OXANDROLONE®

Oxandrolone USP29 Micronized grade

Molecular Formula: $C_{19}H_{30}O_3$
Molecular Weight: 306.44 gm/mol
Active life: 8-12 hours
Detection Time: 3 weeks
Anabolic/Androgenic Ratio (Range): 322-630:24

DESCRIPTION:
Oxandrolone®, brand of Oxandrolone tablets, is an anabolic steroid, a synthetic derivative of testosterone. Each tablet contains 5 mg and 10 mg of Oxandrolone USP29, micronized grade. It is designated chemically as 17β-hydroxy-17α-methyl-2-oxa-5α-androstan-3-one. It occurs as white odourless crystalline powder. Soluble 1 in 5200 of water, 1 in 57 of alcohol, 1 in 69 of acetone, 1 in less than 5 of chloroform and 1 in 860 of ether.

Each tablet also contains lactose monohydrate, sodium starch glycolate, polyvidone 25,000, microcrystalline cellulose and magnesium stearate as excipients. The 10 mg tablet also contains yellow ferric oxide (E172) and indigo carmine aluminium lake (E132) as colouring agent and the 5 mg tablet do not contains any colouring agent.

Oxandrolone® is a well tolerated 17-alpha alkylated anabolic steroid with very low hepatic toxicity. It promotes anabolism through androgen receptor activity and has a low incidence of adverse reactions. When taken in clinical doses, Oxandrolone® promotes improvements in strength and moderate increases in muscle mass. Oxandrolone® has been demonstrated to enhance body fat reduction significantly in both the abdominal and visceral stores (Int. J. Obesity, 1995; 19: 614-624). Oxandrolone® will not aromatize and therefore the anabolic effect of this compound can promote linear growth. Oxandrolone® has shown great promise in nerve regeneration, skin healing in burn victims, and increased rate of healing after traumatic events.

CLINICAL PHARMACOLOGY:
Anabolic steroids are synthetic derivatives of testosterone. 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 disturbances 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 testes. During exogenous administration of anabolic androgens, endogenous testosterone release is inhibited through inhibition of pituitary luteinizing hormone (LH). At large doses, spermatogenesis may be suppressed through feedback inhibition of pituitary follicle stimulating hormone (FSH). Anabolic steroids have been reported to increase low-density lipoproteins and decrease high-density lipoproteins. These levels revert to normal on discontinuation of treatment. In single dose pharmacokinetic studies of Oxandrolone the mean elimination half-life was 13.3 hours in elderly subjects and 10.4 hours in younger subjects.

INDICATIONS:
Oxandrolone® is indicated as adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight, to offset the protein catabolism associated with prolonged administration of corticosteroids, and for the relief of the bone pain frequently accompanying osteoporosis (See **DOSAGE AND ADMINISTRATION**).

DRUG ABUSE AND DEPENDENCE
Oxandrolone® is classified as a controlled substance under the Anabolic Steroids Control Act of 1990 and has been assigned to Schedule III (non-narcotic).

CONTRAINDICATIONS:
1. Known or suspected carcinoma of the prostate or the male breast.
2. Carcinoma of the breast in females with hypercalcemia (androgenic anabolic steroids may stimulate osteolytic bone resorption).
3. Pregnancy, because of possible masculinization of the fetus. Oxandrolone® has been shown to cause embryotoxicity, fetotoxicity, infertility, and masculinization of female animal offspring when given in doses 9 times the human dose.
4. Nephrosis, the nephrotic phase of nephritis.
5. Hypercalcemia.

WARNINGS:

LIVER CELL TUMORS ARE REPORTED. MOST OFTEN THESE TUMORS ARE BENIGN AND ANDROGEN DEPENDENT, BUT FATAL MALIGNANT TUMORS HAVE BEEN REPORTED. WITH DRAWAL 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.
PELIOSIS HEPATIS, A CONDITION ARE ALSO REPORTED IN WHICH LIVER AND SOMETIMES SPLENIC TISSUE IS REPLACED WITH BLOOD-FILLED CYSTS, HAS BEEN REPORTED IN PATIENTS RECEVING 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 DISAPPERRANCE OF LESIONS.
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.

