



# Cidotestone

C 101112 D - 7/12

## For intramuscular injection

### Composition :

Cidoteston 100 mg :  
Each ampoule 1 ml ( oily solution ) contains :  
Testosterone Enanthate 110 mg  
Testosterone Propionate 25 mg

Cidoteston 250 mg :  
Each ampoule 1 ml ( oily solution ) contains :  
Testosterone Enanthate 250 mg

### Pharmacological action :

- Testosterone is an active androgen for I.M. injection.
- It possesses the properties attributable to testicular hormone.
- Enanthate is a long ester attached to testosterone, so it cleaved off slowly from steroids, as a result of that it have a long onset of action while propionate ester have a rapid onset of action.
- Depot effect up to 4 weeks has demonstrated clinically.
- Endogenous androgens are responsible for :
  - \* Normal growth and development of the male sex organs.
  - \* Maintenance of secondary male sex characteristics.
  - \* Increasing protein anabolism and decrease protein catabolism.

### Pharmacokinetics :

Bioavailability :  
- Testosterone in plasma is 98% bound to a specific testosterone-estradiol binding globulin and about 2 % is free. The activity of testosterone depends on reduction to dihydrotestosterone which binds to cytosol receptor protein. The steroid receptor complex is transported to the nucleus where it initiates transcription events and cellular changes related to androgens action, inactivation of testosterone occurs primarily in the liver.

### Excretion :

- About 90 % of a dose of testosterone is excreted in the urine as glucuronic and sulfuric acid conjugates of testosterone and its metabolites; about 6 % of a dose is excreted in the feces, mostly in the unconjugated form.

### Indications & Usage :

#### For male :

- For replacement therapy in conditions associated with :
- Primary hypogonadism ( congenital or acquired ) ; Testicular failure.
  - Hypogonadotropic hypogonadism.
  - Delayed puberty.

#### For Female :

- Androgens may be used secondary in women with advancing inoperable metastatic mammary cancer who are (1-5) year postmenopausal.
- This treatment is also used in premenopausal women with breast cancer who have benefited from oophorectomy and are considered to have a hormone responsive tumor.

### Contra-Indications :

- Men : With breast or prostate carcinoma.
- Women : Pregnant as it cause virilization of external genitalia of the female fetus.
- Hypersensitivity to any of the drug components.

### Side Effects :

#### - Endocrine and Urogenital :

Female : Most common side effects are amenorrhea and menstrual irregularities, inhibition of gonadotropin secretion, deepening of voice and clitoral enlargement.

Male : Gynecomastia-oligospermia

- **Gastrointestinal :** Nausea-cholestatic jaundice-alteration in liver functions.

- **Hematologic :** Suppression of clotting factors II, V, VII, X which cause bleeding in patients with anticoagulant therapy.

- **Nervous system :** Increased or decreased libido, headache, anxiety, depression.

- **Fluid and Electrolyte Disturbances :** Retention of sodium, chloride, water, potassium, calcium and inorganic phosphates.

### Drug Interactions :

- Androgens decrease the effect of coagulant factors and decrease blood glucose so doses of both antidiabetic and anticoagulant drugs should be decreased.
- ACTH and corticosteroids enhance tendency towards edema so caution to be taken when giving these drugs.

### Pregnancy and Lactation :

- Contraindicated in pregnancy as it has teratogenic effects.
- It is not known whether androgens are excreted in human milk, so decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

### Warnings & Precautions :

- Androgen therapy should be used cautiously in the following cases :
  - \* Patients with breast cancer as it may cause hypercalcemia by stimulation of osteolysis, if this happened drug discontinued and appropriate measures instituted.
  - \* If patient suffer from cardiac or renal failure, edema may occur.
  - \* In healthy males with delayed puberty.
  - \* Women : Should observe signs of virilization ( deepening of the voice, hirsutism and menstrual irregularities ).
  - \* Patients with history of myocardial infarction or coronary artery disease should determine serum cholesterol level.
  - \* In children and only by specialists who are aware of the adverse effects on the bone maturation.
- Skeletal maturation must be monitored every 6 months by an x-ray of hand and wrist.
- Decrease of sperms counts may occur.
- Hepatotoxicity in supra physiologic doses may occur.

### Dosage & Administration :

Dosage and duration depend on age, sex, diagnosis, patient's response to treatment and appearance of adverse effects :

#### - Male :

Hypogonadism : The suggested dosage is 50 to 400 mg every 2 to 4 weeks. Delayed puberty : 50 to 200 mg every 2 to 4 weeks for a limited duration.

#### - Female :

Palliation of inoperable mammary cancer : 200 to 400 mg every 2 to 4 weeks is recommended.

### Packing :

- Cidotestone 100 mg : Box of one ampoule ( 1 ml ).
- Cidotestone 250 mg : Box of one ampoule ( 1 ml ).

### Storage :

Store at controlled room temperature.

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sales the medicament.
- The doctor and the pharmacist are experts in medicine. it's benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicament out of children reach.

Council of Arab Health Ministers and Union of Arab Pharmacists