

PRESCRIBING INFORMATION

 DELATESTRYL*

testosterone enanthate

Solution for Injection, 200 mg/mL

Androgens

Theramed Corporation
6891 Edwards Blvd.
Mississauga, ON
L5T 2T9

Date of Preparation:
June 14, 2007

Submission Control No: 110721

* Registered trademark of Theramed Corporation

Table of Contents

PART I: HEALTH PROFESSIONAL INFORMATION.....3
SUMMARY PRODUCT INFORMATION3
INDICATIONS AND CLINICAL USE.....3
CONTRAINDICATIONS3
WARNINGS AND PRECAUTIONS.....4
ADVERSE REACTIONS.....7
DOSAGE AND ADMINISTRATION9
ACTION AND CLINICAL PHARMACOLOGY11
STORAGE AND STABILITY.....13
DOSAGE FORMS, COMPOSITION AND PACKAGING13

PART II: SCIENTIFIC INFORMATION14
PHARMACEUTICAL INFORMATION.....14
CLINICAL TRIALS.....14

PART III: CONSUMER INFORMATION.....16



testosterone enanthate

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Intramuscular Injection	Solution for injection/ 200 mg/mL	<i>For a complete listing see Dosage Forms, Composition and Packaging section.</i>

INDICATIONS AND CLINICAL USE

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

DELATESTRYL (testosterone enanthate) 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 biochemical assays (morning testosterone) before initiating therapy with any testosterone replacement, including DELATESTRYL treatment.

Geriatrics (> 65 years of age):

There are limited controlled clinical study data supporting the use of **DELATESTRYL** in the geriatric population (see **WARNINGS AND PRECAUTIONS** and **CLINICAL TRIALS**).

Pediatrics (< 18 years of age):

DELATESTRYL is not indicated for use in children < 18 years of age since safety and efficacy have not been established in this patient population (see **WARNINGS AND PRECAUTIONS – Special Populations**).

CONTRAINDICATIONS

- **DELATESTRYL** is not indicated for use in women.

- Androgens are contraindicated in men with known or suspected carcinoma of the prostate or breast.
- **DELATESTRYL** should not be used in patients with known hypersensitivity to any of its ingredients, including testosterone USP that is chemically synthesized from soy. For a complete listing, see Dosage Forms, Composition and Packaging section of the Product Monograph.

WARNINGS AND PRECAUTIONS

General

There is very limited data from clinical trials with **DELATESTRYL** in the geriatric male (>65 years of age) to support the efficacy and safety of prolonged use. Impacts to prostate and cardiovascular event rates and patient important outcomes are unknown¹.

DELATESTRYL 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.

DELATESTRYL 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.

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

Testosterone replacement therapy is not a treatment for male infertility.

Special Populations

Pediatrics (<18 years of age):

Androgen therapy should be used cautiously in males with hypogonadism causing delayed puberty. Androgens can accelerate bone maturation without producing compensatory gain in linear growth. This adverse effect may result in compromised adult stature. The younger the child is the greater risk of compromising final mature height. The effect of androgens on bone maturation should be monitored closely by assessing bone age of the wrist and hand on a regular basis.

Geriatrics (>65 years of age):

There are very limited controlled clinical study data supporting the use of testosterone in the geriatric population and virtually no controlled clinical studies on subjects 75 years and over.

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

Geriatric patients and other patients with clinical or demographic characteristics that are recognized to be associated with an increased risk of prostate cancer should be evaluated for the presence of prostate cancer prior to initiation of testosterone replacement therapy.

In men receiving testosterone replacement therapy, surveillance for prostate cancer should be consistent with current practices for eugonadal men.

Carcinogenesis

Prostatic

Geriatric patients treated with androgens may be at an increased risk for the development of prostatic hyperplasia and prostatic carcinoma (see **Special Populations – Geriatrics**).

Breast

Patients using long-term androgen therapy may be at an increased risk for the development of breast cancer².

Hepatic

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 testosterone enanthate, which elevates blood levels for prolonged periods, has produced multiple hepatic adenomas.

Skeletal

Patients with skeletal metastases are at a risk of exacerbating hypercalcemia/hypercalciuria with concomitant androgen therapy.

Cardiovascular

Testosterone may increase blood pressure and should be used with caution in patients with hypertension.

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.

Dependence/Tolerance

DELATESTRYL contains testosterone, a Schedule G controlled substance, as defined by the Food and Drugs Act.

