DECADROL DEPOT

Ampoule

Composition

Decadrol Depot 25 mg Injection
Each ampoule of 1 ml contains Nandrolone decanoate 25 mg in an oily solution.

Decadrol Depot 50 mg Injection
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Action

Decadrol is an injectable anabolic preparation. The pharmacologically active substance is nandrolone. The decanoate ester gives the preparation duration of action of about three weeks after injection.

Nandrolone is chemically related to the male hormone. Compared to testosterone, it has an enhanced anabolic and a reduced androgenic activity. The low androgenicity of nandrolone is confirmed in clinical use.

Decadrol has been shown to positively influence calcium metabolism and to increase bone mass in osteoporosis. In women with disseminated mammary carcinoma, Nandrolone has been reported to produce objective regressions for many months. Furthermore, Nandrolone has a nitrogen-saving action.

This effect on protein metabolism has been established by metabolic studies and is utilized therapeutically in conditions where a protein deficiency exists such as during chronic debilitating diseases and after major surgery and severe trauma. In these conditions, Nandrolone serves as a supportive adjunct to specific therapies and dietary measures as well as parenteral nutrition.

Androgenic effects (e.g. virilisation) are relatively uncommon at the recommended dosages. Nandrolone lacks the C17alpha-alkyl group which is associated with the occurrence of liver dysfunction and cholestasis.

Pharmacokinetics
Nandrolone decanoate is slowly released from the injection site into the blood with a half-life of 6 days. In the blood, the ester is rapidly hydrolyzed to nandrolone with a half-life of one hour or less. The half-life for the combined process of hydrolysis of nandrolone decanoate and of distribution and elimination of nandrolone is 4.3 hours. Nandrolone is metabolised by the liver. 19-Norandrosterone, 19-noretiocholanolone and 19-norepiandrosterone have been identified as metabolites in the urine. It is not known whether these metabolites display a pharmacological action.

Indications

- Adjunctive treatment of catabolic or tissue-depleting processes such as chronic infections, extensive surgery, corticosteroid-induced myopathy, decubitus ulcers, bums, or severe trauma, which require reversal of catabolic processes or protein-sparing effects. Decadrol Depot is an adjunct to, and not a replacement for, conventional treatment of these conditions.
- Treatment of anemia associated with renal insufficiency and as adjuvant therapy for aplastic and sickle cell anemias. Surgically induced anephric patients may be less responsive. Adequate iron intake is necessary for maximum therapeutic response.
- Treatment for palliation of inoperable metastatic breast cancer in postmenopausal women, following inadequate response by the patient to less-toxic medications such as tamoxifen in hormonally responsive breast cancer.
- Treatment of breast cancer in premenopausal women who have undergone Oophorectomy and are considered to have a hormone-responsive tumour.
- Adjunctive therapy in senile and postmenopausal osteoporosis.

- Adjunct in the treatment of growth failure in children caused by pituitary growth hormone deficiency (pituitary dwarfism), or if the response to human growth hormone administration is inadequate.

Contraindications

- Hypersensitivity to Nandrolone or any other anabolic steroids.
- Male patients with carcinoma of the prostate or breast. Carcinoma of the breast in females with hypercalcemia.
- Patients with active hypercalcemia or a history of hypercalcemia, since the condition may become exacerbated or recurrence may result.
- Severe hepatic function impairment.
- Nephrosis or the nephrotic phase of nephritis.
- Contraindicated in pregnancy, primarily because of masculinization of the fetus.
- Enhancement of physical appearance or athletic performance .

Warnings

Peliosis Hepatitis

Peliosis hepatitis, a condition in which liver and sometimes splenic tissue is replaced with blood-filled cysts, has occurred in patients receiving androgenic anabolic steroid therapy. These cysts are sometimes present with minimal hepatic dysfunction, but they have been associated with liver failure. They are often not recognized until life-threatening liver failure or intra-abdominal hemorrhage develops. Withdrawal of the drug usually results in complete disappearance of the lesions.

