical conditions including if you:

- have breast cancer.
- have or might have prostate cancer.
- have urinary problems due to an enlarged prostate.
- have high blood pressure or are being treated for high blood pressure.
- have heart problems.
- have liver or kidney problems.
- have 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 FORTESTA with certain other medicines can affect each other. Especially, tell your healthcare provider if you take:

- insulin
- medicines that decrease blood clotting (blood thinners)
- corticosteroids

How should I use FORTESTA?

- See the detailed **Instructions for Use** for information about how to use FORTESTA at the end of this Medication Guide.
- It is important that you apply FORTESTA exactly as your healthcare provider tells you to.
- Your healthcare provider may change your FORTESTA dose. **Do not** change your FORTESTA dose without talking to your healthcare provider.
- Apply FORTESTA in the morning. If you shower or bathe, FORTESTA should be applied afterwards.

What are the possible side effects of FORTESTA?

FORTESTA can cause serious side effects including:

See **"What is the most important information I should know about FORTESTA?"**

- **If you already have enlargement of your prostate gland your signs and symptoms can get worse** while using FORTESTA. This can include:
  - increased urination at night.
  - trouble starting your urine stream.
  - having to pass urine many times during the day.
  - having an urge to go to the bathroom right away.
  - having a urine accident.
  - being unable to pass urine or weak urine flow.
- **Possible increased risk of prostate cancer.** Your healthcare provider should check you for prostate cancer or any other prostate problems before you start and while you use FORTESTA.
- **Blood clots in the legs or lungs.** Signs and symptoms of a blood clot in your leg can include leg pain, swelling or redness. Signs and symptoms of a blood clot in your lungs can include difficulty breathing or chest pain.
- **Increased blood pressure.** FORTESTA can increase your blood pressure, which can increase your risk of having a heart attack or stroke over time. Your risk may be greater if you have already had a heart attack or stroke or if you have other risk factors for heart attack or stroke. You may need to start new medicines or have medicines changed for high blood pressure while on FORTESTA. If your blood pressure cannot be controlled, FORTESTA may need to be stopped. Your healthcare provider should check your blood pressure while you use FORTESTA.
- **In large doses FORTESTA may lower your sperm count.**
- **Swelling of your ankles, feet, or body, with or without heart failure.**
- **Enlarged or painful breasts.**
- **Have problems breathing while you sleep (sleep apnea).**
- **Increased red blood cell count.**

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

The most common side effects of FORTESTA include:

- skin redness or irritation where FORTESTA is applied
- increased in blood level of Prostate Specific Antigen (a test used to screen for prostate cancer)
- abnormal dreams

Other side effects include more erections than are normal for you or erections that last a long time.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of FORTESTA. 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 FORTESTA?

- Store FORTESTA at room temperature between 68ºF to 77ºF (20ºC to 25ºC).
- When it is time to throw away the canister, safely throw away used FORTESTA in household trash. Be careful to prevent accidental exposure of children or pets.
- Keep FORTESTA away from fire.
- Do not freeze FORTESTA.

Keep FORTESTA and all medicines out of the reach of children.

General information about FORTESTA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use FORTESTA for a condition for which it was not prescribed. Do not give FORTESTA 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 FORTESTA that is written for health professionals.

What are the ingredients in FORTESTA?

Active ingredients: testosterone

Inactive ingredients: propylene glycol, purified water, ethanol, 2-propanol, oleic acid, carbomer 1382, triethanolamine, and butylated hydroxytoluene.

Manufactured by:

Pharbil Waltrop GmbH
Im Wirrigen 25, 45731
Waltrop, Germany

Manufactured for:
Endo USA
Malvern, PA 19355

For more information about FORTESTA, go to www.fortestagel.com or call 1-800-462-3636.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: 07/2025