Endocrine and Metabolism

Androgens have been shown to alter glucose tolerance tests. Diabetics should be followed carefully and the insulin or oral hypoglycemic dosage adjusted accordingly (see **Drug-Drug Interactions**).

Hypercalciuria/hypercalcemia (caused by malignant tumors) may be exacerbated by androgen treatment. Androgens should be used with caution in cancer patients at risk of hypercalcemia (and associated hypercalciuria). Regular monitoring of serum calcium concentrations is recommended in patients at risk of hypercalciuria/hypercalcemia.

Hypercalcemia may occur in immobilized patients. If this occurs, the drug should be discontinued.

Hematologic

Hemoglobin and hematocrit levels should be checked periodically (to detect polycythemia) in patients on long-term androgen therapy (see **Monitoring and Laboratory Tests**).

Alkylated derivatives of testosterone such as methandrostenolone, have been reported to decrease the anticoagulant requirement of patients receiving oral anticoagulants (e.g. warfarin). Patients receiving oral anticoagulants therapy require close monitoring, especially when androgens are started or stopped (see **Drug-Drug Interactions**).

Respiratory

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

Sexual Function/Reproduction

Gynecomastia may frequently develop and occasionally persist in patients being treated for hypogonadism.

Priapism or excessive sexual stimulation may develop.

Oligospermia may occur after prolonged administration or excessive dosage.

Inflammation and pain at the site of intramuscular injection may occur.

Monitoring and Laboratory Tests

The patient should be monitored (including serum testosterone levels) on a regular basis to ensure adequate response to treatment.

Currently there is no consensus about age specific testosterone levels. The normal serum testosterone level for young eugonadal men is generally accepted to be approximately 10.4-34.6 nmol/L (300-1000 ng/dL). It should be taken into account that physiological testosterone levels (mean and range) decrease with increasing age.

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; to detect hepatotoxicity associated with the use of 17-alpha-alkylated androgens;
- 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;
- Diabetics should be followed carefully and the insulin or oral hypoglycemic dosage adjusted accordingly (see **Drug-Drug Interactions**).

ADVERSE REACTIONS

Adverse Drug Reaction Overview

Adverse reactions to DELATESTRYL are similar in nature to reactions to other androgens. The following events have been reported with the use of DELATESTRYL in clinical practice:

Table 1:

<i>MedDRA System Organ Class (SOC)</i>	<i>Adverse Drug Reaction Preferred Term/Collapsed Preferred Term</i>
Blood and the lymphatic system disorders:	Leucopenia; haemostasis: bleeding in patients on concomitant anticoagulant therapy
General disorders and administration site conditions:	Injection site inflammation
Nervous system disorders:	Insomnia
Psychiatric disorders:	Increased libido, decreased libido, habituation (dependence)
Renal and urinary disorders:	Bladder irritability
Reproductive system and breast disorders:	Testicular atrophy, oligospermia, impotence, priapism, gynecomastia, epididymitis
Skin and subcutaneous tissue disorders:	Urticaria, rash, vesiculo-bullous rash, acne

Clinical Trial Adverse Drug Reaction

Clinical safety and efficacy of DELATESTRYL (testosterone enanthate injection) is supported by clinical use with Canadian patients since 1956.

Post-Market Adverse Drug Reactions

In addition to those adverse events reported during clinical trials, the following adverse reactions have been identified during post-marketing use of DELATESTRYL and known reactions of testosterone treatment in general. 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 2: Adverse Drug Reactions from Post-marketing Experience of DELATESTRYL and Known Adverse Drug Reactions of General Testosterone Treatment:

