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Depo-Testosterone (testosterone cypionate) - Drug Summary

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Depo-Testosterone (testosterone cypionate)

THERAPEUTIC CLASS

Androgen

DEA CLASS

CIII

ADULT DOSAGE & INDICATIONS

Testosterone Replacement Therapy

Congenital/Acquired Primary Hypogonadism or Hypogonadotropic Hypogonadism in Males:

Individualize dose based on age, sex, and diagnosis
50-400mg every 2-4 weeks

PEDIATRIC DOSAGE & INDICATIONS

Testosterone Replacement Therapy

Congenital/Acquired Primary Hypogonadism or Hypogonadotropic Hypogonadism in Males:

≥12 Years:
Individualize dose based on age, sex, and diagnosis
50-400mg every 2-4 weeks

ADMINISTRATION

IM route

Administer deep into gluteal muscle
Warm and shake the vial to redissolve any crystals that may have formed during storage at temperatures lower than recommended.

HOW SUPPLIED

Inj: 100mg/mL [10mL], 200mg/mL [1mL, 10mL]

CONTRAINDICATIONS

Males w/ carcinoma of the breast or known/suspected carcinoma of the prostate gland. Serious cardiac, hepatic, or renal disease. Women who are or may become pregnant.

WARNINGS/PRECAUTIONS

May cause hypercalcemia in immobilized patients; d/c if this occurs. Peliosis hepatis, hepatocellular carcinoma, and hepatic adenomas reported w/ prolonged use of high doses. May increase risk of prostatic hypertrophy and prostatic carcinoma in elderly. Venous thromboembolic events reported; evaluate patients who report symptoms of pain, edema, warmth, and erythema in the lower extremity for deep vein thrombosis and those who present w/ acute SOB for pulmonary embolism. D/C treatment and initiate appropriate workup and management if venous thromboembolic event is suspected. Increased risk of major adverse cardiovascular events (MACE) reported. Edema w/ or w/o CHF may be a serious complication in patients w/ preexisting cardiac, renal, or hepatic disease. Gynecomastia may develop and persist. Contains benzyl alcohol; has been associated w/ serious adverse events, including gasping syndrome and death, in pediatric patients. Caution in healthy males w/ delayed puberty; monitor bone maturation by assessing bone age of wrist and hand every 6 months. May accelerate bone maturation w/o producing compensatory gain in linear growth in children; compromised adult stature may result. Acute urethral obstruction in patients w/ benign prostatic hypertrophy (BPH), priapism or

excessive sexual stimulation, and oligospermia after prolonged use or excessive dosage may develop; if these effects appear d/c therapy and if restarted, use a lower dose. Do not use interchangeably w/ testosterone propionate and for enhancement of athletic performance. May increase serum cholesterol. May decrease levels of thyroxin-binding globulins, resulting in decreased total T4 serum concentrations and increased resin uptake of T3 and T4.

ADVERSE REACTIONS

Gynecomastia, excessive frequency/duration of penile erections, oligospermia (if at high doses), male pattern baldness, increased/decreased libido, hirsutism, acne, MI, stroke, nausea, clotting factor suppression, polycythemia, altered LFTs, headache, anxiety.

DRUG INTERACTIONS

May increase sensitivity to oral anticoagulants; may require dose reduction in anticoagulants. May increase levels of oxyphenbutazone. May decrease blood glucose and insulin requirements in diabetic patients.

PREGNANCY AND LACTATION

Category X, not for use in nursing.

MECHANISM OF ACTION

Endogenous androgen; responsible for normal growth and development of male sex organs and for maintenance of secondary sex characteristics.

PHARMACOKINETICS

Absorption: Slow. **Distribution:** Plasma protein binding (98%, specific testosterone-estradiol binding globulin). **Metabolism:** Liver. **Elimination:** Urine (90% [glucuronic and sulfuric acid conjugates of testosterone]), feces (6%[unconjugated]); $T_{1/2}$=8 days.

ASSESSMENT

Assess for breast carcinoma in males, prostate carcinoma, cardiac/hepatic/renal disease, delayed puberty, BPH, drug hypersensitivity, any other conditions where treatment is contraindicated/cautioned, and possible drug interactions. Confirm diagnosis of hypogonadism by measuring testosterone levels on at least 2 separate days prior to initation.

MONITORING

Monitor for signs/symptoms of hypercalcemia, edema w/ or w/o CHF, prostatic hypertrophy/carcinoma in elderly, venous thromboembolic events, MACE and other adverse reactions. Monitor bone maturation by assessing bone age of wrist and hand every 6 months. Periodically check Hgb and Hct in patients receiving long-term androgen therapy. Monitor serum cholesterol levels and LFTs.

PATIENT COUNSELING

Instruct to report to physician if N/V, changes in skin color, ankle swelling, or too frequent or persistent penile erections occurs. Inform of the possible risk of MACE when deciding whether to use or continue to use drug.

STORAGE

20-25°C (68-77°F). Protect from light.

Back to top

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