Product Monograph

Including Patient Medication Information

TLANDO™

Testosterone Undecanoate Capsules

Capsules, 112.5 mg, For oral use

Androgen

Verity Pharmaceuticals Inc.

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Toronto, Ontario, M4T 2S3

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Recent Major Label Changes

None at the time of the most recent authorization.	

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Certain sections or subsections that are not applicable at the time of the preparation of the most recent authorized product monograph are not listed.

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Part 1: Healthcare Professional Information

1. Indications

TLANDO (testosterone undecanoate) capsules is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone (male hypogonadism).

TLANDO should not be used to treat non-specific symptoms suggestive of hypogonadism if testosterone deficiency has not been demonstrated and if other etiologies responsible for the symptoms have not been excluded. Testosterone deficiency should be clearly demonstrated by clinical features and confirmed by two separate validated biochemical assays (morning testosterone) before initiating therapy with any testosterone replacement, including TLANDO treatment.

1.1. Pediatrics

Pediatrics (males < 18 years old): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

1.2. Geriatrics

Geriatrics (males ≥ 65 years): There have not been sufficient numbers of geriatric patients in controlled clinical studies with TLANDO to determine whether use in the geriatric population is associated with differences in safety or effectiveness. Therefore, safety and efficacy of TLANDO in men with age-related hypogonadism has not been established.

2. Contraindications

TLANDO (testosterone undecanoate capsules) is contraindicated in:

- Patients with known hypersensitivity to this drug or to any of its ingredients. For a complete listing of ingredients see 6 Dosage Forms, Composition and Packaging.
- Men with known or suspected carcinoma of the breast or prostate r (See 7 Warnings and Precautions).
- Women and women who are pregnant. Testosterone is teratogenic and may cause fetal harm (see 16 Non-clinical Toxicology) . Testosterone can cause virilization of the female fetus when administered to a pregnant woman (see 7.1.1. Warnings and precautions, Special Populations, Pregnancy).

4. Dosage and Administration

4.1 Dosing considerations

Prior to initiating TLANDO, confirm the diagnosis of hypogonadism by ensuring that serum testosterone concentrations have been measured in the morning on at least two separate days and that these serum testosterone concentrations are below the normal range. TLANDO must be taken with food to ensure adequate absorption.

4.2. Recommended Dose and Dosage Adjustment

The recommended dose of TLANDO is 225 mg testosterone undecanoate (equivalent to 142.4 mg testosterone) taken as two 112.5 mg capsules. TLANDO should be taken twice daily, with food, once in

the morning and once in the evening.

Monitoring for Continued Use or Discontinuation

Monitor serum testosterone (8 to 9 hours after the morning dose) 3 to 4 weeks after initiating TLANDO, and periodically thereafter. Based on serum testosterone measurements, determine if TLANDO should be continued or discontinued:

- Serum testosterone 300 -1080 ng/dL: continue TLANDO
- Serum testosterone < 300 ng/dL: discontinue TLANDO
- Serum testosterone > 1080 ng/dL: discontinue TLANDO

4.3. Missed Dose

If a dose is missed for any reason, a double dose should not be taken. Resume taking the medication at the next scheduled time.

5. Overdose

If you think that you or a person you are caring for have taken too much TLANDO, contact your healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

6. Dosage Forms, Strengths, Composition, and Packaging

Table 1 – Dosage Forms, Strengths, and Composition

Route of Administration	Dosage Form/ Strength/Composition	Non-Medicinal Ingredients
oral	Capsules, 112.5 mg testosterone undecanoate (equivalent to 71.2 mg testosterone). The capsules are white opaque body, grey opaque cap with "112" printed in black ink on the body, with a clear colourless band.	Ammonium hydroxide 28%, ascorbyl palmitate, black iron oxide, dehydrated ethanol, ferrosoferric oxide/black iron oxide, gelatin, glyceryl monolinoleate, isopropyl alcohol, n-butyl alcohol, polyethylene glycol 8000, polyoxyl 40 hydrogenated castor oil, propylene glycol, shellac glaze in ethanol, titanium dioxide.

TLANDO is supplied in HDPE bottles with a foil liner and a child resistant cap. The bottles contain 120 capsules.

7. Warnings and Precautions

General

If testosterone deficiency has not been established, testosterone replacement therapy should not be used for the treatment of sexual dysfunction. With large doses of exogenous androgens, including TLANDO, spermatogenesis may be suppressed through feedback inhibition of pituitary follicle-

stimulating hormone (FSH) possible leading to adverse effects on semen parameters including sperm count.

TLANDO should not be used to attempt to improve body composition, bone and muscle mass, increase lean body mass and decrease total fat mass. Efficacy and safety have not been established. Serious long term deleterious health issues may arise. TLANDO has not been shown to be safe and effective for the enhancement of athletic performance. Because of the potential risk of serious adverse health effects, this drug should not be used for such purpose.

Clinical studies have not established testosterone replacement therapy as a treatment for male infertility.

