

## PRODUCT INFORMATION

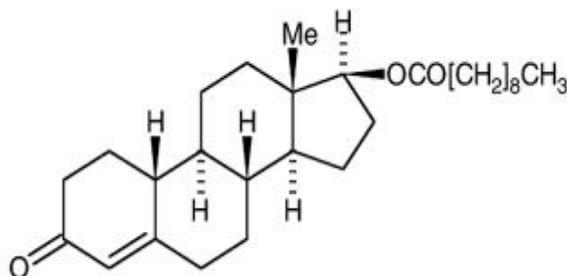
# DECA-DURABOLIN

(*nandrolone decanoate*)

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## NAME OF THE MEDICINE

**Deca-Durabolin** (Solution for injection of nandrolone decanoate)



*Molecular Formula:* C<sub>28</sub>H<sub>44</sub>O<sub>3</sub>    *Molecular mass:* 428.7    *Cas. No:* 360-70-3

*Chemical Name:* 3-oxo-estr-4-en-17β-yl decanoate

Deca-Durabolin is an androgenic oily preparation for intramuscular administration.

## DESCRIPTION

Nandrolone decanoate is a white to creamy white, crystalline powder. It is practically insoluble in water but is freely soluble in chloroform, ethanol, ether, fixed oils and esters.

Deca-Durabolin comes in 1 ml pre-filled syringes containing 1 ml of light yellow oily liquid.

### Composition

Each ml of Deca-Durabolin contains 50 mg of the active ingredient nandrolone decanoate. The product also contains the inactive ingredients benzyl alcohol (0.1 ml) and arachis (peanut) oil making up the volume.

## PHARMACOLOGY

### Pharmacodynamic properties

Deca-Durabolin is an injectable anabolic preparation. The pharmacologically active substance is nandrolone. The decanoate ester gives the preparation a 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. This has been demonstrated in animal bioassays and explained by receptor binding studies. The low androgenicity of nandrolone is confirmed in clinical use. In the human, Deca-Durabolin has been shown to positively influence calcium metabolism and to increase bone mass in osteoporosis. In women with disseminated mammary carcinoma, Deca-Durabolin has been reported to produce objective regressions for many months. Furthermore, Deca-Durabolin has a nitrogen-saving action. This effect on protein metabolism has been established by metabolic studies and is utilised therapeutically in conditions where a protein deficiency exists such as during chronic debilitating diseases and after major surgery and severe trauma. In these conditions,

Deca-Durabolin 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 C17 $\alpha$ -alkyl group which is associated with the occurrence of liver dysfunction and cholestasis.

### **Pharmacokinetic properties**

#### Absorption

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

#### Distribution

In the blood, the ester is rapidly hydrolysed to nandrolone with a half-life of one hour or less. The combined process of hydrolysis, and distribution and elimination of nandrolone has a mean half-life of approximately 4 hours.

#### Metabolism and excretion

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**

- Acute renal failure, chronic renal insufficiency and anaemia of chronic renal failure.
- For the palliative treatment of inoperable mammary carcinoma.
- Osteoporosis (where oestrogen therapy is contraindicated).
- Aplastic anaemia.
- Patients on long-term treatment with corticosteroids.

## **CONTRAINDICATIONS**

- Pregnancy.
- Lactation.
- Known or suspected prostatic carcinoma or mammary carcinoma in the male.
- Hypersensitivity to the active substance, nandrolone decanoate, or any of the excipients, including arachis oil. Deca-Durabolin is therefore contraindicated in patients allergic to peanuts and soya (see **PRECAUTIONS**).
- Nephrosis or the nephrotic phase of nephritis.
- Liver disease with impaired bilirubin excretion.
- Cardiac failure.

## **PRECAUTIONS**

- The recommended dosages should not be exceeded.
- If signs of virilisation develop, discontinuation of the treatment should be considered.
- The Deca-Durabolin injection should not be given if the patient is under the influence of heparin.
- Anabolic steroids should be used with caution in patients with benign prostatic hypertrophy.
- There have been rare reports of hepatocellular neoplasms and peliosis hepatic in association with long-term androgenic-anabolic steroid therapy.
- Deca-Durabolin contains 100 mg benzyl alcohol per mL solution and must not be given to children younger than 3 years, including premature babies or neonates. Benzyl alcohol may cause toxic reactions and anaphylactoid reactions in infants and children up to 3 years old.
- No sufficient data on the use of Deca-Durabolin in children are available. Safety and efficacy have not been determined.

- Deca-Durabolin contains arachis (peanut) oil and should not be taken/ applied by patients known to be allergic to peanut. As there is a possible relationship between allergy to peanut and allergy to soya, patients with soya allergy should also avoid Deca-Durabolin (see **CONTRAINDICATIONS**).
- Patients with the following conditions should be monitored:
  - latent or overt cardiac failure, renal failure or dysfunction, hypertension, epilepsy or migraine (or a history of these conditions), since anabolic steroids may occasionally induce salt and fluid retention;
  - history of myocardial infarction or chronic artery disease. As serum cholesterol may increase or decrease during androgen therapy, caution is required in administration to such patients. Serial determinations of serum cholesterol are of importance.
  - diabetes - See **Interactions with other medicines**;
  - incomplete statural growth, since anabolic steroids in high dosages may accelerate epiphyseal closure;
  - skeletal metastases of breast cancer; these patients may develop hypercalcaemia and hypercalciuria spontaneously in which case Deca-Durabolin should be ceased and the hypercalcaemia treated appropriately. If calcium levels return to normal, anabolic steroid therapy may be resumed;
  - liver dysfunction.
- Prescribers should be careful that Deca-Durabolin will not be misused and should be aware that some individuals may exhibit drug seeking behaviour. The misuse of anabolic substances to enhance ability in sports carries the following serious health risks and is to be discouraged: water retention; testicular atrophy and inhibition of spermatogenesis in males; oligomenorrhoea and virilisation, seen as hoarseness, acne and hirsutism in females; peliosis hepatis or other hepatotoxicity (see **ADVERSE EFFECTS**).

