Testopel should not be used in men with breast cancer due to the potential for development of hypercalcemia or in men with prostate cancer due to increased risk for the development of prostatic carcinoma. Patients should not use Testopel if they have had a previous adverse reaction to Testopel. Testopel is not approved for use in women.

Side effects reported with use of Testopel include: excessive frequency and duration of penile erections, hirsutism, 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, polycythemia, increased or decreased libido, headache, anxiety, depression, and generalized paresthesia. Some men may have breast development, breast discomfort, edema, 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. There is less flexibility for dosage adjustment compared to oral administration or intramuscular injection of oil solutions or aqueous suspension. Surgical removal may be required if testosterone therapy is discontinued.
**ABOUT TESTOPEL®**

TESTOPEL® is indicated for the treatment of conditions associated with low or absent testosterone in adult males. This condition is often referred to as Low Testosterone (Low T) or Testosterone Deficiency Syndrome.

TESTOPEL® is unique. It is the only FDA-approved implantable testosterone pellet. Placed every 3 to 6 months in your doctor’s office, TESTOPEL® is the only testosterone replacement therapy that normalizes testosterone levels for 3-6 months per dose.

Other testosterone therapies may require frequent injections into the muscle or daily topical application. If you have been diagnosed with testosterone deficiency speak with your physician about your treatment options to determine if TESTOPEL® is right for you.

**COMPARISON OF DOSING SCHEDULE**

<table>
<thead>
<tr>
<th>Select Treatment Options</th>
<th>Dosing Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>TESTOPEL® Placement</td>
<td>Every 3-6 months</td>
</tr>
<tr>
<td>Topical Gel Application</td>
<td>Daily</td>
</tr>
<tr>
<td>Injections into Muscle</td>
<td>Every 1-3 weeks</td>
</tr>
</tbody>
</table>

**IMPORTANT SAFETY INFORMATION**

Testopel should not be used in men with breast cancer due to the potential for development of hypercalcemia or in men with prostate cancer due to increased risk for the development of prostatic carcinoma. Patients should not use Testopel if they have had a previous adverse reaction to Testopel. Testopel is not approved for use in women.

Side effects reported with use of Testopel include: excessive frequency and duration of penile erections, hirsutism, 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, polycythemia, increased or decreased libido, headache, anxiety, depression, and generalized paresthesia. Some men may have breast development, breast discomfort, edema, 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. There is less flexibility for dosage adjustment compared to oral administration or intramuscular injection of oil solutions or aqueous suspension. Surgical removal may be required if testosterone therapy is discontinued.
IMPORTANT SAFETY INFORMATION

Testopel should not be used in men with breast cancer due to the potential for development of hypercalcemia or in men with prostate cancer due to increased risk for the development of prostatic carcinoma. Patients should not use Testopel if they have had a previous adverse reaction to Testopel. Testopel is not approved for use in women.

Side effects reported with use of Testopel include: excessive frequency and duration of penile erections, hirsutism, 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, polycythemia, increased or decreased libido, headache, anxiety, depression, and generalized paresthesia. Some men may have breast development, breast discomfort, edema, 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. There is less flexibility for dosage adjustment compared to oral administration or intramuscular injection of oil solutions or aqueous suspension. Surgical removal may be required if testosterone therapy is discontinued.

COMMONLY ASKED QUESTIONS ABOUT TESTOPEL®

Q: What size is a TESTOPEL® pellet?
A: Each TESTOPEL® pellet is small. The photo to the right shows the size of TESTOPEL® relative to a dime.

Q: Where is TESTOPEL® placed?
A: TESTOPEL® is placed just under the skin in the hip-area. Imagine the outer corner of the top of your pants back pocket.

Q: How will my doctor know when to replace my TESTOPEL®?
A: Your doctor may either schedule a follow-up visit or if you feel your symptoms returning you should contact your doctor so your testosterone levels can be measured.

