



## OXANDROLONE

OXANDROLONE USP 10 mg

Presented as blister with 90 capsules

### DESCRIPTION

Oxandrolone is a mild, low androgen 17-alpha alkylated anabolic steroid with very low toxicity. It promotes protein anabolism and has a low incidence of adverse reactions.

Oxandrolone is primarily used to promote strength, muscle hardness and quality physique improvement. In the International Journal of Obesity, (1995; 19: 614-624), it was shown that Oxandrolone enhanced body fat reduction significantly in both the abdominal and visceral stores. Oxandrolone will not aromatize, and therefore the anabolic effect of this compound can actually promote linear growth.

### INDICATIONS AND USAGE

Oxandrolone is indicated as an alternate or adjunctive therapy in patients for the promotion of weight gain following weight loss and/or muscular atrophy associated with extensive surgery, chronic infections, long term hospitalization, or severe trauma.

Oxandrolone is indicated to compensate for protein catabolism consequent to corticosteroid therapy and for the reduction of pain associated with osteoporosis.

### CONTRAINDICATIONS

1. Diagnosed or suspected male breast carcinoma or carcinoma of the prostate.
2. Diagnosed or suspected female breast carcinoma with hypercalcemia as androgenic agents may increase osteolytic bone resorption.
3. Women who are pregnant or may become pregnant because of possible masculinization of the fetus.
4. Nephrosis and the nephrotic phase of nephritis.
5. Hypercalcemia.

### PRECAUTIONS

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

Women on oxandrolone 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.

Anabolic steroids 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.

### DRUG INTERACTIONS

Oral hypoglycemic agents: Oxandrolone may inhibit the metabolism of oral hypo glyceic agents which may require adjustment of dosage.

Adrenal steroids or ACTH: Oxandrolone 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 anabolic steroid therapy as anabolic steroids may increase sensitivity to oral anticoagulants which may require a concomitant reduction in anticoagulant dosage to achieve a desirable prothrombin time (PT). Anticoagulant patients should be monitored regularly during anabolic steroid therapy, particularly during initiation and termination of therapy. Warfarin patients should have INR and PT monitored throughout androgen therapy and warfarin dosages titrated to achieve the desired INR and PT. Such patients should be monitored for occult bleeding.

### PRESENTATION

6 Blisters containing 15 capsules per carton.

### STORAGE

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