



FLUOXYMESTERONE

FLUOXYMESTERONE USP 5 mg
Presented as blister with 60 capsules

COMPOSITION

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 androgens, 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.

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.

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 Fluoxymesterone or any of its components.
4. Patients with serious renal, cardiac, or hepatic dysfunction.

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.

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.

PRESENTATION

5 mg capsules in blister packs of 15 capsules - 4 blisters per box (60 capsules).

STORAGE

Store below 25°C. Store in the original package.