DecaNan®

Nandrolone Decanoate USP 29, Ph.Eur.5.5 Micronized grade

Formula: C_{30}H_{46}O_{3} (CAS-360-70-3, ATC-A14AB01, S01XA1)
Molecular Weight: 428.68 g/mol
Active life: 15 days
Detection time: up to 18 months
Anabolic/Androgenic ratio: 125:37

DESCRIPTION:
Nandrolone Decanoate is a steroid compound that is described chemically as 17β-
hydroxy-5α-4-en-3-ones decanoate. It occurs as a white to creamy-white fine crystalline
powder, odorless or may have a slight odour. Practical insoluble in water, soluble in
alcohol, in acetone, in chloroform and in vegetable.

DecaNan® is a sterile solution of 250mg Nandrolone Decanoate USP29, Ph.Eur.5.5,
Methylglycol 840, Ethyl oleate, Benzyl benzoate, Benzyl alcohol.
DecaNan® is available as a sterile solution of Nandrolone Decanoate, a long-acting anabolic
agent, for only intramuscular injection.

CLINICAL PHARMACOLOGY:
Anabolic steroids are synthetic derivatives of testosterone. Certain clinical effects and
adverse reactions demonstrate the anabolic properties of this class of drugs. And
lack of dissociation of anabolic and androgenic potency has been documented clinically for an
certain 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 gonadotrophic functions of the pituitary and may exert a direct effect on gonadal function.

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 increase low-density lipoproteins and decrease high-density lipoproteins. These changes revert to normal on discontinuation of treatment.

INDICATIONS AND USAGE:
DecaNan® is indicated for the management of the anaemia of renal insufficiency and has been
shown to increase haemoglobin and red cell mass. Surgically induced nephrectomy patients have
been shown to be less responsive to the hormone.

DecaNan® is used alone or as an adjunct in the treatment of anaemia 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 hypercalcaemia (anabolic androgenic steroids may
   stimulate osteolytic bone resorption).
3. Pregnancy, because of possible masculinization of the female fetus. Anabolic androgenic
   steroids are known to cause abnormalities of sexuality, feminization and masculinization of fetal
   animal offspring. DecaNan® 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 advised of the potential hazard to the fetus.
4. Nephrosis or the nephritic phase of nephritis.

WARNING:
Osteoporosis, hepatitis and jaundice occur with 17α-alkylated androgens at a relatively
low dose. If cholestatic hepatitis with jaundice appears or if liver function tests become
abnormal, DecaNan® 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 hypercalcaemia by
stimulating osteolysis. DecaNan® therapy should be discontinued if hypercalcaemia occurs.
Edema with or without congestive heart failure may be a serious complication in patients
with pre-existing cardiac, renal, or hepatic disease. Concurrent 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 final 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 wrist and hand every six
months.

Geriatric patients treated with anabolic androgenic 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 DURATION OF DRUG USE RESULTS IN INCREASED RISK OR RESOLUTION 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.

PIELOPHUSIS HEPATIS, A CONDITION ARE ALSO REPORTED IN WHICH LIVER AND SOMETIMES SPLENIC TISSUE IS REPLACED WITH BLOOD-FILLED CYSTS, HAS BEEN REPORTED IN PATIENTS RECEIVING ANABOLIC STEROID THERAPY. THESE CYSTS ARE SOMETIMES ASSOCIATED 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 DEVELOP. PERSISTENT OR RECURRENT CYSTIC DISEASE USUALLY RESULTS IN COMPLETE DISAPPEARANCE OF LesIONS.

BLOOD LIPID CHANGES THAT ARE KNOWN TO BE ASSOCIATED WITH INCREASED RISK
OF ATHEROSCLEROSIS ARE SEEN IN PATIENTS TREATED WITH ANABOLICS AND ANABOLIC STEROIDS. THESE CHANGES INCLUDE DECREASED HIGH-DENSITY LIPROPROTEIN AND SOMETIMES INCREASED LOW-DENSITY LIPROPROTEIN. 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 estrogen. 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:
Males: Breast enlargement, acne, testicular atrophy, deepening of the voice, hirsutism.
Females: Amenorrhea, acne, changes in menstrual periods, or heavy facial hair.

LABORATORY TESTS:
Women with disseminated breast carcinoma should have frequent determination of urine and
serum calcium level during the course of therapy (see "warranted").
Because of the hepatotoxicity associated with the use of 17α-alkylated androgens, liver
function tests should be obtained periodically.

Drug interactions:
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 cholesterol 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.
Menohemoglobin 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 17α-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
withdrawn.

Oral Hypoglycemic Agent: DecaNan® 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 T₄ serum levels and increased resin uptake of T₃ and T₄. Free thyroid hormone levels remain unchanged.

Anabolic steroids, in particular 17α-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 implantation induced cortical to adrenal metastasized some tumors. 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 tumours and decreased 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 anabolic agents 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 anabolic 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 azoospermia in females have been seen with several other drugs in this class.

Therefore, impairment of fertility is a possible outcome of treatment with DecaNan®.

PREPREGNACY
Teratogenic Effects: Pregnancy Category X. See “Contraindications”.

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.

PEDEATRIC 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
nephropathies and peliosis hepatis 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
brumunaphaethin (BSP) retention, and increases in serum bilirubin, glutamic oxaloacetic
transaminase (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 prostatitis, 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 voice 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.

DOSEAGE AND ADMINISTRATION:
DecaNan® 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.
DecaNan® 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 DecaNan® 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 – DecaNan® injection, solution- Intramuscular-200 mg/ml is supplied in
1 ml vial and -250 mg/ml is supplied in multiple dose 10 ml vial with yellow color flip
off.
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 sunlight
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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