TESTOSTERONE ENANTATE

Rx **VIVRONE**

250 mg/ml
SOLUTION FOR INJECTION (I.M.)
GONADOTROPIC HORMONE

FORMULATION:
Each ml oily solution for injection contains:
Testosterone Enantate B.P. .....250 mg

PRODUCT DESCRIPTION:
Sterile, apyrogenic, clear, no visible particulate matter pale yellow oily solution.

CHEMICAL NAME: Androst-4-en-3-one, 17-[(1-oxoheptyl) oxy],(17ß.)

ACTION AND PHARMACOKINETICS:
Mechanism of action: In normal men,stimulates ribonucleic acid (RNA) Polymerase activity and specific RNA synthesis resulting in an increase in protein production.In most target tissues, androgens are converted to 5 alpha- dihydrotestosterone which suppresses gonadotropin-releasing hormone,LH and FSH through a negative feedback mechanism involving the hypothalamus and anterior pituitary.
Testosterone stimulates production of red blood cells by enhancing production erythropoietic stimulating factors.

Metabolism and Excretion: Metabolism is hepatic and elimination is generally renal.

INDICATIONS:
Used as replacement therapy in male hypogonadal disorders caused by either pituitary or testicular disorders or in hypogonadism following orchidectomy.

ADVERSE REACTIONS:
Peliosis hepatis and hepatic neoplasms including hepatocelluar carcinoma have been associated with long-term,high dose androgen therapy.These adverse reactions can be life-threatening or fatal.
In males, oligospermia with possible infertility may occur during high-dose therapy with androgens because of possible suppression of spermatogenesis. The side effects of testosterone enantate (and cypionate) cannot be quickly reversed by discontinuing medication because of the long durations of action of these medications.
Difficult or frequent urination may occur in geriatric male patients and may be a sign of enlarged prostate or cancer of the prostate.
When androgens are used in children,premature epiphyseal closure may occur in males and females or precoulous sexual development may occur in males When androgens are used in women, specially in high doses(usually) more than 200 -300 mg of testosterone per month and even smaller doses in some women), virilization may occur, most but not all of these effects are reversible if medication is stopped as soon as changes are noticed. Some effects such as deepening of voice may not be reversible. Infection,redness,pain or other irritation at site of injection. Frequent or continuing erection,frequent urge to urinate, swelling of breasts or breast soreness in males,suppression of clotting factors,retenation of water and elecrolytes and increased cholesterol of serum are reported.

PRECAUTIONS:
Determination of hemoglobin,hematocrit, serum alkaline phosphatase, calcium and cholesterol is recommended during therapy.
Women should be checked for signs of virilization,drug must be discontinued when mild virilization,becomes evident.

REPORTING OF SUSPECTED ADVERSE REACTIONS:
To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reactions is necessary.
Healthcare professionals are encouraged to report any suspected adverse reaction/s directly to the importer/distributor and/or to FDA: www.fda.gov.ph.
Patients are advised to seek immediate medical attention at the first sign/s of adverse eactions.

Hepatocelluar carcinoma and hepatic neoplasms has been associated with long-term,high-dose androgen therapy.Hepatic function determinations recommended at regular intervals during therapy.

Use of androgens by athletes is not recommended- objective evidence is conflicting and inconclusive as to whether these medications significantly increase athletic performance by increasing muscle strength.Weight gains reported by athletes are due in part to fluid retention,which is a potentially hazardous side effects of androgen therapy.The risk of other unwanted effects such as spermatogenesis suppression and testicular atrophy in males,peliosis hepatis or other hepatotoxicity,menstrual disturbances and fertilization, and hepatic, cancer, outweight any possible benefit received from androgens.

Androgens may cause masculinization of the external genitalia of female fetus. therefore androgens are not recommended during pregnancy, specially in the first trimester. It is not known whether androgens are excreted in breast milk. Androgens may cause increased risk of prostatic hypertrophy or prostatic cancer in geriatric male patients.

Risk-benefit should be considered in these cases:

Pediatrics cardiac failure,server cardia-renal disease,coronary artery disease,hepatic function impairment, renal function impaiment, diabetes mellitus, edema, hypercalcemia, nephrosis or nephritis, prostatic hypertrophy.

DRUG INTERACTIONS:

Adrenocorticoids (especially mineralocorticoids),corticotropin,sodium-containing medications of foods,anticoagulants, antidiabetic agents, cyclosporine and somatropin.

CONTRAINDICATIONS:

Androgens should not be used in breast cancer in males and prostate cancer.

DOSAGE AND ADMINISTRATIONS:

The dosage used in delayed puberty generally is in the lower range of the usual adult dose for androgen replacement therapy and is given for a limited duration,usually 4 to 6 months, after this period of time, the medication should be discontinued for one to three months and X-Ray taken to determine effect on bone growth or maturation. To determine whether there will be an objective response to antineoplastic therapy, treatment should be continued for at least 3 months.

Priapism is a sign of excessive dosage and an indication for temporary withdrawal of the drug.

In the cases of metastatic breast cancer in women, a short-acting androgen is preferred ,especially during the early 3 stages of androgen therapy. **The Intramuscular Injections** should be administered deeply into gluteal muscle. "Do not administer IV"

It is usually preferable to begin treatment with full therapeutic doses and to adjust later to individual requirements.

Usual adult dose: androgen replacement therapy: 50 to 400 mg every two to four weeks.

Antineoplastic: 200 to 400 mg every two to four weeks.

Antianemic: 400 mg a day for one week,then 400 mg one or two times a week.The maintenance dose is 200 to 400 mg every 4 week.

Usual pediatric dose: Delayed puberty in males 50 to 200 mg every two to four weeks for a limited duration,usually four to six months.

CAUTION: Foods,Drugs,Devices, & Cosmetics Act prohibits dispensing without prescription.

KEEP OUT OF REACH OF CHILDREN.

STORAGE: Store at temperatures not exceeding 30°C.

AVAILABILITY:

1 mL clear glass ampoule (Box of 3's)

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