Q: What can I expect after my TESTOPEL® placement?
A: You can return to work immediately. It is advisable not to swim, use a hot tub or lift heavy weights for a few days after TESTOPEL® is placed, but you may otherwise resume normal activity. You may experience soreness and/or bruising at the site. Please follow your doctor’s instructions.

Q: Are there patients that should not receive TESTOPEL®?
A: Yes, you should not receive any testosterone replacement therapy if you’ve ever had prostate or breast cancer. You should not receive TESTOPEL® if you’ve experienced an allergic reaction to it. Please see the Warnings and Contraindications sections of the complete Prescribing Information accompanying this Patient Information brochure.

Q: Will my insurance pay for TESTOPEL®?
A: The majority of insurance plans will cover TESTOPEL®. It can be treated as either a medical or pharmacy benefit depending on your plan. In either case, you won’t need to go to the pharmacy to get a TESTOPEL® prescription filled. Your doctor’s office can work with the TESTOPEL® Reimbursement Program to determine your exact benefit and provide appropriate direction.
In many tissues the activity of testosterone appears to depend
occurs primarily in the liver. Testosterone is metabolized to various
metabolites; about 6 percent of a dose is excreted in feces,
About 90 percent of a dose of testosterone is excreted
Between the free and bound forms, and the free testosterone
in the plasma will determine the distribution of testosterone
free. Generally, the amount of this sex-hormone binding globulin
uterine bleeding.
There is a lack of substantial evidence that androgens are
effective in fractures, surgery, convalescence, and functional
pain.
Androgens have been reported to stimulate the production of
epiphyseal growth centers and termination of growth process.
Androgens have been reported to increase protein
anabolism and decrease protein catabolism.
Androgens have been reported to cause 
beard, pubic, chest and axillary hair, laryngeal enlargements,
and decreased urinary excretion of calcium.
Androgens have been reported to increase protein
anabolism and decrease protein catabolism.

\[
\text{C}_19\text{H}_28\text{O}_4\text{N}\]
17β-Hydroxyandrostenedione 4-en-3-one

Each TESTOPÉL Pellet (testosterone) for subcutaneous implantation contains 75mg testosterone. In addition each pellet contains the following inactive ingredients: stearic acid USP 0.2mg and polyvinylpyrrolidone USP 2mg.

In clinical practice, the pellets slowly release the hormone for a long acting androgenic effect.

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.
- Hypogonadotrophic hypogonadism (congenital or acquired) - isosexual development or gonadal hypoplasia; or phallic - hypotalamic injury from tumors, trauma or radiation.

If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosteronedeficiency after puberty.

- Androgens may be used to stimulate puberty in carefully selected males with clearly delayed puberties. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be taken every 6 months to assure the effect of treatment on epiphyseal centers (see WARNINGS).

Androgens are contraindicated in men with carcinomas of the breast or who have been suspected carciomas of the prostate. If administered to pregnant women, androgens cause utilization of the external genitalia of the female fetus. The utilization includes cloacogenic, abnormal vaginal development, and fusion of genital folds to form a scrotal-like structure. The degree of masculinization is related to the amount of drug given and the age of the fetus, and is most likely to occur in the female fetus when the drugs are given in the first trimester. If the patient becomes pregnant while taking these drugs she should be apprised of the potential hazard to the fetus.

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 glandular and hepatic neoplasms including hepatocellular carcinoma (see PRECAUTIONS - Carcinogenesis, Mutagenesis, Impairment of Fertility). Prolonged testosterone can be a life-threatening or fatal complication.

Men treated with androgens may be at an increased risk for the development of prostatic hypertrophy and prostatic carcinoma.

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.

Androgen therapy should be used cautiously in healthy males with delayed puberty. The effect on bone maturation should be monitored by assessing bone age of the wrist and hand every 6 months. In children, androgen treatment may accelerate bone maturation without producing compensatory gain in linear growth. This adverse effect may result in compromised adult stature. The younger the child the greater the risk of compromising final mature height.

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 purposes.