Carcinogenesis and Genotoxicity

Prostate

Androgens may accelerate the progression of sub-clinical prostatic cancer and benign prostatic hyperplasia (BPH). Patients receiving testosterone replacement therapy should undergo careful and regular monitoring of the prostate gland consistent with current practices for eugonadal men. Prior to testosterone initiation, at risk patients (those with clinical and familial factors) should be identified and all patients must undergo a detailed examination, including the monitoring of the prostate specific antigen (PSA), in order to detect preexisting prostatic cancer (see Monitoring and Laboratory Tests).

Geriatric patients treated with testosterone products may be at an increased risk for the development of prostatic hyperplasia and prostatic carcinoma.

Breast

Patients using long-term parenteral testosterone replacement therapy may be at an increased risk for the development of breast cancer. In men receiving testosterone replacement therapy, careful and regular monitoring of the breast should be conducted.

Skeletal

Patients with skeletal metastases are at risk of exacerbating hypercalcemia/ hypercalciuria with concomitant testosterone replacement therapy. Regular monitoring of serum calcium concentrations is recommended in these patients.

Cardiovascular

Before starting testosterone therapy, patients should be assessed for any cardiovascular risk factors (e.g., existing ischaemic heart disease) or prior history of cardiovascular events (e.g., myocardial infarction, stroke, or heart failure); ensure that blood pressure is adequately controlled. Check blood pressure approximately 6 weeks after initiating TLANDO and periodically thereafter. Treat new-onset hypertension or exacerbations of pre-existing hypertension and re-evaluate whether the benefits of continued treatment with TLANDO outweigh its risks in patients who develop cardiovascular risk factors or cardiovascular disease.

Cardiovascular risk

The results of TRAVERSE, a randomized, double-blind, placebo-controlled phase 4 clinical trial study, indicated that testosterone-replacement therapy did not influence the incidence of major adverse cardiac events in middle-aged and older patients with hypogonadism and with pre-existing or an increased risk of cardiovascular diseases (topical testosterone gel 7.0% vs. placebo 7.3%). However,

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. In the TRAVERSE Study, topical testosterone gel was associated with a higher risk of VTE (1.7% vs 1.2%) which included deep vein thrombosis (0.6% vs 0.5%) and pulmonary embolism (0.9% vs 0.5%)

Edema

Androgens, including TLANDO, may promote retention of sodium and water. Edema, with or without congestive heart failure, may be a serious complication in patients with pre-existing cardiac, renal, or hepatic disease. Diuretic therapy may be required, in addition to discontinuation of the drug.

Increase in blood pressure

Testosterone may increase blood pressure and is not recommended in patients with uncontrolled hypertension. Based on ambulatory blood pressure monitoring (ABPM) in Study 18-001, TLANDO increased mean systolic/diastolic BP by 4.3/1.4 mm Hg from baseline after 4 months of treatment. In patients with hypertension on antihypertensive therapy, TLANDO increased the mean systolic/diastolic BP by 4.8/1.6 mm Hg from baseline (see 8 Adverse Reactions). Blood pressure increases can increase cardiovascular (CV) risk over time. There have been post-marketing reports of venous thromboembolic events, including deep vein thrombosis (DVT) and pulmonary embolism (PE), in patients using testosterone products. 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 TLANDO and initiate appropriate management.

Dependence, Tolerance and/or Abuse Liability

TLANDO contains testosterone undecanoate, which is a Schedule G controlled substance as defined by the Food and Drugs Act.

Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication(s) and in combination with other anabolic androgenic steroids. 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 presenting with serious cardiovascular or psychiatric adverse events.

Abuse

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 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 (with fatal outcomes in some cases) 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.

Dependence

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.

Endocrine and Metabolism

Androgens, including TLANDO, 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.

Testosterone products have been shown to alter glucose tolerance tests. Diabetics should be followed carefully and the insulin or oral hypoglycemic dosage adjusted accordingly.

In addition, decreases in concentrations of thyroxin-binding globulins may occur, resulting in decreased total T4 serum concentrations and increased resin uptake of triiodothyronine (T3) and thyroxine (T4). Free thyroid hormone concentrations remain unchanged, however, and there is no clinical evidence of thyroid dysfunction.

Changes in serum lipid profile may require dose adjustment of lipid lowering drugs or discontinuation of testosterone therapy.

Genitourinary

Patients with benign prostatic hyperplasia (BPH) may develop acute urethral obstruction. Patients should be monitored for worsening of signs and symptoms of BPH.

Hematologic

Increases in hematocrit levels, reflective of increases in red blood cell mass, may require lowering of dose or discontinuation of therapy. Check hematocrit prior to initiating treatment. It would also be appropriate to re-evaluate hematocrit 3 to 6 months after starting treatment, and then annually. If hematocrit becomes elevated, stop therapy until hematocrit decreases to an acceptable level. If TLANDO is restarted and again causes hematocrit to become elevated, stop TLANDO permanently. An increase in red blood cell mass may increase the risk of thromboembolic events.

Hepatic/Biliary/Pancreatic

Prolonged use of high doses of orally active 17-alpha-alkyl androgens (e.g., 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 intramuscular testosterone enanthate has produced multiple hepatic adenomas. TLANDO is not a 17 alpha-alkyl androgen and is not known to produce hepatic adverse effects associated with 17-alpha-alkyl androgens. Nonetheless, patients should be instructed to report any signs or symptoms of hepatic dysfunction (e.g., jaundice). If these occur, promptly discontinue TLANDO while the cause is evaluated.

