

## CELLTRION OXYMETHOLONE Tab (BP)

### DESCRIPTION

Oxymetholone is a potent anabolic and androgenic drug.

Appearance is white colored round tablet.

Chemical name :  $17\beta$ -hydroxy-2-(hydroxymethylene)-17-methyl-5 $\alpha$ -androstan-3-one.

### COMPOSITION

1 Tab (150mg) contains

Oxymetholone (BP)-----50mg

Excipients-----Q.S

Excipients consist of Lactose, Corn starch, Magnesium stearate.

### CLINICAL PHARMACOLOGY

Oxymetholone (anabolic steroids) is derivatives of testosterone, and improved nitrogen balance but only when there is sufficient intake of calories and protein.

Oxymetholone enhances the production and urinary excretion of erythropoietin in patients with anemia due to bone marrow failure and often stimulate erythropoiesis in anemias due to deficient red cell production.

Certain clinical effects and adverse reactions demonstrate the androgenic properties of this class of drugs.

Complete dissociation of anabolic and androgenic effects has not been achieved.

The actions of anabolic steroids are therefore similar to those of male sex hormones with the possibility of causing serious disturbance of growth and sexual development if given to young children.

They suppress the gonadotropic functions of the pituitary and may exert a direct effect upon the tests.

### INDICATIONS AND USAGE

- Osteoporosis, Pituitary Dwarfism
- Serious marasmic physiological condition by malignant tumor, Post-operation, Trauma, Burn.
- Marasmic bone-marrow condition by aplastic anemia, Myelofibrosis

### DOSAGE & ADMINISTRATION

Adult dosage is 5~15mg per day as a oxymetholone and divide 2~4 times a day through oral administration.

But dosage unit will be changeable depending on age and symptom

### CONTRAINDICATION, CAUTION & SIDE EFFECT

#### 1. WARNING

1) Peliosis hepatis, a condition in which liver and sometimes splenic tissue is replaced with blood-filled cysts, has been reported in patients receiving androgenic anabolic steroid therapy. These cysts are sometimes present with minimal hepatic dysfunction, but at other times they have been associated with liver failure. They are often not recognized until life-threatening liver failure or intra-abdominal hemorrhage develops. Withdrawal of drug usually results in complete disappearance of lesions.

2) Liver cell tumors are also reported. Most often these tumors are benign and androgen-dependent, but fatal malignant tumors have been reported. Withdrawal of drug often results in regression or cessation of progression of the tumor. However, hepatic tumors associated with androgens or anabolic steroids are much more vascular than other hepatic tumors and may be silent until life-threatening intra-abdominal hemorrhage develops.

3) Blood lipid changes that are known to be associated with increased risk of atherosclerosis are seen in patients treated with androgens and anabolic steroids. These changes include decreased high density lipoprotein and sometimes increased low density lipoprotein. The changes may be very marked and could have a serious impact on the risk of atherosclerosis and coronary artery disease.

#### 2. Do not administer to following patients.

- 1) Carcinoma depending androgen hormone (ex : prostate or male breast) and suspected patients (can be induced progression of cancer cell or led to badness condition)
- 2) Patients with hepatic dysfunction (can be led to badness condition)
- 3) Pregnant or may become pregnant woman
- 4) Nephrosis or the nephrotic phase of nephritis
- 5) Carcinoma of the breast in female with hypercalcemia.  
(Androgenic anabolic steroids may stimulate osteolytic resorption of bones)
- 6) Hypersensitivity to the drug.

#### 3. Careful attention shall be needed to following patients.

- 1) Patients with prostatic hypertrophy
- 2) Patients with heart or renal disease and geriatric male patients and cancer patients with bone metastasis, can be induced retention of serum electrolytes (sodium, potassium, calcium, chloride, phosphate)
- 3) Diabetic patients (decrease glucose tolerance)
- 4) Pediatric patients.

