OXANDROLONE

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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.

Oxandrolone is also prescribed for the treatment of osteoporosis.
Chemical: Oxandrolone
CAS Name: (4aS,4bS,6aS,7S,9aS,9bR,11aS)-Tetradecahydro-7-hydroxy-4a,6a,7
trimethylcyclopenta[5,6]naphtho[1,2-c]pyran-2(1H)-one
Additional Names: 17b-hydroxy-17b-methyl-2-oxa-5b-androstan-3-one; dodecahydro-3 hydroxy-6-(hydroxymethyl)-3,3a,6-trimethyl-1H-benz[e]indene-7-acetic acid b-lactone
Molecular Formula: C19H30O3
Molecular Weight: 306.44.
Percent Composition: C 74.47%, H 9.87%, O 15.66%

DESCRIPTION
Each uncoated tablet contains:
Oxandrolone USP 10mg.

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.

INDICATIONS 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.
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.

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.

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.
Laboratory Tests: Periodic liver function tests should be conducted given the association of 17-alpha-alkylated androgens with hepatotoxicity. 17-alpha-alkylated androgens may cause cholestatic hepatitis and jaundice, particularly with larger dosages or prolonged treatment. If cholestatic hepatitis with jaundice appears or if liver function tests (LFT) become abnormal, oxandrolone therapy should be discontinued pending determination of the etiology. Liver function tests should be obtained periodically during therapy.
Examination of bone age by x-ray should be conducted during treatment of children to determine bone maturation rate and effect on epiphyseal centers.
Women with breast carcinoma should have frequent assays of serum and urine calcium throughout the course of treatment.
Androgenic anabolic steroids have been associated with increases in low-density lipoproteins and reduction in high-density lipoproteins in serum. Caution is indicated when administering such medications to patients with cardiovascular disease or at risk for cardiovascular disease. Periodic serum lipid assays are recommended during treatment. Serum assays for hematocrit and hemoglobin are recommended to screen for polycythemia in patients receiving large doses of androgenic anabolic steroids.
Thyroid Testing Interaction: Anabolic steroids have been shown to reduce concentration of thyroxine-binding globulin and consequently decreasing the total serum T4 and increasing uptake of both T3 and T4. Serum concentration of free (unbound) thyroid hormones will not change. Anabolic steroids may decrease PBI and iodine uptake.

DRUG INTERACTIONS
Oral hypoglycemic agents: Oxandrolone may inhibit the metabolism of oral hypo glycemic 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.

PREGNANCY AND LACTATION
Pregnancy Category X
Pregnant women should not receive oxandrolone therapy due to possible masculinization of the fetus. In animal studies, oxandrolone in extremely high doses has demonstrated embryotoxicity, fetotoxicity, infertility, and masculinization of female offspring.
It is not known whether anabolics are excreted in milk, but due to the harm the drug may give infants, a decision should be made by the nursing mother whether to continue the drug or not.

PEDIATRIC USE
Use in children should be closely monitored by x-ray due to the potential for accelerating epiphyseal maturation and potentially compromising adult height. Great caution should be observed during therapy.

ADVERSE REACTIONS
Hepatic: Peliosis hepatis, cholestatic jaundice, and very rarely hepatic necrosis.
Hepatocellular neoplasms after long term use; May affect liver function tests, bromosulfophthalein (BSP), serum bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), and alkaline phosphatase (AP).
CNS: Changes in libido, habituation, excitation, insomnia, and depression.
Hematologic: Bleeding on concomitant anticoagulant therapy.
Breast: Gynecomastia.
Larynx: Deepening of the voice in females.
Fluids and Electrolytes: Retention of electrolytes including sodium, potassium, chlorine, phosphates, and calcium.
Hair: Hirsutism and male pattern baldness (androgenetic alopecia) in females.
Metabolic: Increased serum creatinine phosphokinase (CPK), reduced glucose tolerance, increased creatinine clearance, and inhibition of gonadotrophin secretion.
Skin: Acne Vulgaris, particularly in females and pre-pubertal males.
Skeletal: Premature closure of epiphyses in children.
COPD: Patients with severe COPD should be monitored for exacerbation of COPD and increased fluid retention.
In males:
Pre-pubertal: Increased frequency of erections and enlargement of the phallus, as well as more persistent erections.
Post-pubertal: Inhibition of testicular function, chronic priapism, oligospermia, impotence, epididymitis, and bladder irritability.
In females:
Virilization including clitoral enlargement and menstrual irregularities.

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.

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

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