Cholestatic hepatitis and jaundice may occur with 17-alpha-alkylated androgens at a relatively low dose. If cholestatic hepatitis with jaundice appears or if liver function tests become abnormal, Oxandrolone® should be discontinued and the etiology should be determined. Drug-induced jaundice is reversible when the medication is discontinued.
In patients with breast cancer, anabolic steroid therapy may cause hypercalcemia by stimulating osteolysis. Oxandrolone® therapy should be discontinued if hypercalcemia occurs. Edema with or without congestive heart failure may be a serious complication in patients with pre-existing cardiac, renal, or hepatic disease. Concomitant administration of adrenal cortical steroid or ACTH may increase the edema. In children, androgen therapy may accelerate bone maturation without producing compensatory gain in linear growth. This adverse effect results in compromised adult height, the younger child and the greater risk of compromising final mature height. The effect on bone maturation should be monitored by assessing bone age of the left wrist and hand every 6 months (See **PRECAUTIONS: Laboratory tests**). Geriatric patients treated with androgenic anabolic steroids may be at an increased risk for the development of prostatic hypertrophy and prostatic carcinoma.

ANABOLIC STEROIDS HAVE NOT BEEN SHOWN TO ENHANCE ATHLETIC ABILITY.

PRECAUTIONS:
General: Women should be observed for signs of virilization (deepening of the voice, hirsutism, acne, clitoromegaly). Discontinuation of drug therapy at the time of evidence of mild virilism is necessary to prevent irreversible virilization. Some virilizing changes in women are irreversible even after prompt discontinue of therapy and are not prevented by concomitant use of estrogens. Menstrual irregularities may also occur.
Anabolic steroids may cause suppression of clotting factors II, V, VII, and X and an increase in prothrombin time.
Information for patients:
The physician should instruct patients to report any of the following side effects of androgens: *Males:* Too frequent or persistent erections of the penis, appearance or aggravation of acne.
Females: Hoarseness, acne, changes in menstrual periods, or more facial hair.
All patients: Nausea, vomiting, changes in skin color, or ankle swelling.
Laboratory tests:
Women with disseminated breast carcinoma should have frequent determination of urine and serum calcium levels during the course of therapy (See **WARNINGS**).
Because of the hepatotoxicity associated with the use of 17-alpha-alkylated androgens, liver function tests should be obtained periodically. Periodic (every 6 months) x-ray examinations of bone age should be made during treatment of children to determine the rate of bone maturation and the effects of androgen therapy on the epiphyseal centers. Serum lipids and high-density lipoprotein cholesterol determinations should be done periodically as androgenic anabolic steroids have been reported to increase low-density lipoproteins. Serum cholesterol levels may increase during therapy. Therefore, caution is required when administering these agents to patients with a history of myocardial infarction or coronary artery disease. Serial determination serum cholesterol should be made and therapy adjusted accordingly. Hemoglobin and hematocrit should be checked periodic for polycythemia in patients who are receiving high dose anabolic steroids.
Drug interactions
Anticoagulants:
Anabolic steroids may increase sensitivity to oral anticoagulants. Dosage of the anticoagulant may have to be decreased in order to maintain desired prothrombin time. Patients receiving oral anticoagulant therapy require close monitoring especially when anabolic steroids are started or stopped.
Oral hypoglycemic agents:
Oxandrolone® may inhibit the metabolism of oral hypoglycemic agents.
Adrenal steroids or ACTH:
In patients with edema, concomitant administration with adrenal cortical steroids or ACTH may increase the edema
Drug/Laboratory test interactions:
Anabolic steroids may decrease levels of thyroxine-binding globulin, resulting in decreased total T_4 serum levels and increased resin uptake of T_3 and T_4. Free thyroid hormone levels remain unchanged. In addition, a decrease in PBI and radioactive iodine uptake may occur.
Carcinogenesis, mutagenesis, impairments of fertility
Animal data:
Oxandrolone® has not been tested in laboratory animals for carcinogenic or mutagenic effects. In 2-year chronic orally to studies, a dose-related reduction of spermatogenesis and decreased organ weights (testes, prostate, seminal vesicle, ovaries, uterus, adrenals and pituitary) were shown.
Human data:
Liver cell tumors have been reported in patients receiving long-term therapy with androgenic anabolic steroids in high doses (See **WARNINGS**). Withdrawal of the drugs did not lead to regression of the tumors in all cases. Geriatric patients treated with androgenic anabolic steroids may be at an increased risk for the development of prostatic hypertrophy and prostatic carcinoma.
Pregnancy:
Teratogenic effects in pregnancy category X (See **CONTRAINDICATIONS**).
Nursing mother:
It is not known whether anabolic steroids are excreted in human milk. Because of the potential of serious adverse reactions in nursing infants from Oxandrolone®, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
Pediatric use:
Anabolic agents may accelerate epiphyseal maturation more rapidly than linear growth in children and the effects may continue for 6 months after the drug has been stopped.
Therefore, therapy should be monitored by x-ray studies 6-month intervals in order to avoid the risk of compromising adult height. Androgenic anabolic steroid therapy should be used very cautiously in children and only by specialists who re aware of the effects on bone maturation (See **WARNINGS**).