Liver Cell Tumours

There have been rare reports of hepatocellular neoplasms, most of which are benign and androgen-dependent. However, fatal malignant tumours have occurred. Withdrawal of the drug often results in the regression or cessation of tumour progression. However, hepatic tumours associated with androgens or anabolic steroids are much more vascular than other hepatic tumours and may be silent until life-threatening intra-abdominal hemorrhage develops.

Blood Lipid Changes

Changes in blood lipid levels associated with increased risk of atherosclerosis are seen in patients treated with androgens and anabolic steroids. These changes include decreased high-density lipoprotein (HDL) and sometimes-increased low-density lipoprotein (LDL). These changes may be very marked and could have a serious impact on the risk of atherosclerosis and coronary artery disease.

Risk-benefit should be considered in patients with a history of myocardial infarction or coronary artery disease.

Hypercalcemia

Hypercalcemia may develop spontaneously or because of hormonal therapy in women with disseminated breast carcinoma. Perform frequent urine and serum calcium level examinations. If hypercalcemia occurs, discontinue the drug.

Athletic Performance

The use of anabolic steroids to improve athletic performance by increasing muscle strength is associated with serious risk of side effects, which are sufficiently severe to preclude their use on medical grounds.

Pregnancy

Category X

Nursing Mothers

It is not known whether anabolic steroids are excreted in breast milk. However, because of the potential risks of serious adverse reactions in nursing infants, the mother should either discontinue nursing or discontinue the drug.

Use in Children
The androgenic properties of anabolic agents may cause serious disturbances of growth and sexual development when given to young children. They suppress the gonadotropin functions of the pituitary and may exert a direct effect on the testes.

Anabolic agents may accelerate epiphyseal maturation more rapidly than linear growth in children and the effect may continue for some time after the drug has been discontinued. Therapy must therefore be monitored by x-ray studies at 6-month intervals to avoid the risk of compromising adult height.

Safety and efficacy in children with hereditary angioedema or metastatic breast cancer (rare cases) have not been established.

This preparation contains benzyl alcohol as a preservative. Benzyl alcohol has been associated with a toxic, fatal "gasping syndrome" in low birth-weight neonates. The syndrome is characterized by metabolic acidosis symptoms of progressive encephalopathy, intracranial hemorrhage and respiratory depression with gasping.

Elderly Use
Elderly patients treated with anabolic steroids may be at increased risk of developing prostatic hypertrophy and prostatic carcinoma.

Adverse Reactions
Following intramuscular injection, the patient may experience urticaria at the injection site, post-injection induration, furunculosis.

Hepatotoxicity
Hepatotoxicity is the most serious adverse reaction. Liver function tests should therefore be carried out periodically.

Gastrointestinal
Nausea, vomiting, diarrhea, cholestatic jaundice, hepatic necrosis, hepatocellular neoplasms and peliosis hepatitis.

Central Nervous System
Excitation, insomnia, habituation, depression and chills.

Endocrine
Virilisation is the most common undesirable effect.
Acne occurs frequently in all age groups, but especially in women and prepubertal males.
Anabolic hormones inhibit gonadotropin secretion.

Prepubertal Males
The first signs of virilisation are acne, phallic enlargement and an increase in frequency of erection. Hirsutism and increased skin pigmentation may also occur.

Postpubertal Males
Inhibition of testicular function with oligospermia, gynecomastia, testicular atrophy, chronic priapism, male pattern baldness, epididymitis, bladder irritability, decrease in seminal volume, change in libido and impotence may occur with prolonged or intensive therapy.

Females

Acne or oily skin, unnatural hair growth, hoarseness or deepening of the voice, clitoral enlargement, change in libido, menstrual irregularities, male-pattern baldness. Voice changes, clitoral enlargement, unnatural hair growth and unusual hair loss are usually irreversible, even after prompt discontinuation of the drug. The concurrent use of estrogens will not prevent virilisation in females. Masculinization of the fetus has occurred.

Fluid and Electrolyte Disturbances
Retention of sodium, chloride, water, potassium, phosphates and calcium, ankle swelling, decreased glucose tolerance.

Miscellaneous
Muscle cramps, premature closure of epiphyses in children, habituation, choreiform movement, increased serum cholesterol, increased serum levels of LDL and decreased HDL .

