Primus Ray Laboratories

FLUOXYMESTEROLON (HALOTESTIN) 5MG/TAB

FLUOXYMESTEROLON 5 – FLUOXYMESTEROLON 5 – FLUOXYMESTEROLON USP 5mg

DESCRIPTION:

Fluoxymesterone is a man-made form of testosterone, a naturally occurring sex hormone that is produced in a man's testicles. Small amounts of testosterone are also produced in a woman's ovaries and adrenal system.

Fluoxymesterone is used in men and boys to treat conditions caused by a lack of this hormone, such as delayed puberty or other hormonal imbalances.

Fluoxymesterone is also used in women to treat breast cancer that has spread to other parts of the body. Fluoxymesterone treats only the symptoms of metastatic breast cancer but does not treat the cancer itself.

Fluoxymesterone may also be used for purposes not listed in this medication guide.

Chemical: Fluoxymesterone 5mg/tb
CAS Name: 9a-Fluoro-11b,17b-dihydroxy-17a-methyl-4-androsten-3-one
Molecular Formula: C20H29FO3
Molecular Weight: 336.44.

CONTRAINDICATIONS:

1. Diagnosed or suspected carcinoma of the male breast or prostate.

2. Women who are pregnant or may become pregnant because of possible masculinization of the fetus. When administered to pregnant women, androgens cause virilization of the external genitalia of the female fetus. This virilization includes clitoromegaly, abnormal vaginal development, and fusion of genital folds to form a scrotal-like structure.

3. Patients with a history of hypersensitivity to Methandrostenolone or any of its components.

4. Patients with serious renal, cardiac, or hepatic dysfunction.

WARNINGS:

1. In breast cancer patients, androgen therapy may cause hypercalcemia through stimulated osteolysis. Frequent monitoring of urine and serum calcium is indicated in such patients. If hypercalcemia presents, the androgen should be discontinued.

2. Prolonged usage of high doses of androgens has been associated with peliosis hepatis, hepatic neoplasms, and hepatocellular carcinoma as well as azoospermia, oligospermia, and reduced ejaculatory volume.

3. If liver function tests become abnormal or the patient presents with cholestatic hepatitis with jaundice, androgen therapy should be discontinued pending determination of the etiology.

4. Edema due to sodium and water retention may be a serious complication in patients with pre-existing cardiac, renal, or hepatic disease, migraines, epilepsy, and other conditions. Edema may be increased in patients on concurrent adrenal cortical steroid or ACTH therapy.

5. Liver cell tumors have also been reported, most often benign and androgen-dependent, although fatal malignant tumors have also been reported. Termination of the drug generally results in regression or the cessation of tumor progression.

6. Geriatric patients receiving androgen therapy may be at increased risk for prostate hypertrophy and prostatic carcinoma.

7. Virilization of female patients may occur. If signs of virilization present during treatment of breast carcinoma, androgen therapy should be discontinued.

PRECAUTIONS:

Any nausea, vomiting, changes in skin color or ankle swelling should be monitored by a qualified physician, particularly in patients with a history of severe heart, liver, and kidney disease.

Androgen therapy patients receiving concurrent warfarin treatment may present with unexpected increases in the INR and/or pro-thrombin time (PT). When administered to these patients, the dosing of warfarin may need to be reduced significantly to maintain the desired INR level and reduce the risk of serious bleeding.

Because androgens may alter serum cholesterol concentration, caution should be used when administering these drugs to patients with a history of myocardial infarction or coronary artery disease.

Androgens may reduce clotting factors II, V, VII, and X, and may increase pro-thrombin time (PT). Patients should be instructed to report any use of warfarin and any irregular bleeding.

For Women: Women on androgen therapy should be observed for signs of virilization which may include the deepening of the voice, hirsutism, or clitoromegaly. Therapy should be discontinued upon signs of virilism to reduce the risk of irreversible virilization. Some virilizing effects may be irreversible after cessation of therapy even with concurrent administration of estrogens. Menstrual irregularities may also occur.

SIDE EFFECTS:

Males: Gynecomastia, frequent or persistent penile erections.

Females: Amenorrhea, other menstrual irregularities, inhibition of gonadotropin secretion, virilization (e.g., deepening of the voice, clitoral enlargement).

All patients: Nausea, vomiting, changes in

skin color, or ankle swelling.

Laboratory Tests and Patient Monitoring:

Examination of bone age by x-ray should be conducted during treatment of children to determine bone maturation rate and effect on epiphyseal centers.