Monitoring and Laboratory Tests

The patient should be monitored (including serum testosterone levels) at baseline and on a regular basis to ensure adequate response to treatment. The following laboratory tests, performed routinely, are recommended to ensure that adverse experience possibly caused by or related to testosterone replacement therapy is detected and addressed:

- hemoglobin and hematocrit levels should be checked periodically (to detect polycythemia);
- liver function tests;
- prostate specific antigen (PSA), digital rectal examination (DRE), especially if the patient presents with progressive difficulty with urination or a change in voiding habits;
- lipid profile, total cholesterol, LDL, HDL, and triglycerides; serum cholesterol levels may increase and/or decrease during androgen therapy; serum prolactin levels may increase, monitor prior and following initiation of treatment;
- diabetics should be followed carefully and the insulin or oral hypoglycemic dosage adjusted accordingly (see 9.4 Drug-Drug Interactions).

Reproductive Health

- **Fertility**

  Oligospermia may occur after prolonged administration or excessive dosage. With large doses of exogenous androgens, including TLANDO, spermatogenesis may be suppressed through feedback inhibition of pituitary follicle-stimulating hormone (FSH) possibly leading to adverse effects on semen parameters including sperm count. Patients should be informed of this possible risk when deciding whether to use or to continue to use TLANDO.

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. With either type of use, the impact on fertility may be irreversible.

- **Function**

  Gynecomastia may develop and persist in patients being treated for hypogonadism. Priapism or excessive sexual stimulation may develop.

  If testosterone deficiency has not been established, testosterone replacement therapy should not be used for the treatment of sexual dysfunction.

Respiratory

The treatment of hypogonadal men with testosterone products may potentiate sleep apnea in some patients, particularly for those with risk factors such as obesity or chronic lung diseases.

7.1. Special Populations

7.1.1. Pregnancy

TLANDO is contraindicated in pregnant women and not indicated for use in females. TLANDO may cause fetal harm when administered to a pregnant woman based on data from animal studies and its mechanism of action (see 2 Contraindications, 10 Clinical Pharmacology and 16 Nonclinical Toxicology). Testosterone exposure during pregnancy has been reported to be associated with fetal abnormalities. Testosterone is known to cause virilization of the external genitalia of the female fetus when administrated to pregnant women. 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. If a pregnant woman is exposed to testosterone, she should be apprised of the potential hazard to the fetus (see 16 Non-Clinical Toxicology).

7.1.2. Breastfeeding

TLANDO should not be used in nursing women. TLANDO may cause serious adverse reactions in nursing infants. It is unknown if testosterone undecanoate is excreted in human milk.

7.1.3. Pediatrics

No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

7.1.4. Geriatrics

There have not been sufficient numbers of geriatric patients in controlled clinical studies with TLANDO to determine whether efficacy or safety in those over 65 years of age differs from younger subjects. Therefore, safety and efficacy of TLANDO in men with age-related hypogonadism has not been established.

8. Adverse Reactions

8.1. Adverse Reaction Overview

Safety of TLANDO was evaluated in Phase 1, 2, and 3 trials with treatment duration between 1 day and 52 weeks at doses of 50 to 225 mg (for single dose studies) and between 75 and 300 mg BID (for multiple dose studies). Among the 654 patients that received TLANDO, the following Treatment-Related Treatment Emergent Adverse Events were reported in at least 1.0% of the patients: headache (1.5%), increased hematocrit (1.2%).

In addition, 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 7 Warnings and Precautions, Dependence, Tolerance and/or Abuse Liability).

8.2. Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. The adverse reaction rates observed in the clinical trials, therefore, may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse reaction information from clinical trials may be useful in identifying and approximating rates of adverse drug reactions in real-world use.

TLANDO was evaluated in multiple clinical trials conducted in hypogonadal men, a total of 654 subjects were exposed to TLANDO, including 210 subjects who participated in a 52-week pivotal safety study, 95 subjects who participated in a pivotal efficacy study and 138 subjects who participated in the ambulatory blood pressure monitoring (ABPM) study.

The 52-week pivotal safety study (Study 13-001) was an active controlled randomized study with dose titration in hypogonadal men, including 210 subjects receiving TLANDO and 104 receiving Health Canada approved topical gel product AndroGel 1.62% (active control arm). All subjects started at the dose of 225 mg BID that could be increased to 300 mg BID or decreased to 150 mg BID (based on testosterone levels) after approximately 3 and 7 weeks of treatment. Throughout the study (after week 3), between 52% and 58% of the subjects were dosed at 225 mg BID. Subject's mean age at baseline was 53.1 years. Mean weight and BMI of subjects at baseline were 97.8 kg and 30.9 kg/m2, respectively. Most of the subjects enrolled were white (83.8%), followed by black or African American (13.3%), while subjects of other races comprised less than 3%.

