DecaMax®

COMPOSITION:
Each ml contains:
Nandrolone Decanoate USP29, Ph.Eur.5.5, 200 mg
Nandrolone Cypionate 100 mg
Nandrolone Phenylpropionate USP29, BP2005, 50 mg
Miglyol 840
Ethyl oleate
Benzyl benzoate
Benzyl alcohol

Nandrolone Formula: $C_{18}H_{26}O_2$ (CAS-434-22-0, ATC-A14AB01;S01XA11)
Molecular Weight (base): 274.4 gm/mol
Active life: 15 days
Detection time: up to 18 months
Anabolic/Androgenic ratio: 37:125

DESCRIPTION:
Nandrolone Decanoate is a steroid compound that is described chemically as 17β-hydroxyestr-4-en-3-one decanoate. It occurs as a white to creamy-white fine crystalline powder, odourless or may have a slight odour. Practical insoluble in water, soluble in alcohol, in acetone, in chloroform and in vegetable.
Nandrolone Cypionate is a steroid compound that is described chemically as 17β-hydroxyestr-4-en-3-one cypionate. It is our special laboratory quality control.
Nandrolone Phenylpropionate is a steroid compound that is described chemically as 17β-hydroxyestr-4-en-3-one 3- phenylpropionate. It occurs as a white to creamy-white crystalline powder with characteristic odour. Practical insoluble in water, soluble in alcohol.
DecaMax® is combined acting Nandrolone mix which is an oil based solution of 3 Nandrolone esters: Decanoate USP29, Ph.Eur.5.5, Cypionate and Phenylpropionate USP29, BP2005 which is designed for combination of slow and fast acting Nandrolone in reasonable concentration.
DecaMax® is available as a sterile solution of Nandrolone Mix, a suitable-action anabolic agent, for only intramuscular injection.

CLINICAL PHARMACOLOGY:
Anabolic steroids are synthetic derivatives of testosterone. Certain clinical effects and adverse reactions demonstrate the androgenic properties of this class of drugs. No dissociation of androgenic and anabolic potency has been demonstrated clinically for any anabolic steroid although there is some suggestion from animal studies that such dissociation may be possible.
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. 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-stimulation hormone (FSH).
Anabolic steroids increase low-density lipoproteins and decrease high-density lipoproteins. These changes revert to normal on discontinuation of treatment.

INDICATIONS AND USAGE:
DecaMax® is indicated for the management of the anemia of renal insufficiency and has been shown to increase hemoglobin and red cell mass. Surgically induced nephric patients have been reported to be less responsive.
DecaMax® is used alone or as an adjunct in the treatment of anemia secondary to bone marrow failure, breast cancer in postmenopausal women, non-small cell lung cancer, and postmenopausal osteoporosis.

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 female fetus. Androgenic anabolic steroids are known to cause embryotoxicity, fetotoxicity, and masculinization of female animal offspring. DecaMax® is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, she should be apprised of the potential hazard to the fetus.
4. Nephrosis or the nephrotic phase of nephritis.

WARNINGS:
Cholestatic hepatitis and jaundice occur with 17-alpha-alkylated androgens at a relatively low dose. If cholestatic hepatitis with jaundice appears or if liver function tests become abnormal, DecaMax® 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. DecaMax® 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 add to the edema.
In children, androgen therapy may accelerate bone maturation without producing compensatory gain in linear growth. This adverse effect results in compromised adult stature, 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 wrist and hand every six months.
Geriatric patients treated with androgenic anabolic steroids may be at an increased risk for the development of prostatic hypertrophy and prostatic carcinoma.

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.

THERE IS NO PERSUASIVE EVIDENCE THAT ATHLETIC PERFORMANCE IS IMPROVED BY USING ANABOLIC STEROIDS.

PRECAUTIONS:
Women should be observed for signs of virilization (deepening of the voice, hirsutism, acne, clitoromegaly). Such virilization is usual following anabolic steroid use in high doses. Discontinuation of drug therapy at time of evidence of mild virilism is necessary to prevent irreversible. Some virilizing changes (facial hair growth, clitoromegaly, deepening of the voice) in women are irreversible even after prompt discontinuation 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.
Insulin or oral hypoglycemic dosage may need adjustment in diabetic patients who receive anabolic steroids.

INFORMATION FOR PATIENTS:
The physician should instruct patients to report any of the following side effects of androgens:
Adult or Adolescent Males: Too frequent or persistent erections of the penis, appearance of 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 six months) x-ray examinations of bone age should be made during treatment of prepubertal males and females 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 anabolic androgenic steroids have been reported to increase low-density lipoproteins and decrease high-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 determinations of serum cholesterol should be made and therapy adjusted accordingly.
Hemoglobin and hematocrit should be checked periodically for polycythemia in patients who are receiving high doses of anabolic steroids.

DRUG INTERACTIONS:
Anticoagulants: Anabolic steroids, in particular 17-alpha-alkylated steroids, may increase sensitivity to oral anticoagulants. Dosage of the anticoagulant may have to be decreased in order to maintain prothrombin time at the desired therapeutic level. Patients receiving oral anticoagulant therapy require close monitoring, especially when anabolic steroids are started or stopped.
Oral Hypoglycemic Agent: DecaMax® may inhibit the metabolism of oral hypoglycemic agents.