PREGNANCY AND NURSING MOTHERS

It is not known whether androgens are excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from androgens, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Androgen therapy should be used very cautiously in children and only by specialists who are aware of the adverse effects on bone maturation. Skeletal maturation must be monitored every 6 months by an x-ray of the hand and wrist (see INDICATIONS AND USAGE and WARNINGS).

ADVERSE REACTIONS

Endocrine and metabolic.
- Male. Gynecomastia and excessive frequency and duration of penile erections. Oligospermia may occur at high dosages (see CLINICAL PHARMACOLOGY).
- Skin and appendages. Hiruseum, male pattern of baldness, and acne.
- Fluid and Electrolyte Disturbances. Retention of sodium, chloride, water, potassium, calcium and inorganic phosphates.
- Gastrointestinal. Nausea, cholestatic jaundice, alterations in liver function tests, rarely hepatocellular neoplasms and peliosis hepatitis (see WARNINGS).
- Nervous System. Increased or decreased libido, headache, anxiety, depression, and generalized paresthesia.
- Metabolic. Increased serum cholesterol.
- Miscellaneous. Inflammation and pain at the site of subcutaneous implantation of testosterone containing pellets, and rarely anaphylactic reactions.

DRUG ABUSE AND DEPENDENCE

The suggested dosage for androgens varies depending on the age, and diagnosis of the individual patient. Dosage is adjusted according to the patient's response and the appearance of adverse reactions. The dosage guideline for the testosterone pellets for replacement therapy in androgen-deficient males is 150mg to 450mg subcutaneously every 3 to 6 months. Various dosage regimens have been used to induce pubertal changes in hypogonadal males; some experts have advocated lower doses initially, gradually increasing the dose as puberty progresses, with or without a decrease in maintenance levels. Other experts emphasis that higher dosages are needed to induce pubertal changes and lower dosages can be used for maintenance after puberty. The chronological and skeletal ages must be taken into consideration, both in determining the initial dose and in adjusting the dose.

Dosages in delayed puberty generally are in the lower range of that listed above and, for a limited duration, for example 4 to 6 months.

The number of pellets to be implanted depends upon the minimal daily requirements of testosterone propionate determined by a gradual reduction of the amount administered parenterally. The usual dosage is as follows: implant two 75mg pellets for each 25mg testosterone propionate required weekly. Thus when a patient requires injections of 75mg per week, it is usually necessary to implant 450mg (6 pellets). With injections of 50mg per week, implantation of 300mg (4 pellets) may suffice for approximately three months. With lower requirements by injection, correspondingly lower amounts may be implanted. It has been found that approximately one-third of the material is absorbed in the first month, one-fourth in the second month and one-sixth in the third month. Adequate effect of the pellets ordinarily continues for three to four months, sometimes as long as six months.

HOW SUPPLIED

Testosterone pellets of 75mg. One pellet per vial in boxes of 10 (NDC: 43773-1001-2), 24 (NDC: 43773-1001-4) and 100 (NDC: 43773-1001-3). Store in a cool dry place.

CAUTION: Federal Law prohibits dispensing without prescription.

Manufactured by Bartor Pharmacal
70 High St., Rye N.Y. 10580
Rev. 1/09
Marketed by
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you have a decrease in libido (sex drive)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Do you have a lack of energy?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Do you have a decrease in strength and/or endurance?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Have you lost height?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Have you noticed a decreased enjoyment in life?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Are you sad and/or grumpy?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Are your erections less strong?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Have you noted a recent deterioration in your ability to play sports?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Are you falling asleep after dinner?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Has there been a recent deterioration in your work performance?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If you answered yes to questions 1 OR 7, or answered yes to any three questions, you may be suffering from Low T. Share your results with your doctor and ask about a simple blood test that can help better diagnose Low T and your treatment options.

For More Information About TESTOPEL®, call 866.SLATE.50 or visit www.testopel.com.

Now Available At Our Practice


Please see accompanying complete Prescribing Information for TESTOPEL®.

©2010 Slate Pharmaceuticals. All rights reserved. Printed in the USA. Testopel 40453