Table 2 Treatment Emergent Adverse Events (TEAE) reported in ≥2% of the subjects in either treatment arm in Study 13-001 - Safety set

System organ class/preferred term	TLANDO n = 210 subjects (%)	Androgel 1.62% n = 104 subjects (%)
Gastrointestinal disorders		
Diarrhoea	6 (2.9)	1 (1.0)
General disorders and administration site conditions		
Fatigue	5 (2.4)	7 (6.7)

System organ class/preferred term	TLANDO n = 210 subjects (%)	Androgel 1.62% n = 104 subjects (%)
Infections and infestation		
Upper respiratory tract infection	11 (5.2)	6 (5.8)
Nasopharyngitis	8 (3.8%)	5 (4.8%)
Bronchitis	3 (1.4)	3 (2.9)
Sinusitis	5 (2.4)	1 (1.0)
Investigations		
Weight increased	10 (4.8)	1 (1.0)
Musculoskeletal and connective tissue disorders		
Back pain	6 (2.9)	3 (2.9)
Arthralgia	3 (1.4)	4 (3.8)
Nervous system disorders		
Headache	10 (4.8)	5 (4.8)
Skin and subcutaneous disorders		
Acne	7 (3.3)	3 (2.9)
Vascular disorders		
Hypertension	6 (2.9)	5 (4.8)

Of the 210 subjects randomized to TLANDO in the 52-week study, 11 subjects (5.2%) discontinued treatment because of adverse reactions.

No treatment-related serious adverse reactions to TLANDO or active control were reported during the 52-week study or in any clinical trial conducted with TLANDO. No serious adverse reactions (including hepatic, renal, gastrointestinal or cardiac related) were reported during 52 weeks of treatment with TLANDO or active control.

Change in blood pressure were assessed in the 4-month, 24-hour ABPM clinical study, conducted in 138 patients, 126 of whom completed the study. ABPM was conducted at 2 distinct 24-hour time periods: at Baseline and following about 16 weeks of treatment with TLANDO. A total of 123 patients had acceptable 24-hour ABPM recordings at both time periods. In that group, the mean change in systolic BP from Baseline to End of Study was + 4.3 mmHg (95% CI 2.1 – 6.5) and the mean change in diastolic BP was 1.4 mmHg (95% CI 0.5 – 2.3).

In the 4-month ABPM clinical study, hypertension was reported in 7 patients (5.1%), increases in hematocrit to ≥54% were reported for 6 patients (4.3%) and upper respiratory tract infection was reported in 5 patients (3.6%)who received TLANDO. While the study did not pre-define clinical adverse

events related to increased hematocrit, polycythemia was reported as a medically significant adverse event in the investigator's clinical judgment in 1.4% of treated patients. TLANDO dosing resulted in mean ± SD hemoglobin increases of 0.87 ± 1.05 g/dL and mean ± SD hematocrit increases of 3.2 ± 3.6% at about 16 weeks.

In Study 16-002, 95 hypogonadal males were treated with TLANDO 225 mg twice daily with morning and evening meals for approximately 24 days. The dose of TLANDO was not titrated. Patients had a median age of 56 years (range 29-74), 81% were White, 16% were Black, 2% were mixed race, and 1% were Asian; 26% were Hispanic. In 95 hypogonadal male patients, 70% (n=66) were obese (BMI ≥ 30 kg/m2), 23% (n=22) reported a history of type 2 diabetes, and 50% (n=47) reported a history of hypertension. Adverse Reactions reported in ≥2% of patients included: Blood prolactin increased in 6 (6.3%), weight increased in 2 (2.1%), Headache in 2 (2.1%) and Musculoskeletal pain in 2 (2.1%) of the patients. One of the 95 patients (1.1%) reported an adverse reaction (gastric ulcer hemorrhage) that led to premature discontinuation from the study. The mean increase from baseline in serum prolactin was 7.0 ng/mL (n=93).

8.3. Less Common Clinical Trial Adverse Reactions

Blood and Lymphatic System:	anaemia, blood triglyceride increased, hemoblobin increased, high density lipoprotein decreased, hypercholesterolaemia, hyperlipidaemia, lipids Increased, polycythaemia, red blood cell count increased
Cardiovascular Disorders:	atrial fibrillation, blood pressure increased, cardiac flutter, electrocardiogram change/abnormal, electrocardiogram T wave inversion, enzyme level increased, heart rate increased, mitral valve incompetence, palpitations, tachycardia, tricuspid valve incompetence, ventricular hypertrophy
Endocrine investigations:	blood prolactin increased
Gastrointestinal disorders:	constipation
General disorders:	oedema peripheral
Hepatic System:	alanine aminotransferase increased
Nervous System:	dizziness, sleep apnea syndrome, tension headache, transient ischaemic attack
Psychiatric System:	abnormal dreams, agitation, anxiety, insomnia, irritability, libido decreased, mood altered, panic attack, restlessness
Renal and Reproductive System:	prostatic specific antigen increased, prostatitis, prostatomegaly, urinary retention
Other Potential Androgen Effects:	gynaecosmastia, hirsutism, oedema

8.5. Post-Market Adverse Reactions

The following adverse reactions have been identified during post-approval use of testosterone replacement products. 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.

