

WHEN TREATING HYPOGONADAL MEN WITH
TESTOSTERONE REPLACEMENT THERAPY (TRT),

PUT TRT IN ITS PLACE



INDICATION

MALES

Androgens are indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

- a. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome; or orchiectomy
- b. Hypogonadotropic hypogonadism (congenital or acquired) - gonadotropic LHRH deficiency, or pituitary - hypothalamic injury from tumors, trauma or radiation

Safety and efficacy of TESTOPEL® in men with “age-related hypogonadism” have not been established.

IMPORTANT SAFETY INFORMATION ABOUT TESTOPEL® CONTRAINDICATIONS

- Androgens are contraindicated in men with carcinomas of the breast or with known or suspected carcinomas of the prostate

Please see pages 9 and 10 for Important Safety Information.

Please [click here](#) for full Prescribing Information for TESTOPEL®.

LONG-ACTING **TESTOPEL**[®]
(testosterone pellets) 

WHICH OF YOUR LOW T PATIENTS ARE RIGHT FOR TESTOPEL®?

TESTOSTERONE PELLETS— A LOW T TREATMENT OPTION

Jeff, 43

- Married with children, ages 4 and 7
- Height: 5'11"
- Weight: 190 lbs
- IT specialist
- Diagnosed with primary hypogonadism
- Testosterone blood levels: 220 ng/dL
- Previously used a daily testosterone gel. Looking for another treatment option without a daily application routine



According to the 2018 Endocrine Society Guidelines, testosterone pellets are a suggested formulation along with other TRTs¹

The Endocrine Society suggests monitoring testosterone levels 3 to 6 months after initiation — TESTOPEL® can be administered every 3 to 6 months. It also suggests monitoring testosterone levels at the end of the dosing interval, at 12 months, and annually after initiation.^{1,2}

Henry, 62

- Single
- Height: 5'9"
- Weight: 167 lbs
- Recently retired, traveler
- Diagnosed with primary hypogonadism
- Testosterone blood levels: 250 ng/dL
- Previously used a testosterone replacement injection therapy



The Endocrine Society does not recommend testosterone therapy for men with¹:

- Breast or prostate cancer
- Palpable prostate nodule or induration or prostate-specific antigen level greater than 4 ng/mL or greater than 3 ng/mL in men at high risk for prostate cancer without further urological evaluation
- Elevated hematocrit
- Untreated severe obstructive sleep apnea
- Severe lower urinary tract symptoms with International Prostate Symptom Score above 19
- Uncontrolled or poorly controlled heart failure
- A desire for fertility in the near term
- Thrombophilia
- Myocardial infarction or stroke within the last 6 months

Not actual patients. For illustrative purposes only.

IMPORTANT SAFETY INFORMATION ABOUT TESTOPEL® (con't) CONTRAINDICATIONS (con't)

- If administered to pregnant women, androgens cause virilization of the external genitalia of the female fetus. If the patient becomes pregnant while taking these drugs, she should be apprised of the potential hazard to the fetus

WARNINGS

- In patients with breast cancer, androgen therapy may cause hypercalcemia by stimulating osteolysis. In this case, the drug should be discontinued
- Prolonged use of high doses of androgens has been associated with the development of peliosis hepatis (which can be a life-threatening or fatal complication) and hepatic neoplasms including hepatocellular carcinoma

Please see pages 9 and 10 for Important Safety Information.
Please [click here](#) for full Prescribing Information for TESTOPEL®.

TESTOPEL® dosage and administration

Prior to initiating TESTOPEL®, 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.

The TESTOPEL® label outlines the dosage guidelines for replacement therapy in androgen-deficient males as 150 mg to 450 mg subcutaneously every 3 to 6 months.²

LONG-ACTING **TESTOPEL**[®]
(testosterone pellets) 

PUT TESTOPEL® IN, TAKE DAILY APPLICATION OUT²

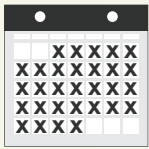
TESTOPEL® is implanted no more than 4 times per year²

For your appropriate hypogonadal patients, TESTOPEL® is implanted between 2 to 4 times per year.^{1,2}

Different TRTs have different dosing regimens^{1,2}

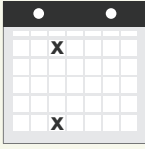
Topical Gels/Solutions

Daily

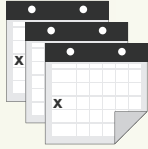


Injections

Every 2-4 weeks (short-acting)

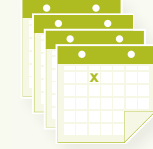


Every 10 weeks (long-acting)



TESTOPEL®

Every 3-6 months



TESTOPEL® dosage and administration

Prior to initiating TESTOPEL®, 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.