MedDRA System Organ Class (SOC)	Adverse Drug Reaction
Blood and the lymphatic system disorders:	Polycythemia, erythropoiesis abnormal
Endocrine disorders:	Abnormal accelerated growth (growth accelerated)
Gastrointestinal disorders:	Nausea, vomiting, diarrhea, abdominal pain, gastrointestinal bleeding
General disorders and administration site conditions:	Edema, malaise, fatigue, application site burning, application site induration, application site rash, application site dermatitis, application site blister, application site erythema
Hepatobiliary disorders:	Hepatic neoplasms, peliosis hepatis
Immune system disorders:	Allergic reaction, hypersensitivity reaction
Investigations:	Weight increase, fluctuating testosterone levels, testosterone decreased, abnormal liver function tests (e.g. elevated GGTP), lipid abnormalities
Metabolism and nutrition disorders:	Increased appetite, electrolyte changes (nitrogen, potassium, phosphorus, sodium), urine calcium decrease, glucose tolerance impaired, elevated cholesterol
Musculoskeletal and connective tissue disorders:	Myalgia, arthralgia
Nervous system disorders:	Insomnia, headache, dizziness
Psychiatric disorders:	Personality disorder, confusion, anger, aggression, depression, anxiety, decreased libido, cognitive disturbance
Renal and urinary disorders:	Dysuria, hematuria, incontinence, bladder irritability
Reproductive system and breast disorders:	Prostate carcinoma, enlarged prostate (benign), free prostate-specific antigen increased, testicular atrophy, epididymitis, oligospermia, priapism, impotence, precocious puberty, gynecomastia, mastodynia
Respiratory, thoracic and mediastinal disorders:	Dyspnea, sleep apnea
Skin and subcutaneous tissue disorders:	Pruritus, rash, urticaria, vesiculo-bullous rash, seborrhea, acne, alopecia, male pattern baldness, hirsutism
Vascular Disorders:	Hypertension

DRUG INTERACTIONS

Drug-Drug Interactions

Insulin: In diabetic patients, the metabolic effects of androgens may decrease blood glucose and, therefore, insulin requirements.

Propranolol: In a published pharmacokinetic study of an injectable testosterone product, administration of testosterone cypionate led to an increased clearance of propranolol in the majority of men tested. It is unknown if this would apply to DELATESTRYL.

Corticosteroids: The concurrent administration of testosterone with ACTH or corticosteroids may enhance edema formation; thus these drugs should be administered cautiously particularly in patients with cardiac, renal or hepatic disease.

Anticoagulants: Androgens may increase sensitivity to oral anticoagulants. Dosage of the anticoagulant may require reduction in order to maintain satisfactory therapeutic hypoprothrombinemia.

Drug-Food Interactions

Interactions with food have not been established.

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^{3,4}.

Drug-Laboratory Interactions

Androgens 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.

DOSAGE AND ADMINISTRATION

Dosing Considerations

Dosage and duration of therapy with DELATESTRYL (Testosterone Enanthate Injection) will depend on age, diagnosis, patient's response to treatment, and appearance of adverse effects. When properly given, injections of DELATESTRYL are well tolerated.

In general, total doses above 400 mg per month are not required because of the prolonged action of the preparation. Injections more frequently than every two weeks are rarely indicated.

Recommended Dose and Dosage Adjustment

For replacement in hypogonadal male, the usual dose is 100-400 mg every four weeks.

The AACE Hypogonadism Task Force suggested the following regimen of parenteral testosterone preparations in treatment of hypogonadism in adult male patients⁵:

DELATESTRYL (testosterone enanthate) and testosterone cypionate are long-acting testosterone esters suspended in oil to prolong absorption. Peak levels occur about 72 hours after intramuscular injection and are followed by a slow decline during the subsequent 1 to 2 weeks.

For complete androgen replacement, the regimen should be between 50 and 100 mg of testosterone enanthate administered intramuscularly every 7 to 10 days, which will achieve relatively normal levels of testosterone throughout the time interval between injections. Longer time intervals are more convenient but are associated with greater fluctuations in testosterone levels. Higher doses of testosterone produce longer-term effects but also higher peak levels and wider swings between peak and nadir circulating testosterone levels; the result is fluctuating symptoms in many patients.

The use of 100 to 150 mg of testosterone every 2 weeks is a reasonable compromise. Use of 300 mg injections every 3 weeks is associated with wider fluctuations of testosterone levels and is generally inadequate to ensure a consistent clinical response. With use of these longer-interval regimens, many men will have pronounced symptoms during the week preceding the next injection. In such instances, a smaller dose at closer intervals should be tried.

As a guide, testosterone levels should be above the lower limit of normal, in the range of 250 to 300 ng/dL, just before the next injection. Excessive peak levels and side effects should also be monitored and used to adjust the dosing regimens.