Cardiovascular Disorders: myocardial infarction, stroke

Vascular Disorders: venous thromboembolism

9. Drug Interactions

9.4. Drug-Drug Interactions

Table 3 – Established or Potential Drug-Drug Interactions

[Non-proprietary name(s) of the drug product(s)]	Source of evidence	Effect	Clinical comment
Analgesic and cold medications	T	Some prescription drugs, nonprescription analgesic and cold medications can increase blood pressure.	Concomitant administration of these medications with TLANDO™ may lead to additional increases in blood pressure (see 7 Warnings and Precautions).
Corticosteroids	CT	The concurrent use of testosterone with ACTH or corticosteroids may result in increased fluid retention	Co-medication should be monitored cautiously, particularly in patients with cardiac, renal or hepatic disease.
Insulin	CT	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, insulin requirements.
Oral anticoagulants	CT	Changes in anticoagulant activity may be seen with androgens.	More frequent monitoring of INR and prothrombin time is recommended in patients taking anticoagulants, especially at the initiation and termination of androgen therapy.

Legend: C = Case Study; CT = Clinical Trial; T = Theoretical; PBPK = Physiologically based pharmacokinetic modeling; popPK = Population pharmacokinetic modeling

9.5. Drug-Food Interactions

When TLANDO was given with breakfast containing approximately 15% (low-fat meal), 20-35% (standard-fat meal) or 50% (high-fat meal) of fat, the exposure (AUC0-24h) to testosterone was increased by about 40%, 40%, 61% and Cmax by 170%, 177%, 183% respectively, compared to when taken under fasted conditions.

TLANDO should be taken with food as food enhances absorption of TLANDO (see 4 Dosage and Administration **and** 10 Clinical Pharmacology**).**

9.6. Drug-Herb Interactions

It was found that some herbal products (e.g. St. John's Wort) which are available as over-the-counter (OTC) products might interfere with steroid metabolism and therefore may decrease plasma testosterone levels.

9.7. Drug-Laboratory Test Interactions

Testosterone products may decrease levels of thyroxine-binding globulin, resulting in decreased total T4 serum levels and increased resin uptake of T3 and T4. Free thyroid hormone levels remain unchanged, however, and there is no clinical evidence of thyroid dysfunction. Testosterone products may decrease levels of thyroxine-binding globulin, resulting in decreased total T4 serum levels and increased resin uptake of T3 and T4. Free thyroid hormone levels remain unchanged, however, and there is no clinical evidence of thyroid dysfunction.

10. Clinical Pharmacology

10.1. Mechanism of Action

Testosterone undecanoate, an orally active testosterone preparation, is a fatty acid ester of the natural androgen testosterone. TLANDO delivers physiologic amounts of testosterone, producing circulating testosterone levels that approximate normal levels (e.g. 10.4-37.48 nmol/L [300-1080 ng/dL]) seen in young healthy men.

10.2. Pharmacodynamics

There is insufficient data to characterize an exposure-response relationship or time course of pharmacodynamic response.

10.3. Pharmacokinetics

Pharmacokinetics of TLANDO were evaluated in Study M12-778, a randomized, placebo controlled, dose-escalating study in hypogonadal men. Patients had a median age of 44.6 years, mean weight was 83.4 kg, 85% were White and 15% were Black. A total of 16 hypogonadal men received 225 mg of TLANDO twice a day for 15 days.

Table 4– Summary of 225 mg of Testosterone Pharmacokinetic Parameters in Hypogonadal Man (n=16)

PK Parameter (units)*	Day 1	Day 8**	Day 15**
T_{max} (h)	5.8 ± 1.4	5.5 ± 0.9	8.67 ± 4.7
C_{max} (ng/dL)	1422 ± 555	1566 ± 674	1169 ± 356
$AUC_{0-\tau}$ (ng•h/dL)	11875 ± 2542	12440 ± 3858	10693 ± 3872
C_{avg0-t} (ng/dL)	495 ± 106	518 ± 161	445 ± 161

* T_{max}, C_{max}, AUC_{0-t} and C_{avg0-t} are for Hour 0-24 after AM dose;
** On Days 8 and 15, Group 3 (225 mg), N = 15.

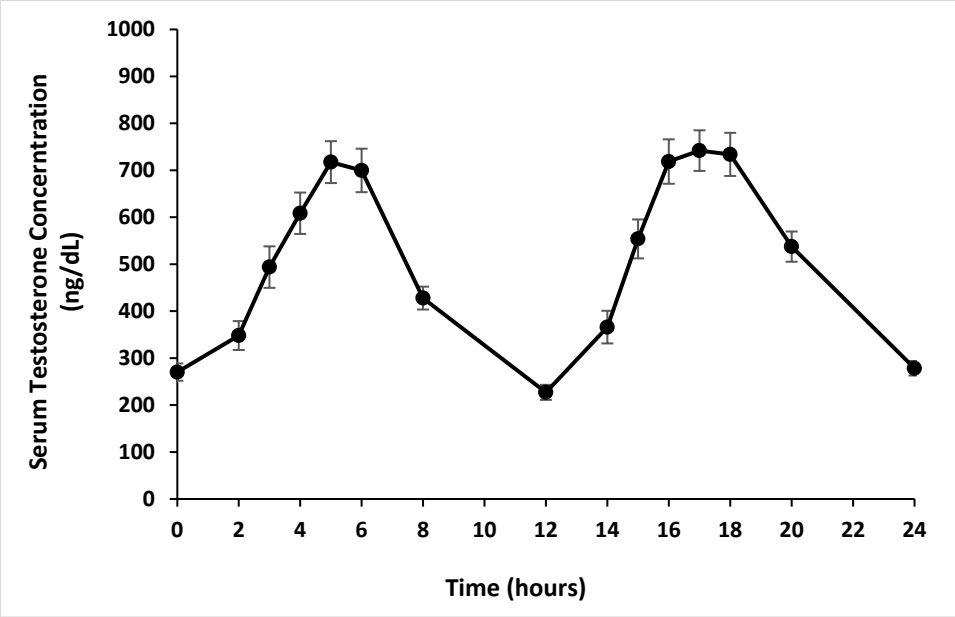
Absorption
Testosterone undecanoate is a lipophilic molecule that is primarily absorbed into the lymphatic system after oral administration and then released into the general blood circulation by the thoracic duct, avoiding absorption into the portal vein thereby circumventing first-pass metabolism in the liver. Testosterone undecanoate is converted to testosterone following absorption.