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.
Anabolic steroids, in particular 17-alpha-alkylated steroids, may cause an increase in prothrombin time.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY:
Animal Data:
Testosterone has been tested by subcutaneous injection and implantation in mice and rats. The implant induced cervical-uterine tumors in mice, which metastasized in some cases. There is suggestive evidence that injection of testosterone into some strains of female mice increases their susceptibility to hepatoma. Testosterone is also known to increase the number of tumors and decrease the degree of differentiation of chemically-induced carcinomas of the liver in rats.
Human Data:
There are rare reports of hepatocellular carcinoma in patients receiving long-term therapy with androgens in high doses. Withdrawal of the drugs did not lead to regression of the tumors in all cases.
Geriatric patients treated with androgens may be at an increased risk of developing prostatic hypertrophy and prostatic carcinoma although conclusive evidence to support this concept is lacking.
This compound has not been tested for mutagenic potential. However, as noted above, carcinogenic effects have been attributed to treatment with androgenic hormones. The

potential carcinogenic effects likely occur through a hormonal mechanism rather than by a direct chemical interaction mechanism.
Impairment of fertility was not tested directly in animal species. However, oligospermia in males and amenorrhea in females have been seen with several other drugs in this class. Therefore, impairment of fertility is a possible outcome of treatment with DecaMax®.

PREGNANCY
Teratogenic Effects: Pregnancy Category X. See "Contraindicatiions".

NURSING MOTHERS
It is not known whether anabolic steroids are excreted in human milk. Many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from anabolic steroids; a decision should be made whether 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 effect may continue for six months after the drug has been stopped. Therefore, therapy should be monitored by x-ray studies at six-month intervals in order to avoid the risk of compromising adult height. Anabolic androgenic steroid therapy should be used very cautiously in children and only by specialists who are aware of the effects on bone maturation.

ADVERSE REACTIONS:
Hepatic: Cholestatic jaundice with, rarely, hepatic necrosis and death. Hepatocellular neophasms and peliosis hepatitis have been reported in association with long-term use of androgenic anabolic steroids, particularly those that are 17-alpha-alkylated (see "Warnings"). Reversible changes in liver function tests also occur including increased bromsulphalein (BSP) retention, and increases in serum bilirubin, glutamic oxaloacetic transamine (SGOT) and alkaline phosphatase.
Genitourinary System:
In men:
Prepubertal: Phallic enlargement and increased frequency of erections.
Postpubertal: Inhibition of testicular function, testicular atrophy and oligospermia, impotence, chronic priapism, epididymitis and bladder irritability.
In women: Clitoral enlargement, menstrual irregularities.
In both sexes: Increased or decreased libido.
CNS: Habituation, excitation, insomnia, depression.
Gastrointestinal: Nausea, vomiting, diarrhea.
Hematologic: Bleeding in patients on concomitant anticoagulant therapy (see "*Precaution, Drug Interactions"*).
Breast: Gynecomastia.
Larynx: Deepening of the vioce in women.
Hair: Hirsutism and male pattern baldness in women.
Skin: Acne (especially in women and prepubertal boys).
Skeletal: Premature closure of epiphyses in children (see"*Precaution, Pediatric Use"*).
Fluid and Electrolytes: Edema, retention of serum electrolytes (sodium chloride, potassium phosphate, calcium).
Metabolic/Endocrine: Decreased glucose tolerance (see "*Precautions, Drug Interactions"*), increased serum levels of low-density lipoproteins and decreased levels of high-density lipoproteins (see *"Precautions, Laboratory Tests"*), increased creatine and creatinine excretion, increased serum levels of creatine phosphokinase (CPK). Some virilizing changes in women are irreversible even after prompt discontinuance of therapy and are not prevented by concomitant use of estrogens (see *"Precautions"* section).

OVERDOSAGE:
There have been no reports of acute overdosage with the androgens.

DOSAGE AND ADMINISTRATION:
DecaMax® is intended only for deep intramuscular injection preferably into the gluteal muscle. Dosage should be based on therapeutic response and consideration of the benefit/risk ratio. Duration of therapy will depend on the response of the condition and the appearance of adverse reactions. If possible, therapy should be intermittent.
DecaMax® should be regarded as adjunctive therapy and adequate quantities of nutrients should be consumed in order to obtain maximal therapeutic effects. When it is used in the treatment of refractory anemias, for example, adequate iron intake is required for a maximal response.
Adult dose: average 25 mg to 50 mg every three weeks.

ANEMIA OF RENAL DISEASE
A dose of 50-100 mg per week DecaMax® is recommended for women and 100-200 mg per week for men. Drug therapy should be discontinued if no hematologic improvement is seen within the first six months. When used in the treatment of renal insufficiency, adequate iron intake is required for maximal response. For children from 2 to 13 years of age, the average dose is 25-50 mg every 3 to 4 weeks.

Body building: male 200-600 mg per week, female 50-100 mg per week.

HOW SUPPLIED – DecaMax® injection, solution- Intramuscular-350 mg/ml is supplied in multiple dose 10 ml vial with black color flip cap.

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)

Do not freeze

This drug should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Warming and shaking the vial should redissolve any crystals that may have formed during storage at temperatures lower than recommended.

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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