Women with breast carcinoma should have frequent assays of serum and urine calcium throughout the course of treatment.

Androgens have been associated with increases in low-density lipoproteins and reduction in high-density lipoproteins in serum. Periodic serum lipid assays are recommended during treatment.

Serum assays for hematocrit and hemoglobin are recommended to screen for polycythemia in patients receiving large doses of androgens.

Hepatic function determinations should be made periodically including at a minimum AST and ALT, particularly with concomitant use of hepatotoxic medications or with a history of liver disease.

Androgen therapy patients, particularly those over 50 years of age, should be evaluated periodically for prostatic acid phosphatase and prostate specific antigen (PSA) total and free.

Total testosterone, free testosterone, and bioavailable testosterone in serum should assayed periodically and dosing titrated as necessary to achieve desired levels.

For treatment of breast carcinoma:

-Alkaline phosphatase serum values, physical examination, and x-rays of known or suspected metastases.

-Calcium

For gender change androgen therapy:

- LH (Luteinizing Hormone)

- ALT (Alkaline aminotransferase)

Thyroid Testing Interaction: Androgens have been shown to reduce concentration of thyroxine-binding globulin and consequently decreasing the total serum T4 and increasing uptake of both T3 and T4. Serum concentration of free (unbound) thyroid hormones will not change.

DRUG INTERACTIONS:

Anti-diabetic drugs and Insulin: In diabetic patients, the metabolic effects of androgens may reduce blood glucose, insulin, and anti-diabetic medication requirements.

Adrenal steroids or ACTH: May exacerbate edema in patients on concurrent adrenal-cortical steroids or ACTH therapy.

Anticoagulants: Patients on anticoagulants such as warfarin should be carefully monitored during androgen therapy as androgens may increase sensitivity to oral

anticoagulants which may require a concomitant reduction in anticoagulant dosage to achieve a desirable prothrombin time (PT). Concurrent use of anti-diabetic agents, insulin, cyclosporines, hepatotoxic medications, and/or human growth hormone (somatropin) has been reported to decrease anticoagulant requirements. Anticoagulant patients should be monitored regularly during androgen therapy, particularly during initiation and termination of therapy.

Oxyphenbutazone: Elevated serum levels of oxyphenbutazone may result.

PREGNANCY AND LACTATION:

Pregnancy Category X

Pregnant women should not receive androgen therapy due to possible masculinization of the fetus.

It is not known whether anabolics are excreted in milk, but due to the harm the drug may give infants, a decision should be made by the nursing mother whether to continue the drug or not.

ADVERSE REACTIONS:

GI/Hepatic: Nausea, peliosis hepatis, cholestatic jaundice, and very rarely hepatic necrosis. Hepatocellular neoplasms after long term use; May affect liver function tests.

CNS: Changes in libido, headache, habituation, excitation, generalized paresthesia, insomnia, anxiety and depression.

Hematological: Suppression of clotting factors II, V, VII, and X. Bleeding on concomitant anticoagulant therapy. Polycythemia.

Breast: Gynecomastia.

Larynx: Deepening of the voice in females.

Fluids and Electrolytes: Retention of electrolytes including sodium, potassium, chlorine, water, calcium, and inorganic phosphates.

Hair: Hirsutism and male pattern baldness (androgenetic alopecia)

Metabolic: Increased serum cholesterol

Skin: Acne vulgaris, flushing of the skin.

Skeletal: Premature closure of epiphyses in children.

Other: Rarely, anaphylactoid reactions; inflammation or pain at the injection site.

In males: Excessive frequency, duration, and persistence of penile erections. Gynecomastia, Priapism, Inhibition of gonadotrophin secretion, and Oligospermia at high doses.

In females: Virilization including clitoral enlargement, menstrual irregularities, amenorrhea, inhibition of gonadotrophin secretion, and deepening of the voice. In pregnant women, virilization of external genitalia of the female fetus.

DOSAGE AND ADMINISTRATION:

Male Androgen Replacement Therapy: The dose of these medicines will be different for different patients. Follow your doctor’s orders or the directions on the label . The following information includes only the average doses of these medicines. If your dose is different, do not change it unless your doctor tells you to do so.

PRESENTATION:

5 mg/tablets, 2x blister of 25tablets per blister, 50 tablets per box

STORAGE:

Store at room temperature between 59-86 degrees F (15-30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.