When full androgen replacement is not required, patients should receive lower doses of testosterone. One such category includes adult male patients with prepubertal onset of hypogonadism who are going through puberty for the first time during therapy and who often may require psychologic counseling, especially when a spouse is involved as well. In these patients, testosterone therapy should be initiated at 50 mg every 3 to 4 weeks and then gradually increased during subsequent months, as tolerated, up to full replacement within 1 year. Men with appreciable benign prostatic hypertrophy who have hypogonadism and symptoms may be given 50 to 100 mg of testosterone every 2 weeks as an initial regimen and maintained on this dosage with careful monitoring of urinary symptoms and prostate examinations; therapy can be withdrawn if necessary.

Attaining full virilization in the patient with hypogonadism may take as long as 3 to 4 years. Follow-up intervals should be between 4 and 6 months to monitor progress, review compliance, and determine whether any complications or psychologic adjustment problems are present.

Administration

Care should be taken to inject the preparation deeply into the gluteal muscle following the usual precautions for intramuscular administration.

NOTE: Use of a wet needle or wet syringe may cause the solution to become cloudy; however

this does not affect the potency of the material.

Missed Dose

A missed dose should be administered as soon as possible. However, if it is almost time for the next regularly scheduled dose, then the missed dose should be skipped and next one should be taken as directed.

OVERDOSAGE

Symptoms of a testosterone overdose are not known. No specific antidote is available. Symptomatic and supportive treatment should be given.

ACTION AND CLINICAL PHARMACOLOGY

Pharmacodynamics

Testosterone and Hypogonadism:

Testosterone and dihydrotestosterone (DHT), endogenous androgens, are responsible for normal growth and development of male sex organs and for 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; alterations in body musculature; and fat distribution.

Male hypogonadism results from insufficient secretion of testosterone and is characterized by low serum testosterone concentrations. Symptoms associated with male hypogonadism include decreased sexual desire with or without impotence, fatigue and loss of energy, mood depression, regression of secondary sexual characteristics, and osteoporosis. Hypogonadism is a risk factor for osteoporosis in men.

General Androgen Effects:

Drugs in the androgen class also promote retention of nitrogen, sodium, potassium, phosphorus, and decreased urinary excretion of calcium.

Androgens have been reported to increase protein anabolism and decrease protein catabolism. Nitrogen balance is improved only when there is sufficient intake of calories and protein. Androgens have been reported to stimulate the production of red blood cells by enhancing erythropoietin production.

Androgens are responsible for the growth spurt of adolescence and for the eventual termination of linear growth brought about by fusion of the epiphyseal growth centers. In children, exogenous androgens accelerate linear growth rates but may cause a disproportionate

advancement in bone maturation. Use over long periods may result in fusion of the epiphyseal growth centers and termination of the growth process.

During exogenous administration of androgens, endogenous testosterone release may be inhibited through feedback inhibition of pituitary luteinizing hormone (LH). At large doses of exogenous androgens, spermatogenesis may also be suppressed through feedback inhibition of pituitary follicle-stimulating hormone (FSH).

Pharmacokinetics

DELATESTRYL is a sterile, long acting preparation of an esterified derivative of the naturally occurring androgenic hormone, testosterone. Testosterone esters are less polar than free testosterone. Testosterone esters in oil injected intramuscularly are absorbed slowly from the lipid phase; thus testosterone enanthate can be given at intervals of two to four weeks.

Absorption:

One study was performed to provide comparison of the serum testosterone levels achieved by injection of testosterone enanthate or testosterone cypionate in equivalent doses.

Testosterone enanthate (194 mg) and testosterone cypionate (200 mg) were injected so that the amount of unesterified testosterone was the same in both preparations (140 mg).

The serum testosterone levels were identical after both preparations. The concentrations increased sharply, reaching maximal levels three times above basal on days one and two after injection, and decreased gradually thereafter, so that basal levels were reached on day ten.

In an earlier study, the same authors were investigating serum testosterone and LH concentrations in normal and hypogonadal men after injection of 250 mg of testosterone enanthate. Increasing the dose of injected testosterone enanthate from 194 mg to 250 mg did not influence the maximal concentration but rather the duration of the effect⁶.

Distribution:

Circulating testosterone is chiefly bound in the serum to sex hormone-binding globulin (SHBG) and albumin. The albumin-bound fraction of testosterone easily dissociates from albumin and is presumed to be bioactive. The portion of testosterone bound to SHBG is not considered biologically active. Approximately 40% of testosterone in plasma is bound to SHBG, 2% remains unbound (free) and the rest is bound to albumin and other proteins. The amount of SHBG in the serum and the total testosterone level will determine the distribution of bioactive and nonbioactive androgen.