Precautions

Virilisation in females may occur.
If amenorrhea or menstrual irregularities develop during treatment, discontinue the drug until the etiology is determined and pregnancy is ruled out as the cause.

Edema, with or without congestive heart failure, may occur. Use with caution in patients with cardiac, renal or hepatic impairment, epilepsy, migraine or other conditions that may be aggravated by fluid retention.
Use with caution in patients with benign prostatic hypertrophy. Further enlargement may occur.
Hepatic function determinations and measurement of serum concentrations of calcium and cholesterol are recommended at regular intervals during therapy.

Periodic determinations of serum iron and total iron binding capacity (TIBC) are recommended because of possible iron deficiency anemia, manifested by low serum iron and a decrease in percentage of transferrin saturation.

Tolerance to glucose may be altered. Therefore, sugar levels in the blood and urine should be carefully monitored in diabetic patients. Insulin or oral hypoglycemic dosage may need to be adjusted.
In patients with seizure disorders, an increase in the frequency of seizures may be noted.

Drug Interactions

Anabolic Steroids/ Oral Anticoagulants
Concurrent use may potentiate oral anticoagulant effects. The dosage of the anticoagulant may have to be adjusted based on prothrombin time determinations. Avoid this combination if possible.

Anabolic Steroids/ Hepatotoxic Drugs
Concurrent use may result in an increased incidence of hepatotoxicity. Patients, especially those receiving long-term therapy or those with a history of liver disease, should be monitored carefully.

Anabolic Steroids/ Insulin/ Oral hypoglycaemic Agents
Anabolic steroids may decrease blood glucose concentration. Diabetic patients should be closely monitored for signs of hypoglycaemia and the dosage of the hypoglycaemic agent should be adjusted accordingly.

Anabolic Steroids/ Corticosteroids/Adrenocorticotropic Hormone/ Sodium-containing Medications or Food
Concurrent use of anabolic steroids with corticosteroids (especially those with significant mineralocorticoid activity), ACTH (especially in prolonged therapeutic use), or sodium-containing medications or food may increase the possibility of edema. Concurrent use of anabolic steroids with glucocorticoids or ACTH may promote the development of severe acne.

Anabolic Steroids/ Somatropin
Concurrent use may accelerate epiphyseal maturation.

Diagnostic Interference
Fasting blood sugar, glucose tolerance test, and metyrapone test may be altered.
Radioactive iodine uptake and thyroxin-binding capacity (TBC) may be decreased. The decreased levels of thyroxin -binding globulin result in decreased total T3 and T4 serum levels and increased resin uptake of T3 and T4. Altered tests usually persist for 2-3 weeks after discontinuing anabolic therapy.

Serum concentrations of alanine aminotransferase (ALT, SGPT), alkaline phosphatase, aspartate aminotransferase (AST, SGOT), bilirubin, calcium, chloride, inorganic phosphates, potassium, and sodium, may be increased.
Concentrations of clotting factors II, V, VII and X may be increased. Prothrombin time may be increased. Creatine and creatinine excretion may be increased, lasting up to 2 weeks following discontinuation of therapy HDL levels may be lowered, and LDL levels may be elevated. Urinary 17-ketosteroid excretion may be decreased.

Dosage and Administration
Decadrol Depot is intended for deep intramuscular injection, preferably into the gluteal muscle.
Many of the side effects of anabolic steroids are dose-related. Therefore, patients should receive the lowest possible effective dose.

The usual adult dose is 50-100 mg as a single intramuscular injection, every 3-4 weeks.
Therapy may be continued for up to 12 weeks. If necessary, the treatment cycle may be repeated, if the second course is preceded by a 4-week rest period.

In the treatment of severe disease states, such as metastatic breast cancer and refractory anemias, a higher dose, based on therapeutic response and risk-benefit ratio, may be required.

A well-balanced diet that provides adequate proteins and calories should accompany all anabolic steroid therapy to achieve a maximum therapeutic effect.
In the treatment of anemia associated with renal insufficiency, adequate iron intake is required for maximum therapeutic response.

Presentation
Decadrol Depot 25 mg
Box of one ampoule.

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