Following administration of 225 mg of TLANDO in ninety-five hypogonadal males, maximum serum testosterone concentrations were observed at a median (T_{max}) of about 5 hours. The mean maximum

(C_{max}) serum testosterone concentrations observed were 979 ng/dL and 989 ng/dL following the morning and evening TLANDO doses, respectively. The average serum testosterone concentrations over 24 hours ($C_{avg0\text{-}24h}$) observed following TLANDO™ administration was 476 ng/dL.

Figure 1 shows the mean serum total testosterone concentration-time profile for hypogonadal men (N=90) administered TLANDO™.

Figure 1: Mean (±SEM) Serum Total Testosterone Concentrations (ng/dL)



Following TLANDO administration, the mean serum dihydrotestosterone (DHT) $C_{avg0\text{-}24h}$ was 108 ng/dL, the mean serum testosterone undecanoate Cavg0-24h was 11,100 ng/dL and the mean serum dihydrotestosterone undecanoate $C_{avg0\text{-}24h}$ was 4,700 ng/dL. No significant differences in food effect on testosterone exposure was observed when TLANDO was dosed with a low-fat meal (15% of fat) or with a high-fat meal (50% of fat) as compared to a standard-fat meal (20-35% of fat). However, when TLANDO was administered with different breakfasts containing approximately 15%, 20-35%, and 50% of fat, the exposure (AUC0-24h) of testosterone was increased by about 40%, 40% and 61% respectively, compared to when given under fasted conditions.

Distribution

Circulating testosterone is primarily bound in 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 bound to albumin and other proteins.

Metabolism

Testosterone undecanoate is metabolized to testosterone via ester cleavage of the undecanoate group and reduced to DHTU by 5α-reductase. Testosterone is metabolized to various 17-keto steroids. The major active metabolites of testosterone are DHT and estradiol. Cytochrome P450 3A4 metabolizes testosterone primarily in the liver by conversion to various hydroxy steroids.

Elimination

The elimination half-life of testosterone undecanoate is approximately 2 hours. Once testosterone is formed from testosterone undecanoate, there is considerable variation in the half-life of testosterone

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 and sulfuric acid conjugates of testosterone and its metabolites. About 6% of a dose is excreted in the feces, mostly in the unconjugated form.

11. Storage, Stability, and Disposal

Store at 15°C to 25°C. Protect from light and moisture. Keep out of reach of children.

Dispose of unused TLANDO by returning it to your pharmacy where possible.

Part 2: Scientific Information

13. Pharmaceutical Information

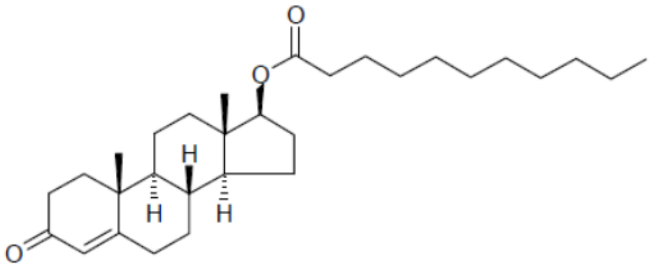
Drug Substance

Non-proprietary name of the drug substance(s): Testosterone undecanoate

Chemical name: 17β-undecanoyloxy-4-androsten-3-one

Molecular formula and molecular mass: $C_{30}H_{48}O_3$ / 456.7

Structural formula:



Physicochemical properties: Melting point 63°C; solubility: insoluble in water; testosterone undecanoate is a white to off-white crystalline substance

14. Clinical Trials

14.1. Clinical Trials by Indication

The efficacy and safety of TLANDO was evaluated in Study 16-002 a multicenter, open-label, single-arm study in adult hypogonadal male patients (NCT03242590). Patients received TLANDO 225 mg, orally twice daily with food for approximately 24 days; no titration was performed to adjust the dosage.

