DECANOL – 25mg./50mg. INJ.

FOR I.M.USE ONLY

DECANOL – 25mg.

Composition :

Each ml contains:

Nandrolone Decanoate I.P.	25mg.
Ethyl Oleate I.P.	q.s.

DECANOL -50mg.

Composition :

Each ml contains:

Nandrolone Decanoate I.P.	50mg.
Ethyl Oleate I.P.	q.s.

DESCRIPTION :

Nandrolone Decanoate is an anabolic steroid. It has both androgenic as well as anabolic properties. Anabolic steroids are synthetic derivatives of testosterone. Nandrolone Decanoate has a pretty long release period, about 3-4 weeks. It may not be so for single injection, when the release time is about 1-2 weeks, but from multiple injections we can expect to benefit from its good effect for a longer duration. The chemical structure of this compound is similar to that of testosterone with minor difference but which makes it much less androgenic then any kind of testosterone.

Chemical formula of Nandrolone Decanoate is $C_{18}H_{26}O_2$

MECHANISM OF ACTION :

Reverses catabolic processes and negative nitrogen balance by promoting protein anabolism and stimulating appetite if there is concurrently a proper intake of calories and proteins.

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. Anabolic steroids suppress the gonadotropic functions of the pituitary and may exert a direct effect upon the testis. Anabolic steroids have been reported to increase low-density lipoproteins and decrease high-density lipoproteins. These changes revert to normal on discontinuation of treatment.

Pharmacodynamics :

Androgenic action: Nandrolone exerts inhibitory effects on hormone-responsive breast tumors and metastases.

Erythropoietic action: Nandrolone stimulates kidney production of erythropoietin, leading to increases in red blood cell mass and volume.

Anabolic action: Nandrolone may reverse corticosteroid-induced catabolism and promote tissue development in severely debilitated patients.

Pharmacokinetic :

Absorption :
Nandrolone decanoate is slowly released from the injection site into the blood with a half-life of 6 days.

Distribution :
The ester is rapidly hydrolyzed to nandrolone in the blood 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.

Biotransformation and excretion :
Nandrolone is metabolized 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. The elimination half-life of nandrolone is 6 to 8 days.

Bioavailability : 100 % through intramuscular.

Excretion : Approximate 21 days.

INDICATIONS :

Nandrolone Decanoate injection is indicated in – Debilitating illness, postmenopausal osteoporosis, osteoporosis, convalescence after surgery, burn or major illness, postmenopausal metastatic mammary carcinoma.

CONTRAINDICATIONS AND PRECAUTIONS :

Contraindicated in pregnant women, breast-feeding women, patients hypersensitive to anabolic steroids, men with breast cancer or prostate cancer, patients with nephrosis, patients experiencing the nephrotic phase of nephritis, and women with breast cancer and hypercalcemia

Use cautiously in patients with renal, cardiac, or hepatic disease; diabetes; epilepsy; migraine; or other conditions that may be aggravated by fluid retention.

WARNING :

Peliosis hepatitis, a condition which liver and sometimes splenic tissue is replaced blood - filled cysts has been reported in patients receiving 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 lever failure or intra abdominal hemorrhage develops. With withdrawal of drug usually results in complete disappearance of lesions. Liver cell tumors are also reported. Most often these tumors are benign and androgen dependent, but fatal malignant tumors have been reported. Withdrawal of drug often results in regression or cessation of progression of the tumors. 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. 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 marked and could have a serious impact on the risk of atherosclerosis and coronary artery disease.

Hypercalcaemia may develop both spontaneously and as a result of androgen therapy in women with disseminated breast carcinoma. If it develops while on this agent, the drug should be discontinued. Caution is required in administering these agents to patients with cardiac, renal or hepatic disease.

Cholestatic jaundice is associated with therapeutic use of anabolic and androgenic steroids. Edema may occur occasionally with or without congestive heart failure. In children, anabolic steroid treatment may accelerate bone maturation without producing compensatory gain in linear growth. This adverse effect may result in compromised adult stature. The younger the child the greater the 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. This drug has not been shown to be safe and effective for the enhancement of athletic performance. Because of the potential risk of serious adverse health effects, this drug should not be used for such purpose.

PRECAUTIONS :

General : Women should be observed for signs of virilization like deepening of the voice, hirsutism, acne, clitorimegaly and menstrual irregularities. Discontinuation of drug therapy at the time of evidence of mild virilism is necessary to prevent irreversible virilization. Such virilization is usual following anabolic steroid use in high doses. The insulin or oral hypoglycemic dosage may need adjustment in diabetic patients who receive anabolic steroids.