The TESTOPEL® label outlines the dosage guidelines for replacement therapy in androgen-deficient males as 150 mg to 450 mg subcutaneously every 3 to 6 months.²

TESTOPEL® may be right for hypogonadal patients who want^{2,3}:

- A long-acting TRT with no daily application routine
- A discreet choice
- A treatment option that does not carry the risk of transference
- An in-office procedure

2-4 implantations per year²

IMPORTANT SAFETY INFORMATION ABOUT TESTOPEL® (con't) WARNINGS (con't)

- Men treated with androgens may be at an increased risk for the development of prostatic hypertrophy and prostatic carcinoma
- There have been postmarketing reports of venous thromboembolic events (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE), in patients using testosterone products, such as TESTOPEL®. Evaluate patients who report symptoms of DVT or PE. If a VTE is suspected, discontinue treatment with TESTOPEL® and initiate appropriate workup and management
- Some postmarketing studies have shown an increased risk of major adverse cardiovascular events (MACE) with use of testosterone replacement therapy. Patients should be informed of this possible risk when deciding to use or to continue to use TESTOPEL®

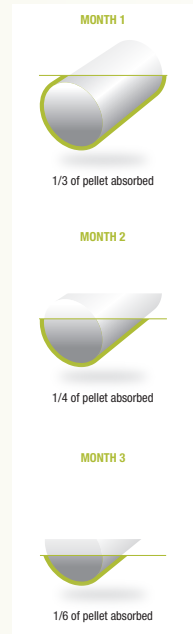
Please see pages 9 and 10 for Important Safety Information.
Please [click here](#) for full Prescribing Information for TESTOPEL®.

HELP RESTORE TESTOSTERONE LEVELS, MONTH AFTER MONTH²

TESTOPEL® can deliver an adequate effect for 3-4 months, sometimes up to 6 months²

TESTOPEL® pellets are absorbed gradually, helping to normalize testosterone levels for 3-6 months.²

TESTOPEL® slowly releases testosterone over time for a long-acting androgenic effect²



TESTOPEL® dosage and administration

- When TESTOPEL® pellets are implanted subcutaneously, the pellets slowly release the hormone for a long-acting androgenic effect²
- TESTOPEL® provides a treatment option for hypogonadal patients that does not carry the risk of transference³

- The suggested dosage and administration of TESTOPEL® is 2 to 6 pellets every 3 to 6 months²
- Dosage can be adjusted according to patient response and tolerability²
- Suggested dosage varies for patients depending on their age and diagnosis²

Not actual size. Visual intended for demonstrative purposes only.

IMPORTANT SAFETY INFORMATION ABOUT TESTOPEL® (con't) WARNINGS (con't)

- Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication and in combination with other anabolic steroids. Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions. If testosterone abuse is suspected, check serum testosterone concentrations to ensure that 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 androgenic steroid abuse in suspected patients who present with serious cardiovascular or psychiatric adverse events
- Edema with or without congestive heart failure may be a serious complication in patients with preexisting cardiac, renal, or hepatic disease. In addition to discontinuation of the drug, diuretic therapy may be required

LONG-ACTING **TESTOPEL**[®]
(testosterone pellets)

SEE HOW TESTOPEL® CAN FIT INTO YOUR PRACTICE

The TESTOPEL® implantation procedure³ can be completed in approximately 15 minutes in your office⁴



1. PREP

Clean the insertion site



2. NUMB & INCISE

Numb and make a small incision in the skin



3. INSERT

Implant pellets into subdermal fat layer



4. POST-CARE

Seal the incision with Steri-Strips

For more detailed overview of the implantation procedure, [click here](#) for the TESTOPEL® Implantation Guide.

15-minute procedure

TESTOPEL® administration is an approximately 15-minute, in-office, implantation procedure.⁴

With a few implantations needed per year, TESTOPEL® should be considered as an option for your appropriate hypogonadal patients.²

Post-administration

For your patients

A post-treatment tips and considerations guide is available in print and online formats.



Download the **POST-TREATMENT TIPS AND CONSIDERATIONS GUIDE** for your patients at testopel.com

IMPORTANT SAFETY INFORMATION ABOUT TESTOPEL® (con't) WARNINGS (con't)

- Gynecomastia frequently develops in patients and occasionally persists in patients being treated for hypogonadism
- Postmarketing cases associate TESTOPEL® insertion with implant site infection (cellulitis and abscess) and/or pellet extrusion. Infection and/or extrusion can occur at any time and may require further treatment
- This drug has not been shown to be safe and effective for the enhancement of athletic performance. Because of the potential risk for serious adverse health effects, this drug should not be used for such purpose

Please see pages 9 and 10 for Important Safety Information. Please [click here](#) for full Prescribing Information for TESTOPEL®.