Table 5 - Summary of Patient Demographics for Clinical Trials in Adult Males with Deficiency or Absence of Endogenous Testosterone

Study #	Study design	Dosage, route of administration and duration	Study subjects (n)	Age (range)	Sex
16-002	Multicenter, open-label, single-arm study in adult hypogonadal male patients	225 mg twice daily Oral 24 days	95	56 years (29-74 years)	Males

A total of 95 hypogonadal men received a dose of TLANDO and were included in the efficacy evaluation. Patients had a median age of 56 years (range 29-74 years), 81% were White, 16% were Black, 2% were mixed race, and 1% were Asian; 26% were Hispanic.

14.2. Study Results

The primary endpoint in the efficacy study (16-002) was the percentage of patients who achieved a 24-hour average serum testosterone concentration ($C_{avg0-24h}$) within the normal range of 300-1080 ng/dL on the final visit of the study.

Table 6 - Results of study 16-002 in Adult Males with Deficiency or Adults Males with absence of Endogenous Testosterone

Primary Endpoints	Associated value and statistical significance for Drug at specific dosages
% subjects with testosterone, Cavg0-24h 300 to 1080 ng/dL at day 24	80% 95% confidence interval (72%, 88%)

Secondary endpoints were the percentage of patients with maximum total testosterone concentration (Cmax) meeting three predetermined limits: less than or equal to 1.5 times the upper limit of the normal range (ULN) (1620 ng/dL) in at least 85%, between 1.8 and 2.5 times ULN (1944 - 2700 ng/dL) in less than 5%, and greater than 2.5 times ULN (2700 ng/dL) in none of the patients.

The percentage of patients who received TLANDO and had T Cmax threshold less than or equal to 1620 ng/dL, between 1944 ng/dL and 2700 ng/dL, and greater than 2700 ng/dL at the PK visit were 82%, 5%, and 0%, respectively.

16. Non-Clinical Toxicology

General Toxicology

TLANDO has been evaluated in 26-week repeat-dose oral (gavage) toxicity studies in male rats at 20, 50 and 150 mg/kg, and 90-day repeat-dose oral (capsule) toxicity studies in male beagle dogs at 80, 240 and 1,000 mg/kg; at these doses, the multiple of exposure were roughly 0,7, 2.6 and 7.5 for the rat and 6, 25 and 35 times the clinical exposure, based on AUC levels of 12,440 ng•h/dL.

TLANDO caused expected pharmacological effects on androgen-responsive tissues, including testes, epididymides, prostate, and seminal vesicles, at exposures to testosterone undecanoate. In the rat study, interstitial cell atrophy, germ cell degeneration/depletion, and spermatid depletion were observed, and a No Observed Adverse Effect Level (NOAEL) could not be determined due to these testicular microscopic findings and semenology data at all dose levels (>=20 mg/kg/day). In the dog study, histopathologic changes in the reproductive organs, including hypospermatogenesis, depletion of germ cells, and reduced sperm content, were present at doses >= 80 mg/kg/day, correlating with reduced testicular size and weight. Consequently, a NOAEL for the male reproductive system in dogs was not determined.

In adrenal glands, thinning of the zona fasciculata and zona reticularis was observed in dogs at doses >= 80 mg/kg/day, correlating with decreased adrenal weights. Additionally, thymic atrophy/lymphocyte depletion was noted in both species. Regarding non-reproductive effects in dogs, a NOAEL was considered to be 240 mg/kg/day, based on evidence of hepatotoxicity at the 1000 mg/kg/day dose level. The clinical significance of the adrenal, thymic, and other findings is uncertain.

Genotoxicity

Mutagenic effects of testosterone undecanoate were not detected in a battery of in vitro tests

including bacterial mutation assays (Ames test) and chromosomal aberration tests in human lymphocytes. Testosterone undecanoate was also negative in an in vivo bone marrow micronucleus assay in rats. Testosterone was negative in the in vitro Ames and in the in vivo mouse micronucleus assays.

Carcinogenicity

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

Reproductive and developmental toxicology

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.

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 females and offspring in rats exposed to doses approximately twice those used for testosterone replacement therapy.

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

TLANDO™

Testosterone Undecanoate Capsules

This patient medication information is written for the person who will be taking **TLANDO**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **TLANDO** talk to a healthcare professional.

What TLANDO is used for:

TLANDO is used to treat low testosterone (also called hypogonadism). It is prescribed when your body does not make enough testosterone on its own.

How TLANDO works:

TLANDO (testosterone undecanoate) works by replacing testosterone in males who have low testosterone levels. After you take it, your body absorbs the medicine and changes it into testosterone. You may start to notice its effects within a few weeks.

The ingredients in TLANDO are:

Medicinal ingredients: testosterone undecanoate

Non-medicinal ingredients: Ammonium hydroxide 28%, ascorbyl palmitate, black iron oxide, dehydrated ethanol, ferrosoferric oxide/black iron oxide, gelatin, glycerol monolinoleate, isopropyl alcohol, n-butyl alcohol, polyethylene glycol 8000, polyoxyl 40 hydrogenated castor oil, propylene glycol, shellac glaze in ethanol, titanium dioxide.

TLANDO comes in the following dosage form(s):

Each capsule contains 112.5 mg of testosterone undecanoate. The capsules are white opaque body, grey opaque cap with “112” printed in black ink on the body, with a clear colourless band.

