

4-CHLORODEHYDROMETHYLTESTOSTERONE

4-chlorodehydromethyltestosterone is an oral androgen, a derivative of Dihydrotestosterone (DHT). It was originally developed to treat hereditary angioedema. As with most androgens, 4-chlorodehydromethyltestosterone will help to create a state of anabolism and contribute to a significant increase in muscle tissue. Structurally, this hormone is not capable of converting into estrogens therefore will not contribute to water retention which may be the case with other androgens. Also unlike most anabolic steroids, is not esterified. The drug has a large oral bioavailability, due to a C17 α -alkylation which allows the hormone to survive first pass liver metabolism when ingested.

4-chlorodehydromethyltestosterone is approved for use for the following indication:

Hormone Replacement Therapy in men suffering from androgen deficiency;
Severe case of catabolism.

Chemical: 4-chlorodehydromethyltestosterone, 10mg/tb
CAS Name: (17 β)-4-Chloro-17-hydroxy-17-methylandrosta-1,4-dien-3-one
Molecular Formula: C₂₀H₂₇O₂Cl
Molecular Weight: 334.8854.

Prescription Medicine

DESCRIPTION

Each uncoated 4-chlorodehydromethyltestosterone tablet contains:
4-chlorodehydromethyltestosterone USP 10mg

CLINICAL PHARMACOLOGY

Anabolic steroids such as 4-chlorodehydromethyltestosterone are synthetic derivatives of testosterone.

4-chlorodehydromethyltestosterone has been found to increase low-density lipoproteins and decrease high-density lipoproteins. These changes are not associated with any increase in total cholesterol or triglyceride levels and revert to normal on discontinuation of treatment.

Hereditary angioedema (HAE) is an autosomal dominant disorder caused by a deficient or nonfunctional C1 esterase inhibitor (C1 INH) and clinically characterized by episodes of swelling of the face, extremities, genitalia, bowel wall, and upper respiratory tract. In small clinical studies, 4-chlorodehydromethyltestosterone was effective in controlling the frequency and severity of attacks of angioedema and in increasing serum levels of C1 INH and C4.

4-chlorodehydromethyltestosterone is not effective in stopping HAE attacks while they are under way. The effect of 4-chlorodehydromethyltestosterone on increasing serum levels of C1 INH and C4 may be related to an increase in protein anabolism.

INDICATIONS AND USES

Hereditary Angioedema: 4-chlorodehydromethyltestosterone is indicated prophylactically to decrease the frequency and severity of attacks of angioedema.

CONTRAINDICATIONS

The use of hormone is contraindicated in the following:

Male patients with carcinoma of the breast or with known or suspected carcinoma of the prostate.

Carcinoma of the breast in females with hypercalcemia; androgenic anabolic steroids, may stimulate osteolytic resorption of bone. Nephrosis or the nephrotic phase of nephritis.

Medication can cause fetal harm when administered to a pregnant woman.

Medication is contraindicated in women who are or may become pregnant while taking this drug; the patient should be apprised of the potential hazard to the fetus.

PRECAUTIONS

General: Anabolic steroids may cause suppression of clotting factors II, V, VII and

X and an increase in prothrombin time.

Women should be observed for signs of virilization (deepening of the voice, hirsutism, acne, and clitoromegaly). To prevent irreversible change, drug therapy must be discontinued, or the dosage significantly reduced when mild virilism is first detected.

Such virilization is usual following androgenic anabolic steroid use of high doses. Some virilizing changes women are irreversible even after prompt discontinuance of therapy and are not prevented by concomitant use of estrogens.

Menstrual irregularities may also occur.

Oral hypoglycemic dosage may need adjustment in diabetic patients who receive anabolic steroids.

DRUG INTERACTIONS

4-chlorodehydromethyltestosterone may increase sensitivity to anticoagulants; therefore, dosage of anticoagulants may have to be decreased in order to maintain the prothrombin time at the desired therapeutic level.

ADVERSE REACTIONS

Hepatic: Cholestatic jaundice with rarely, hepatic necrosis and death. Hepatocellular neoplasms and peliosis hepatis have been reported in association with long-term androgenic anabolic steroid. Reversible changes in liver function tests also occur, including increased bromsulphalein (BSP) retention and increases in serum bilirubin, glutamic oxaloacetic transaminase (SGOT), and alkaline phosphatase.

Genitourinary System (Prepubertal men): Phallic enlargement and increased frequency of erections.

Genitourinary System (Post pubertal men): Inhibition of testicular functions, testicular atrophy, and oligospermia, impotence, chronic priapism, epididymitis and bladder irritability.

Genitourinary System (Women): Clitoral enlargement, menstrual irregularities.

In both sexes: increased or decreased libido.

CNS: Habituation, excitation, insomnia, and depression.

Gastrointestinal: Nausea, vomiting, diarrhea.

Hematologic: Bleeding in patients on concomitant anticoagulant therapy.

Breast: Gynecomastia.

Larynx: Deepening of the voice in women.

Hair: Hirsutism and male pattern baldness in women.

Skin: Acne (especially in women and prepubertal boys.)

Skeletal: Premature closure of epiphyses in children.

Fluid and Electrolytes: Edema, retention of serum electrolytes (Sodium chloride, potassium, phosphate, and calcium).

DOSAGE AND ADMINISTRATION

The use of anabolic steroids may be associated with serious adverse reactions.

Many of which are dose related; therefore patients should be placed on the lowest possible effective dose.

Hereditary Angioedema. The dosage requirements for continuous treatment of hereditary angioedema with 4-chlorodehydromethyltestosterone should be individualized on the basis of clinical response of the patient. It is recommended the patient be started on 2 mg three times a day. After a favourable initial response is obtained in terms of prevention of episodes of edematous attacks, the proper continuing dosage should be determined by decreasing the dosage at intervals of one to three months to a maintenance dosage of 2 mg alternate day schedule. During the dose-adjusting phase close monitoring of the patient's has a history of airway involvement.

The prophylactic dose of 4-chlorodehydromethyltestosterone to be used prior to dental extraction or other traumatic or stressful situations has not been established and may be substantially larger.

PRESENTATION:

10mg tablets in blister packs of 10 tablets – 10 blisters per box (100 tablets).

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