### **Effects on Fertility**

Standard fertility and early embryonic development studies in adult animals have not been conducted with nandrolone decanoate.

### **Use in Pregnancy (Category D)**

Contraindicated. Anabolic steroids and other substances with androgenic effects may have a virilising effect on the foetus.

### **Use in Lactation**

Contraindicated. Anabolic steroids may have a virilising effect on the neonate and the amount of nandrolone esters excreted in breast milk is unknown.

### **Carcinogenicity**

Studies on the carcinogenic effects of nandrolone decanoate in animals have not been conducted.

### **Genotoxicity**

Studies on the genotoxic effects of nandrolone decanoate have not been conducted.

### **Interactions with other medicines**

- Anticoagulants: Anabolic steroids may increase sensitivity to oral anticoagulants. Dosage of the anticoagulants 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 anabolics are started or stopped.
- Insulin and other hypoglycaemic agents: in diabetic patients the metabolic effects of anabolics may decrease blood glucose and thereby decrease requirements for insulin and other hypoglycaemic agents.

## Effects on laboratory tests

- Anabolics may decrease levels of protein-bound iodine (PBI), thyroxine binding capacity and radioactive iodine uptake.
- Anabolics may cause alterations in the glucose tolerance test and metyrapone test (pituitary functioning).

## ADVERSE EFFECTS

Adverse effects are dependant on dosage, dose interval and individual sensitivity. The adverse effects are due to the androgenic activity of the preparation.

System Organ Class	Common	Uncommon	Rare
General		Water retention	
Endocrine	Virilisation (in females*) shown as: hoarseness acne hirsutism increased/decreased libido.	Inhibition of spermatogenesis Oligospermia Testicular atrophy Impotence Gynaecomastia Increased frequency of erections Increased penile size (pre-pubescent boys) Hypertrophy of the clitoris Increased growth of pubic hair Oligomenorrhoea Amenorrhoea	
Metabolic		Hyperlipidaemia Decreased serum HDL cholesterol	
Haematological		Increased haemoglobin to abnormal high levels	
Cardiovascular		Hypertension	
Gastrointestinal		Nausea	
Hepatobiliary			Abnormal liver function Jaundice Peliosis hepatitis
Genitourinary		Epididymitis Bladder irritability Reduced urine flow Benign prostate hypertrophy Priapism	
Musculoskeletal		Premature epiphyseal closure (in children)	
Skin & Appendages		Acne	Oily skin Greasy hair Rash Pruritus Exanthema Urticaria at injection site Furunculosis

(\* At high dosage, long term treatment and frequent administration, signs of virilisation may occur in women who are sensitive to hormonal treatment. If signs of virilisation occur, interruption of treatment should be considered. Hoarseness can be the first sign of voice changes that can be long-lasting and sometimes irreversible.)

## DOSAGE AND ADMINISTRATION

Deca-Durabolin should only be administered by deep intramuscular injection. Vials and ampoules are intended for single use only.

- *Renal conditions such as acute renal failure and chronic renal insufficiency:* 25-50 mg every 2-3 weeks. Initially, higher dosages (50 mg every week) may be required.
- *For the palliative treatment of inoperable mammary carcinoma:* 50 mg every 2-3 weeks.
- *Osteoporosis (where oestrogen therapy is contraindicated):* 50 mg every 2-3 weeks.
- *For patients on long-term treatment with corticosteroids:* 50 mg every 2-3 weeks.
- N.B. For an optimal anabolic effect it is necessary to administer adequate amounts of vitamins, minerals and protein in a calorie-rich diet.
- For the treatment of anaemia:
  - *Aplastic anaemia:* 50-150 mg every week.
  - *Anaemia of chronic renal failure:* 100mg for females, 200mg for males once a week.

After a satisfactory improvement or a normalization of the red blood picture has been obtained, treatment should be withdrawn gradually on the basis of regular monitoring of the haematological parameters. Should a relapse occur at any time whilst the dose is being reduced or after stopping the treatment, reinstatement of therapy should be considered.

The onset of a therapeutic effect may vary widely among patients. If no satisfactory response occurs after 3-6 months of treatment, administration should be discontinued.

*Paediatric patients:* Deca-Durabolin is not recommended in paediatric patients (see **PRECAUTIONS**).

## OVERDOSAGE

There are no specific recommendations for the management of overdosage with Deca-Durabolin. The acute intramuscular toxicity of nandrolone esters is very low.

## PRESENTATION AND STORAGE CONDITIONS

Deca-Durabolin Orgaject 50mg/ml solution for injection (AUST R 10655): 1 ml in a disposable glass syringe.

Store below 25°C and protect from light.

## NAME AND ADDRESS OF THE SPONSOR

Merck Sharp & Dohme (Australia) Pty Limited  
54-68 Ferndell Street  
South Granville NSW 2142  
Australia

Merck Sharp & Dohme (New Zealand) Ltd  
PO Box 99 851  
New Market  
Auckland 1149  
New Zealand

## POISON SCHEDULE OF THE MEDICINE

Schedule 4 – Prescription Only Medicine

## **DATE OF APPROVAL**

Date of TGA approval: 22 February 2007

Date of most recent amendment: 06 October 2011

**The information supplied relates only to Deca-Durabolin 50mg and should not be used in relation to any other product which may also contain the same active ingredient.**