METHANDIENONE®

Methandienone Pharmacopoeias. In *Pol.* grade

Molecular Formula: $C_{20}H_{28}O_2$
Molecular Weight: 300.441 gm/mol
Active life: 6-8 hours
Detection Time: up to 6 weeks
Anabolic/Androgenic Ratio (Range): 90-210:40-60

DESCRIPTION:
Methandienone®, brand of Methandienone tablets, is an anabolic steroid, a synthetic derivative of testosterone. Each tablet contains 5 mg and 10 mg of Methandienone Pharmacopoeias. In *Pol.* grade. It is designated chemically as 17β-hydroxy-17α-methylandrosta-1,4-dien-3-one.

Each tablet also contains lactose monohydrate, sodium starch glycolate, polyvidone 25,000, microcrystalline cellulose and magnesium stearate as excipients. The 5 mg tablet also contains red ferric oxide (E172) as colouring agent and the 10 mg tablet also contains indigo carmine aluminium lake (E132)

Methandienone® is a 17-alkylated oral steroid that exerts its effects through the androgen receptor. Methandienone acts on the androgen receptor which results in increased protein synthesis and nitrogen retention within muscle cells resulting in dramatic increases in strength and muscle mass.

CLINICAL PHARMACOLOGY:
Anabolic steroids are synthetic derivatives of testosterone. Certain clinical effects and adverse reactions demonstrate the androgenic properties of these drugs. Complete dissociation of anabolic and androgenic effects has not been achieved. The actions of anabolic steroids are thus similar to those of male sex hormones. Anabolic steroids 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).

Methandienone has been 17 -alkylated to reduce liver clearance making it practical for oral dosing. Methandienone acts directly on androgen receptors resulting in increased nitrogen retention and protein synthesis. Methandienone is subject to aromatization yielding estrogenic side effects if not offset with an aromatase inhibitor. Methandienone metabolism is hepatic with a half-life of 4.5 to 6 hours.

INDICATIONS:
1. Rapidly restore muscle tissue atrophied during recovery from a traumatic injury.
2. Offset muscle catabolism in patients with a wasting syndrome.
3. Treat certain types of anemia which are non-responsive to first line agents.

CONTRAINDICATIONS:
The use of Methandienone® is contraindicated in the following:
1. Not indicated for women, children, or the elderly.
2. Patients with diagnosed or suspected male breast carcinoma or carcinoma of the prostate.
3. Patients with diagnosed or suspected female breast carcinoma with hypercalcemia as androgenic agents may increase osteolytic bone resorption.
4. Women who are pregnant or may become pregnant because of possible masculinization of the fetus.
5. Patients with nephrosis or the nephrotic phase of nephritis.
6. Patients with hypercalcemia.
7. Patients with pre-existing cardiac, renal, and/or hepatic disease.
8. This product is hepatotoxic and requires Hepatic Monitoring. Discontinue if jaundicing presents.
9. Hypersensitivity to Methandienone

PRECAUTIONS:
Elevated liver enzymes and in extreme cases hepatic liver dysfunction may occur. 17-alpha-alkylated androgens may cause cholestatic hepatitis and jaundice, particularly with larger dosages or prolonged treatment. Liver function should be monitored for changes including serum bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), and alkaline phosphatase (AP).
Edema may be increased in patients on concurrent adrenal cortical steroid or ACTH therapy.
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.

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.

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. Periodic liver function tests should be conducted given the association of 17-alpha-alkylated androgens with hepatotoxicity.

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.

ADVERSE REACTIONS:
In Males
Prepubertal: phallic enlargement; increased frequency of erections.
Postpubertal: inhibition of testicular function, oligospermia; gynecomastia.
In Females
Hirsutism; male pattern baldness; deepening of the voice; clitoral enlargement. These changes are usually irreversible even after prompt discontinuance of therapy and are not prevented by concomitant use of estrogens. In addition, the following may occur: menstrual irregularities; masculinization of the fetus.
In Both Sexes
Nausea; fullness; loss of appetite; vomiting; burning of the tongue; increased or decreased libido; acne (especially in females and prepubertal males); inhibition of gonadotropin secretion; bleeding in patients on concomitant anticoagulant therapy; premature closure of epiphyses in children; jaundice. There have been rare reports of hepatocellular neoplasms and peliosis hepatic in association with long-term androgenic–anabolic steroid therapy.
Alterations may occur in the following clinical laboratory tests: metyrapone test; glucose tolerance tests; thyroid function tests (decrease in protein bound iodine, thyroxine-binding capacity and radioactive iodine uptake); electrolytes retention of sodium, chloride, water, potassium, phosphate, and calcium); hepatic function tests (increased BSP, serum cholesterol, SGOT, serum bilirubin, and alkaline phosphatase; blood coagulation tests (suppression of clotting factors II, V, VII, and X); decreased 17-ketosteroid excretion.

OVERDOSE:
Signs and symptoms of overdosage are those associated with the known effects of the drug. See Adverse Reactions section. Treatment is symptomatic and supportive. Evacuate stomach contents by emesis and, if indicated, lavage, taking care to prevent aspiration. Monitoring of liver function is advised.

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.
Methandienone® therapy is adjunctive to and not a replacement for conventional therapy. Duration of therapy will depend on the response of the condition and the appearance of adverse reactions. Therapy should be intermittent and no longer than necessary for optimal results. The usual initial adult dosage is 5 mg daily. For maintenance, 2.5 to 5 mg daily is usually sufficient. Intermittent therapy is recommended when Methandienone® is administered over long periods. For example, after six weeks of treatment, there should be an interval of two to four weeks before resuming therapy. Proper diet, particularly adequate protein intake, is required to assure the full anabolic benefits of Methandienone®.

Body building: Adult males: 25-50 mg taken orally per day in divided doses for a duration of 3 to 6 weeks.

HOW SUPPLIED:
– **Methandienone®** 5 mg is supplied in bottle of 1,000 pink tablets.
– **Methandienone®** 10 mg is supplied in 2 packages of 100 blue tablets bottle and 500 blue tablets bottle.

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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