Get TESTOPEL® in your practice



TESTOPEL® can be obtained in two different ways, depending on your practice:

- Available via buy and bill through Besse Medical*
 - Purchase TESTOPEL® pellets, then bill your patients' insurance
- Available from a Specialty Pharmacy

*Contact Besse Medical at:

Phone: 1-888-252-5585

Mail: 9075 Centre Pointe Drive, Suite 140, West Chester, OH 45069

LONG-ACTING **TESTOPEL**® 75mg
(testosterone pellets)

SUGGESTED CODING FOR TESTOPEL®

TESTOPEL® is covered by a majority of commercial insurance plans^{5*}

TESTOPEL® implantation is a procedure with possible billing codes†

CPT1 (Procedure) Code	11980	Subcutaneous hormone pellet implantation (implantation of testosterone pellets beneath the skin)
HCPCS Code (Private Insurance)	S0189	Testosterone pellet, 75 mg
HCPCS Code (Medicare)	J3490	Unclassified drugs
NDC Code (For Medicare claims)	66887-004-20 (10-digit) 66887-0004-20 (11-digit)	100-count box. Use in Box 19 of CMS 1500 form
NDC Code (For Medicare claims)	66887-004-10 (10-digit) 66887-0004-10 (11-digit)	10-count box. Use in Box 19 of CMS 1500 form

*Insurance coverage and reimbursement for TESTOPEL® are not guaranteed. Coverage and reimbursement depend on an individual patient's insurance plan. We recommend that you contact the insurance provider to verify TESTOPEL® coverage and reimbursement.

†NOTE: Coding is part of the clinical decision. Please use codes that most accurately reflect the procedure performed. Suggestions by Endo Pharmaceuticals Inc. do not guarantee reimbursement or take the place of professional coding advice. The NDC product code may vary.

IMPORTANT SAFETY INFORMATION

INDICATION

MALES

Androgens are indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

- Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome; or orchiectomy
- Hypogonadotropic hypogonadism (congenital or acquired) - gonadotropic LHRH deficiency, or pituitary - hypothalamic injury from tumors, trauma or radiation

Safety and efficacy of TESTOPEL® in men with "age-related hypogonadism" have not been established.

IMPORTANT SAFETY INFORMATION ABOUT TESTOPEL® CONTRAINDICATIONS

- Androgens are contraindicated in men with carcinomas of the breast or with known or suspected carcinomas of the prostate
- If administered to pregnant women, androgens cause virilization of the external genitalia of the female fetus. If the patient becomes pregnant while taking these drugs, she should be apprised of the potential hazard to the fetus

WARNINGS

- In patients with breast cancer, androgen therapy may cause hypercalcemia by stimulating osteolysis. In this case, the drug should be discontinued
- Prolonged use of high doses of androgens has been associated with the development of peliosis hepatis (which can be a life-threatening or fatal complication) and hepatic neoplasms including hepatocellular carcinoma
- Men treated with androgens may be at an increased risk for the development of prostatic hypertrophy and prostatic carcinoma
- There have been postmarketing reports of venous thromboembolic events (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE), in patients using testosterone products, such as TESTOPEL®. Evaluate patients who report symptoms of DVT or PE. If a VTE is suspected, discontinue treatment with TESTOPEL® and initiate appropriate workup and management
- Some postmarketing studies have shown an increased risk of major adverse cardiovascular events (MACE) with use of testosterone replacement therapy. Patients should be informed of this possible risk when deciding to use or to continue to use TESTOPEL®
- Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication and in combination with other anabolic steroids. Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions. If testosterone abuse is suspected, check serum testosterone concentrations to ensure that 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 androgenic steroid abuse in suspected patients who present with serious cardiovascular or psychiatric adverse events
- Edema with or without congestive heart failure may be a serious complication in patients with preexisting cardiac, renal, or hepatic disease. In addition to discontinuation of the drug, diuretic therapy may be required
- Gynecomastia frequently develops in patients and occasionally persists in patients being treated for hypogonadism
- Postmarketing cases associate TESTOPEL® insertion with implant site infection (cellulitis and abscess) and/or pellet extrusion. Infection and/or extrusion can occur at any time and may require further treatment

Please see pages 9 and 10 for Important Safety Information.
Please [click here](#) for full Prescribing Information for TESTOPEL®.

