

# Muscular Modification Assistance LABS®

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#### OXANDROLONE 10mg - TABLETS Oxandrolone 10mg

Molecular Formula:

C19H30O3

Molecular Weight: 306.446 g/mol

Structure:



## DESCRIPTION

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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 Oxandralone 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.

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Oxandrolone is also prescribed for the treatment of osteoporosis.

Oxandrolone 10 tablets contain 10 mg of the oral anabolic steroid Oxandrolone. Oxandrolone is  $17\beta$ -hydroxy- $17\alpha$ -methyl-2-oxa- $5\alpha$ - androstan-3-one with the following structure:

## CLINICAL PHARMACOLOGY

Anabolic steroids are synthetic derivatives of testosterone, having actions similar to the endogenous male sex hormone testosterone. There is not a complete dissociation of the anabolic versus androgen action.

Anabolic steroids may suppress gonadotrophic function of the pituitary and may also have a direct effect on the testes. During exogenous administration of anabolic steroids and androgens, endogenous testosterone release is inhibited through feedback inhibition of pituitary luteinizing hormone (LH). With large doses, spermatogenesis may be suppressed through feedback inhibition of pituitary follicle stimulating hormone (FSH).

The actions of anabolic steroids are similar to male sex hormones. Anabolic steroids may cause growth disturbances and induce premature sexual development if administered to young children.

Anabolic steroid hormones may increase low-density lipoproteins (LDL) and decrease high density lipoproteins (HDL). Lipids levels generally return to normal upon discontinuation of treatment.

In a single dose pharmacokinetic study of oxandrolone in geriatric subjects, the average elimination half-life was 13.3 hours. In a similar pharmacokinetic study in younger subjects, the average elimination half-life was 10.4 hours. No significant differences between geriatric and younger test subjects were found for time to peak absorption, peak plasma concentration, or AUC after a single dose. The correlation between plasma level and therapeutic effect has not yet been established.

## INDICATION AND USAGE

Oxandrolone 10 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.

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4. Nephrosis and the nephrotic phase of nephritis.

5. Hypercalcemia.



#### WARNINGS

Peliosis Hepatis has been reported in patients receiving androgenic anabolic steroid therapy. This condition may include blood-filled cyst formation in the liver and may present with or without hepatic dysfunction. Termination of the steroid therapy generally results in the disappearance of the lesions. Liver cell tumors have also been reported, most often benign and androgen-dependent, although malignant tumors have also been reported. Termination of the drug, generally results in cessation of tumor progression or regression.

Androgenic anabolic steroids have been associated with changes in serum lipids, generally with decreases in high-density lipoprotein (HDL) concentration and increases in low-density lipoprotein (LDL) concentration, a profile known to be associated with increased risk of atherosclerosis and associated risk of coronary artery disease.

Oxandrolone therapy may cause hypercalcemia by stimulating osteolysis in breast cancer patients. If hypercalcemia occurs, oxandrolone therapy should be discontinued.

Edema may be a serious complication in patients with pre-existing cardiac, renal, and/ or hepatic disease. Edema may be increased in patients on concurrent adrenal cortical steroid or ACTH therapy.

Geriatric patients receiving androgenic anabolic steroid therapy may be at an increased risk of prostate hypertrophy and prostatic carcinoma.

## SIDE EFFECTS

Males: Frequent or persistent penile erections and increases in the appearance of acne vulgaris.

Females: Hoarseness of the voice, acne, changes in menstrual periods, or more facial hair. All patients: Nausea, vomiting, changes in skin color, or ankle swelling.

#### DRUG INTERACTIONS

Oral hypoglycemic agents: Oxandrolone may inhibit the metabolism of oral hypoglycemic 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.

#### OVERDOSAGE

No symptoms or signs associated with oxandrolone overdose have been reported. The LD50 of oxandrolone in dogs is in excess of 5,000mg/kg. No antidotes are known. In event of overdose, gastric lavage may be used.

### DOSAGE AND ADMINISTRATION

Adults: Daily dosage of 5 mg to 20 mg in 2 to 4 divided doses may be required to achieve the desired response.

Children: For children the total daily dosage of Oxandrolone is <= 0.1 mg/kg of body weight. Therapy may be repeated intermittently as indicated.

Geriatric: Geriatric dosing of 5 mg twice per day is recommended.

The duration of therapy will vary with the patient and the extent of adverse side effects.

## PACKAGING

10 mg/tablets, 100 tablets per box

### STORAGE

Store at room temperature between 59-86 degrees F (15-30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.



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