Metabolism:

There is considerable variation in the half-life of testosterone as reported in the literature, ranging from ten to 100 minutes.

Testosterone is metabolized to various 17-keto steroids through two different pathways. The major active metabolites of testosterone are estradiol and dihydrotestosterone (DHT).

Testosterone is metabolized to DHT by steroid 5 α reductase located in the skin, liver, and urogenital tract of the male. Estradiol is formed by an aromatase enzyme complex in the brain,

fat, and testes. DHT binds with greater affinity to SHBG than does testosterone. In many tissues, the activity of testosterone depends on its reduction to DHT, which binds to cytosol receptor proteins. The steroid-receptor complex is transported to the nucleus where it initiates transcription and cellular changes related to androgen action. In reproductive tissues, DHT is further metabolized to 3- α and 3- β androstanediol.

Excretion:

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 dose is excreted in the feces, mostly in the unconjugated form. Inactivation of testosterone occurs primarily in the liver.

STORAGE AND STABILITY

Store at controlled room temperature between 15°C and 30°C.

DOSAGE FORMS, COMPOSITION AND PACKAGING

DELATESTRYL is a sterile, oily testosterone enanthate solution for intramuscular use. It is available in a potency of 200 mg per mL formulated in sesame oil with 0.5% chlorobutanol as a preservative. It is available in glass vials containing 5 mL, sealed with latex free stoppers.

PART II: SCIENTIFIC INFORMATION

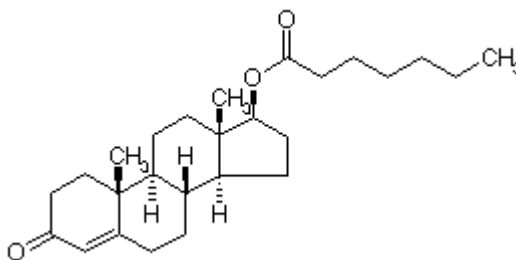
PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: testosterone enanthate

Chemical name: androst-4-en-one, 17-(1-oxoheptyl)oxy-, (17 β)-.

Molecular formula and molecular mass: C₂₆H₄₀O₃, 400.59



Structural formula:

Physicochemical properties: A white or yellowish-white crystalline powder. It is odourless or has a faint odour characteristic of heptanoic acid. Practically insoluble in water; very soluble in ether, dehydrated alcohol; freely soluble in fatty oils.

CLINICAL TRIALS

Clinical Trial data is not available.

Clinical safety and efficacy of DELATESTRYL (testosterone enanthate injection) is supported by clinical use with Canadian patients since 1956 without incidence.

REFERENCES

1. Bhasin S, Cunningham GR, Hayes FJ, Matsumoto AM, Snyder PJ, Swerdloff RS et al. Testosterone therapy in adult men with androgen deficiency syndromes: An endocrine society clinical practice guideline. *J Clin Endocrinol Metab* 2006;91(6):1995-2010.
2. Medras M, Filus A, Jozkow P, Winowski J, Sicinska-Werner T. (2006) Breast cancer and long-term hormonal treatment of male hypogonadism. *Breast Cancer Research and Treatment* 96:263-265.
3. Markowitz JS, Donovan JL, DeVane CL, Taylor RM, Ruan Y, Wang J, Chavin KD. (2003) Effect of St John's Wort on drug metabolism by induction of cytochrome P450 3A4 enzyme. *JAMA* 290(11):1500-1504.
4. Donovan JL, DeVane CL, Lewis JG, Wang J, Ruan Y, Chavin KD, Markowitz JS. (2005) Effects of St John's Wort (*Hypericum perforatum* L.) extract on plasma androgen concentrations in healthy men and women: A pilot study. *Phytotherapy Research* 19:901-906.
5. AACE Medical guidelines for clinical practice for evaluation and treatment of hypogonadism in adult male patients: *Endocrine Practice* 2002; 8(No.6): 449.
6. Schulte-Berubuhl M et al., Comparison of testosterone, dihydrotestosterone, luteinising hormone, and follicle-stimulating hormone in serum after injection of testosterone enanthate and testosterone cypionate. *Fertility and Sterility* (1980) 33.2 : 201-203.

PART III: CONSUMER INFORMATION

DELATESTRYL*
 (testosterone enanthate injection)

This leaflet is part III of a three-part "Prescribing Information" and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about DELATESTRYL. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

Your doctor has prescribed this medicine because your body is not making enough testosterone. The medical term for this condition is hypogonadism.