LONG-ACTING **TESTOPEL**[®]
(testosterone pellets) 

IMPORTANT SAFETY INFORMATION (con't)

IMPORTANT SAFETY INFORMATION ABOUT TESTOPEL® (con't) WARNINGS (con't)

- This drug has not been shown to be safe and effective for the enhancement of athletic performance. Because of the potential risk for serious adverse health effects, this drug should not be used for such purpose

PRECAUTIONS

- There is less flexibility for dosage adjustment compared to oral, intramuscular, or aqueous suspension. Surgical removal may be required if testosterone therapy is discontinued

ADVERSE REACTIONS

- Side effects reported with the use of TESTOPEL® include: excessive frequency and duration of penile erections, hirsutism, oligospermia at high doses, nausea, cholestatic jaundice, rare hepatic neoplasms, increased serum cholesterol, acne, acceleration of bone maturation without compensatory gain in linear growth in children, male pattern baldness, alterations in liver function tests, suppression of clotting factors, bleeding in patients on concomitant anticoagulation therapy, polycythemia, fluid and electrolyte disturbances, increased or decreased libido, headache, anxiety, depression, generalized paresthesia, edema, and/or prostate enlargement accompanied by difficulty urinating
- TESTOPEL® insertion may cause pain at the site of subcutaneous implantation of pellets and is rarely associated with anaphylactoid reactions

DRUG ABUSE AND DEPENDENCE

- Abuse and misuse of testosterone are seen in male and female adults and adolescents. Testosterone, often in combination with other anabolic androgenic steroids, may be abused by athletes and bodybuilders
- 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 been reported in men: transient ischemic attacks, convulsions, hypomania, irritability, dyslipidemia, testicular atrophy, subfertility, and infertility
- The following 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
- Withdrawal symptoms can be experienced upon abrupt discontinuation in patients with addiction. Withdrawal symptoms include depressed mood, major depression, fatigue, craving, restlessness, irritability, anorexia, insomnia, decreased libido, and hypogonadotropic hypogonadism. Drug dependence in individuals using approved doses for approved indications have not been documented.

Please [click here](#) for full Prescribing Information for TESTOPEL®.

References: 1. Bhasin S, Cunningham G, Brito JP, et al.; and the Endocrine Society Task Force. Testosterone therapy in men with hypogonadism: An endocrine society clinical practice guideline. *J Clin Endocrinol Metab.* 2018;103(5):1-30. 2. TESTOPEL® [package insert]. Endo Pharmaceuticals Inc. 3. Cavender RK, Fairall M. Subcutaneous testosterone pellet implant (TESTOPEL®) therapy for men with testosterone deficiency syndrome: a single-site retrospective safety analysis. *J Sex Med.* 2009;6(11):3177-3192. 4. Handelsman D, Mackey MA, Howe C, Turner L, Conway AJ. An analysis of testosterone implants for androgen replacement therapy. *Clin Endocrinol (Oxf).* 1997;47(3):311-316. 5. Data on file. TESTOPEL® TRP Transactions Report. May 2018 (data compiled February 1, 2018 through May 14, 2018). Endo Pharmaceuticals Inc. 6. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, 38th Edition. Food and Drug Administration Website. <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf>. Accessed June 2018.

WHEN TREATING HYPOGONADAL MEN WITH TESTOSTERONE REPLACEMENT THERAPY (TRT),

PUT TRT IN ITS PLACE



with TESTOPEL®, the only FDA-approved
testosterone pellet available⁶



TESTOPEL® helps restore
testosterone for 3-4 months,
sometimes up to 6 months²



TESTOPEL® is covered by
a majority of commercial
insurance plans^{5*}



TESTOPEL® pellets slowly
release testosterone over time for
a long-acting androgenic effect²

Offer your Low T patients long-acting TESTOPEL®²

*Insurance coverage and reimbursement for TESTOPEL® are not guaranteed. Coverage and reimbursement depend on an individual patient's insurance plan. We recommend that you contact the insurance provider to verify TESTOPEL® coverage and reimbursement.

LONG-ACTING **TESTOPEL**[®]
(testosterone pellets)

INDICATION

MALES

Androgens are indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

- a. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome; or orchiectomy
- b. Hypogonadotropic hypogonadism (congenital or acquired) - gonadotropic LHRH deficiency, or pituitary - hypothalamic injury from tumors, trauma or radiation

Safety and efficacy of TESTOPEL® in men with “age-related hypogonadism” have not been established.

IMPORTANT SAFETY INFORMATION ABOUT TESTOPEL®

CONTRAINDICATIONS

- Androgens are contraindicated in men with carcinomas of the breast or with known or suspected carcinomas of the prostate

Please see pages 9 and 10 for Important Safety Information.

Please [click here](#) for full Prescribing Information for TESTOPEL®.

LONG-ACTING **TESTOPEL**[®]
(testosterone pellets)[Ⓜ]



Rx Only

TESTOPEL® is a registered trademark of Endo International plc or one of its affiliates.
© 2018 Endo Pharmaceuticals Inc. All rights reserved. Malvern, PA 19355
TP-05093/June 2018 www.testopel.com 1-800-462-ENDO (3636)