#### 4. Adverse reaction

- 1) Hepatic : Rarely, cholestatic jaundice with hepatic necrosis and death, sometimes increase AST, ALT value and delay BSP excretion time can be represented. Especially in case of long term administration, hepatocellular neoplasms and peliosis hepatitis can be represented, so periodic liver function tests are recommended. In the case of finding abnormal hepatic function, reduced administering dosage unit or discontinue administration temporarily or appropriate treatment shall be recommended.
- 2) Urogenital : If following syndrome has been found, discontinue the administration.
  - ① Female : menstrual irregularities, clitoral enlargement, hysterrhea, parphyllary expansion, hypersensitive parphyllar, increase excretion of facial sebum
  - ② Male : Phallic enlargement, impotence, chronic priapism in case of high dosage administration, inhibition of testicular function like as decrease sperm number, seminal volume, gynecomastia, testicular atrophy, epididymitis, bladder irritability, erection disability, oligospermia
  - ③ Male & Female : Increase or decrease of libido.
- 3) Hypersensitivity : If hypersensitive syndrome will be occurred, discontinue administration.
- 4) Gastrointestinal : Sometimes nausea, vomit, constipation, diarrhea can be occurred.
- 5) CNS : Sometimes headache, vertigo, rarely excitation, insomnia, dry mouth can be occurred.
- 6) Skin : Sometimes rash, acne, pigmentation can be occurred.
- 7) Hair : ① Female : Hirsutism and male-pattern baldness  
② Male : Hair loss in postpubertal male
- 8) Hematologic : Iron deficiency anemia, bleeding in patients on concomitant anticoagulant therapy.
- 9) Larynx : Deepening of the voice in women
- 10) Others : Sometimes chill, edema, flushing, muscle pain, exhaustion, neck-shoulder stiffness, paralytic sense of mouth, retention of serum electrolytes, decrease glucose tolerance can be occurred.

#### 5. General caution

- 1) Anabolic steroids may cause suppression of clotting factors II, V, VII and X and an increase in prothrombin time.
- 2) Women with disseminated breast carcinoma should have frequent determination of urine and serum calcium levels during the course of androgenic anabolic steroid therapy.
- 3) Because of the hepatotoxicity associated with the use of 17-alpha-alkylated androgens, liver function tests should be obtained periodically.
- 4) Liver function, hemoglobin and hematocrit should be checked periodically in patients who are receiving anabolic steroid hormone.
- 5) Anabolic steroid hormone therapy may decrease levels of thyroxine-binding globulin resulting in decreased T<sub>4</sub> serum levels and increased resin uptake of T<sub>3</sub> and T<sub>4</sub>

#### 6. Drug Interaction

- 1) When it make combined therapy with Insulin or oral hypoglycemic agent, it can decrease glucose tolerance. So careful attention shall be followed.
- 2) Anabolic steroids may increase sensitivity to anticoagulants, therefore, dosage of an anticoagulant may have to be decreased in order to maintain the prothrombin time at the desired therapeutic level, so to make combined therapy with anticoagulants, careful attention shall be followed.

#### 7. Pregnancy and lactating women

- 1) It is contraindicated to pregnant or may become pregnant women for signs of virilization of female fetus.
- 2) Because it is not known whether anabolics are excreted in human milk, breast feeding has to be fully excluded.

#### 8. Pediatric use

- 1) It can be induced early closing of epiphyseal maturation and early sexual maturation, so anabolic steroids should be used cautiously in children.
- 2) Anabolic agents may accelerate epiphyseal maturation more rapidly than linear growth in children, and the effect may continue for 6 months after the drug has been stopped. Therefore, therapy should be monitored by x-ray studies at 6-months interval in order to avoid the risk of compromising the adult height.

#### 9. Geriatric patients

When it use to geriatric patients, retention of electrolytes(sodium, potassium) and hypercalcemia will be easily represented, therefore it should be used cautiously.

#### 10. Laboratory Test Interferences

Anabolic steroid hormone therapy

- 1) may decrease serum PBI value.
- 2) may decrease levels of thyroxine-binding globulin resulting in decreased total T<sub>4</sub> serum levels and increased resin uptake of T<sub>3</sub> and T<sub>4</sub>.
- 3) may cause an increase in prothrombin time.
- 4) can alter fasting blood suger and glucose tolerance tests.

#### 11. Others

In case of long term and high dosage administration of anabolic steroid hormone therapy, liver cell tumor or peliosis hepatitis has been reported.

#### STORAGE

Tight closed container under room temperature.