OVERDOSAGE:
No symptoms or signs associated with overdosage have been reported. It is possible that sodium and water retention may occur. The oral LD_{50} of oxandrolone in mice and dogs is greater than 5,000 mg/kg. No specific antidote is known, but gastric lavage may be used.

DRUG INTERACTION:
Oral hypoglycemic agents: may inhibit the metabolism of oral hypoglycemic agents which may require adjustment of dosage.
Anticoagulants: Patients on anticoagulants should be carefully monitored during anabolic steroid therapy as anabolic steroids may increase sensitivity to oral anticoagulants. Patients should be monitored regularly during anabolic steroid therapy, particularly during initiation and termination of therapy. Therefore, dosage of an anticoagulant may have to be decreased in order to maintain the prothrombin time at the desired therapeutic level.

PATIENT MONITORING:
Lipid profile: Serum Cholesterol, HDL, LDL, TG.
Hemoglobin and Hematocrit,
Liver function test: Total protein, Albumin, Globulin, Total and direct bilirubin, AST, ALT and alkaline phosphatase, tumor marker for liver: AFP and CA19-9
Prostatic specific antigen: PSA, Testosterone: total, free, and bioavailable.
Dihydrotestosterone & Estradiol
Male patients over 40 should undergo a digital rectal examination and evaluate PSA prior to androgen use. Periodic evaluations of the prostate should continue while on androgen therapy, especially in patients with difficulty in urination or with changes in voiding habits.

DOSAGE AND ADMINISTRATION:
The use of anabolic steroids may be associated with serious adverse reactions, many of which are dose related; therefore, patients should be placed on the lowest possible effective dose.
Adult males: 10–30 mg taken orally per day in 2 to 3 divided doses for 6 to 8 weeks under care of physician.
For body building: Adult male: 20-100 mg per day or 0.125 mg/kg-body weight.
Adult female: 2.5-20 mg per day

HOW SUPPLIED:
– **Oxandrolone®** 5 mg is supplied in bottle of 50 white tablets
– **Oxandrolone®** 10 mg is supplied in bottle of 30 green tablets

For shelf-life please refer to the imprint on the pack.

Keep out of reach of children.

Should be at controlled room temperatures 15-30°C (59-86°F)

Protect from sun light

This drug has not been shown to be safe and effective for the enhancement of athletic performance!

Manufactured and Distributed by: LA Pharma S.r.l.

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