What it does:

DELATESTRYL delivers medicine into your bloodstream by intramuscular injection. **DELATESTRYL** helps raise your testosterone to normal levels.

When it should not be used:

- If you have or it is suspected that you have prostate or breast cancer.
- If you have difficulty in urinating due to an enlarged prostate.
- Known allergy to any of its components [the active ingredient is testosterone, which may be synthesized from soy; (see "What the nonmedicinal ingredients are" in this section)]

DELATESTRYL should **NOT** be used by **women**.

What the medicinal ingredient is:
testosterone enanthate**What the nonmedicinal ingredients are:**
sesame oil
chlorobutanol**What dosage forms it comes in:**

A 200 mg/mL solution for intramuscular injection.

WARNINGS AND PRECAUTIONS

There is very little information from clinical trials with testosterone in the older male (>65 years of age) to support safe use for a long period of time.

You should not use testosterone in an attempt to reduce weight and increase muscle, or improve athletic performance as it may cause serious health problems.

You should not use testosterone to treat sexual dysfunction or male infertility.

Before using DELATESTRYL, talk to your doctor if you:

- have difficulty urinating due to an enlarged prostate. Older patients may have a higher risk of developing an enlarged prostate or prostate cancer;
- have prostate cancer (confirmed or suspected);
- have liver, kidney or heart disease;
- have high blood pressure (hypertension);
- have diabetes;
- have breathing problems during sleep (sleep apnea).

Drug Abuse and Dependence:

DELATESTRYL contains testosterone, which is a controlled substance under Schedule G of the Food and Drugs Act.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or have recently taken any other drugs or herbal products, even those without a prescription.

Drugs that may interact with **DELATESTRYL** include:

- Insulin
- Corticosteroids
- Propranolol
- Warfarin

PROPER USE OF THIS MEDICATION

What should I do if I miss a dose of DELATESTRYL?

If you missed a dose, you should consult your health care provider (physician).

What should I do in case of overdose?

Contact your doctor or pharmacist immediately if you suspect an overdose.

Never share your **DELATESTRYL** with anyone. Every patient is different. Your doctor has prescribed **DELATESTRYL** specifically for your needs. To get the best results from **DELATESTRYL**, it is essential that you take it exactly as your doctor has prescribed.

Use **DELATESTRYL** only for the condition for which it was prescribed. If you have any questions or concerns about **DELATESTRYL** treatment, ask your health care provider or pharmacist. They can answer your questions and may be able to give you additional printed information about **DELATESTRYL**.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, **DELATESTRYL** can have side effects. The following side effects have been reported for products containing testosterone:

- Skin irritation or redness or rash at the application site;
- increased prostatic specific antigen (PSA);
- enlarged prostate (benign prostatic hyperplasia);
- an increase in red blood cell count (hematocrit and hemoglobin);
- acne;
- change in mood, depression;
- prolonged or painful erection;
- sleep disturbances caused by breathing problems;
- aggression or aggressive behaviour;
- breast enlargement and breast pain;
- loss of hair and baldness;
- high blood pressure;
- weight gain;
- headache, dizziness.

This is not a complete list of side effects. For any unexpected effects while taking **DELATESTRYL**, contact your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/Effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Urinary symptoms (i.e. change in frequency/color, dribbling, pain on urination straining, weak stream, small amounts)		✓	
Common (after prolonged use)	Breast enlargement or breast pain		✓	
Uncommon	Swelling of ankles and legs (in patients with heart, kidney or liver damage)			✓
Uncommon	Erections that are too frequent or continue for too long		✓	
Uncommon	Liver problems, with symptoms such as nausea, vomiting, along with yellowed or darkened skin			✓

HOW TO STORE IT

DELATESTRYL should be stored at controlled room temperature between 15°C and 30°C.

Keep out of reach of children and pets.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345

toll-free fax 866-678-6789

By email: cadrmp@hc-sc.gc.ca

By regular mail:

Canadian Adverse Drug Reaction Monitoring Program
(CADRMP)

Marketed Health Products Directorate

Health Canada

Tunney's Pasture, AL 0701C

Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.website.document>

or by contacting the sponsor, Theramed Corporation, at:
1-800-305-4441

This leaflet was prepared by Theramed Corporation.

Last revised: June, 2007.