Do not use TLANDO if you:

- are allergic to testosterone undecanoate or any ingredient in TLANDO.
- have or might have prostate cancer;
- have breast cancer;
- are a woman

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TLANDO . Talk about any health conditions or problems you may have, including if you:

- have high blood pressure or are treated for high blood pressure.
- have heart problems.
- have high red blood cell count (hematocrit) or high hemoglobin laboratory value.
- have urinary problems due to an enlarged prostate.

- have liver or kidney problems.
- have a history of mental health illness including suicidal thoughts or actions, depression, anxiety or mood disorder.
- have problems breathing while you sleep (sleep apnea).
- have diabetes.
- have benign prostatic hyperplasia (BPH).
- have cancer.

Other warnings you should know about:

- You should not use TLANDO to treat sexual dysfunction or infertility.

Drug abuse and dependence: TLANDO contains testosterone, which is a controlled substance. TLANDO has the potential to be abused. You should not use TLANDO in an attempt to improve body composition, bone and muscle mass, or fat loss. TLANDO can be a target for people who abuse prescription medicines. Keep your medicines in a safe place and never give it 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.

- **Blood tests and monitoring:** Your doctor should check your progress at regular visits in order to make sure this medicine does not cause unwanted side-effects. TLANDO can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.
- Any male adolescent patient receiving androgens for delayed puberty should have bone development checked every six months.
- TLANDO can increase your blood pressure, which can increase your risk of having a heart attack or stroke and can increase your risk of death due to a heart attack or stroke. 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. If your blood pressure increases while on TLANDO, blood pressure medicines may need to be started. If you are taking blood pressure medicines, new blood pressure medicines may need to be added or your current blood pressure medicines may need to be changed to control your blood pressure. If your blood pressure cannot be controlled, TLANDO may need to be stopped. Your healthcare provider will monitor your blood pressure while you are being treated with TLANDO.
- Always take this medicine exactly as your doctor or pharmacist has told you. You can get serious side effects if you take too much of it on its own or with other drugs similar to TLANDO called anabolic androgenic steroids (AAS). These include heart and blood vessel problems which can lead to death, liver problems and mental health problems. If you abuse TLANDO you may become dependent on it and you may get withdrawal symptoms when you take less or stop taking it suddenly. Do not abuse TLANDO alone or with other drugs called AAS because you can get serious side effects.
- A condition called oligospermia (low sperm count) may occur with long-term use or high doses of TLANDO.
- TLANDO may cause reduced fertility, which may be irreversible.
- A condition called gynecomastia (noncancerous overgrowth of breast tissues) may occur
- A condition called priapism (prolonged painful erection of the penis) may occur
- TLANDO is contraindicated in women and therefore it should not be used by pregnant and/or nursing women.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with TLANDO:

- insulin;
- anticoagulants, medicines that decrease blood clotting (blood thinners);
- corticosteroids;
- cold medicines and pain medicines.

How to take TLANDO:

- Take TLANDO exactly as your healthcare provider tells you take it.
- Take TLANDO with food.

Usual dose:

Take TLANDO by mouth two times daily. Take 2 capsules in the morning and take 2 capsules in the evening.

Overdose:

If you think you, or a person you are caring for, have taken too much **TLANDO**, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If a dose is missed for any reason, a double dose should not be taken. Resume taking the medication at the next scheduled time.

Possible side effects from using TLANDO:

These are not all the possible side effects you may have when taking TLANDO. If you experience any side effects not listed here, tell your healthcare professional.

The most common side effects of TLANDO include:

- high blood pressure
- common cold
- increased weight
- headache
- increased hematocrit
- infections and infestations
- fatigue
- acne
- diarrhea
- joint and muscle pain
- back pain
- dizziness

- abnormal dreams, insomnia
- changes in mood, anxiety, irritability, panic attack, restlessness

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

Testosterone can be abused, when taken at higher than prescribed doses and when used with other anabolic androgenic steroids. Abuse can cause serious heart and psychological side effects.

Serious side effects and what to do about them

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
COMMON			
Azoospermia (decreasing sperm count): low sex drive, erectile dysfunction, less facial or body hair		√	
Benign Prostatic Hyperplasia (enlarged prostate): increased urination at night, frequent urination, inability to pass urine or weak flow, urge to urinate immediately		√	
Edema: swelling of your ankles or feet		√	
Hepatic effects (Liver problems): nausea or vomiting, yellowing of the skin or whites of the eyes, dark urine, pain on the right side of your stomach		√	
Gynecomastia: Enlarged or painful breasts	√		
Polycythemia (increased red blood cells): tiredness, shortness of breath, headaches, blurry vision, sleep disorders, joint pain, itchy skin, numbness and or tingling		√	
Sleep Apnea: breathing problems while you sleep		√	
Venous thromboembolism (VTE), which includes Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE) (blood clots in the legs or lungs): pain, swelling of redness of the leg; difficulty breathing or chest pain			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects
You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store TLANDO in the bottle supplied at room temperature (15°C to 25°C). This will protect it from light and moisture. Keep out of reach and sight of children.

If you want more information about TLANDO:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.veritypharma.com; or by calling 1-800-977-9778.

This leaflet was prepared by Verity Pharmaceuticals Inc.

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