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 nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use : The safety and efficacy of Nandrolone decanoate in children with metastatic breast cancer (rarely found) has not been established. 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 the adult height.

Geriatric patients : Assess elderly men for the development of prostatic hypertrophy and prostatic carcinoma.

SPECIAL WARNING AND PRECAUTION FOR USE :

Patients, especially the elderly, with the following conditions should be monitored for:

Tumours : Mammary carcinoma, hypernephroma, bronchial carcinoma and skeletal metastases. In these patients hypercalcaemia or hypercalciuria may develop spontaneously, and also during androgen therapy. Nevertheless, the hypercalcaemia or hypercalciuria should first be treated appropriately and after restoration of normal calcium levels, if judged necessary and taking into account the risks and benefits on a case by case basis, hormone therapy can be resumed, with caution.

Pre-existing conditions : In patients with pre-existing cardiac, renal or hepatic insufficiency/disease or epilepsy or migraine anabolic steroid treatment may cause complications characterized by oedema with or without congestive heart failure. In such cases treatment must be stopped immediately. Patients who experienced myocardial infarction, cardiac, hepatic- or renal insufficiency, hypertension, epilepsy, or migraine should be monitored due to the risk of deterioration of or reoccurrence of disease. In such cases treatment must be stopped immediately.

Diabetes mellitus : Nandrolone Decanoate Injection can improve glucose tolerance in diabetic patients .

Anti-coagulant therapy : Nandrolone Decanoate Injection can enhance the anti-coagulant action of coumarin-type agents .

Liver dysfunction : Caution Nandrolone Decanoate should be used in patients with severe hepatic impairment and should only be used if the benefits outweigh the risks.

DRUG INTERACTION :

Anticoagulants : Anabolic steroids may increase sensitivity to oral anticoagulants. Dosage of the anticoagulant may have to be decreased in order to maintain the prothrombin time at the desired therapeutic level. Patients

receiving oral anticoagulant therapy require close monitoring, especially when anabolic steroids are started or stopped.

Sulfonylureas : Decreases blood glucose level. Dosage adjustment of antidiabetic or insulin may be needed.

ADVERSE REACTION :

Central Nervous System : Excitation, insomnia, habituation, depression.
Cardio Vascular: Edema.

Gastro Intestinal : Nausea, vomiting, diarrhea.
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.

Hematologic: Suppression of clotting factors.

Hepatic : Reversible jaundice, liver cell tumors, and hepatocellular neoplasms and peliosis hepatitis have been reported in association with long-term androgenic anabolic steroid therapy .

Metabolic : Hypercalcemia.

Breast: Gynecomastia.

Skin : Pain and induration at injection site.

Larynx : Deepening of the voice in women.

DOSAGE AND ADMINISTRATION :

Nandrolone decanoate injection is intended for deep intramuscular injection only, into the gluteal muscle preferably.
Dosage should be based on therapeutic response and consideration of the benefit to 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.

Nandrolone decanoate should be regarded as adjunctive therapy and adequate quantities of nutrients should be consumed in order to obtain maximal therapeutic effects. For example, when it is used in the treatment of refractory anemia, adequate iron intake is required for a maximal response.

Usual adult and adolescent dose :

Females : Intramuscular, 50 to 100 mg given at one- to four-week intervals.
Males : Intramuscular, 50 to 200 mg given at one- to four-week intervals.

Usual pediatric dose :
Children up to 2 years of age : Dosage has not been established.
Children 2 to 13 years of age : Intramuscular, 25 to 50 mg every three to four weeks.

Anemia of Renal Disease :
A dose of 50 to 100 mg per week is recommended for women and 100 to 200 mg per week for men. Drug therapy should be discontinued if no hematologic improvement is seen within the first six months. For children from 2 to 13 years of age, the average dose is 25 to 50 mg every 3 to 4 weeks.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever the solution and container permit.

OVERDOSE AND TREATMENT :

The acute toxicity of nandrolone decanoate in animals is very low. There are no reports of acute over dosage with Nandrolone Decanoate in the human.

SPECIAL PRECAUTION FOR STORAGE :

Store below 30°C. Do not refrigerate or freeze. Store in the original package in order to protect from light.

PRESENTATION :

Decanol – 25mg./ml. : 1ml. clear ampoule with a sterile syringe in a mono pack.
Decanol – 50mg./ml. : 1ml.clear ampoule with a sterile syringe in a mono pack.