

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 can increase cardiovascular (CV) risk over time. Monitor blood pressure periodically in men using testosterone products, especially in men with hypertension. Testosterone products are not recommended for use in patients with uncontrolled hypertension.
- 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
- 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
- Patients receiving oral anticoagulant therapy require close monitoring, especially when androgens are started or stopped
- In diabetic patients the metabolic effects of androgens may decrease blood glucose and insulin requirements

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

- TESTOPEL contains testosterone, a Schedule III controlled substance
- 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 see full **Prescribing Information**.

TESTOPEL®
75mg
(testosterone pellets) 

