



Important Safety Information.

TESTOPEL® is approved for testosterone replacement therapy in adult males for conditions associated with low or absent testosterone in the body. TESTOPEL® should not be used in men with breast cancer or those that have or might have prostate cancer. Patients should not use TESTOPEL® if they have had a previous adverse reaction to TESTOPEL®. TESTOPEL® is not approved for use in women.

Prolonged use of high doses of androgens has been associated with the development of peliosis hepatis and hepatic neoplasms including hepatocellular carcinoma. Peliosis hepatis can be a life-threatening or fatal complication.

Edema with or without congestive heart failure may be a serious complication in patients with preexisting cardiac, renal, or hepatic disease. In these instances the drug should be discontinued.

Side effects reported with use of TESTOPEL® include: excessive frequency and duration of penile erections, hirsutism, increased serum cholesterol and acne. Some men may have breast development, breast discomfort, edema, prostate enlargement accompanied by difficulty urinating.

TESTOPEL® insertion may cause pain at the site of subcutaneous implantation of pellets and rarely anaphylactoid reactions. Physicians should provide appropriate counsel regarding post-implant care.