# Deca-Durabolin®

oily solution
for intramuscular use

**Composition**
Each ml of the oily solution contains Nandrolone Decanoate BP 50 mg.

**Characteristics**
DECA-DURABOLIN® 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. 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 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, 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 C 17 alpha-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 hydrolysed 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 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.

**Dosage and Administration**
DECA-DURABOLIN® should be administered by deep intramuscular injection.

| Indications | Recommended Dosage |
|---|---|
| Established Osteoporosis | 50 mg every 3 weeks |
| Disseminated breast cancer in women (palliative therapy) | 50 mg every 3 weeks |
| Protein deficiency states occurring after major surgery or trauma | 50 mg every 2-3 weeks |
| Anemia | |
| - Anemia due to chronic renal failure | 50-200 mg per week |
| - Aplastic anemia | 50-150 mg per week |
| - Anemia due to cytotoxic therapy | 200 mg per week |
| Chronic debilitating disease in elderly | 100 mg |
| Postsurgical and post-traumatic catabolism | 25-50 mg every 3 weeks |
| During glucocorticosteroid therapy | 50 mg every 2-3 weeks |

*N.B. : For an optimal therapeutic effect it is necessary to administer adequate amounts of vitamins, minerals and protein in a calorie-rich diet.*

**Contraindications**
- Pregnancy
- Male breast carcinoma
- Prostatic carcinoma
- DECA-DURABOLIN® should not be administered to the patients allergic to peanuts & soya and hypersensitive to the active substance or to any of the excipients including arachis oil.

**Use during pregnancy and breast-feeding**
This medicine is contraindicated during pregnancy because of possible masculinization of foetus. There are insufficient data on the use of this medicine in pregnant women, during breast-feeding to assess potential harm to the infant or a possible influence on milk production.

**Warnings and precautions**
- If signs of virilisation develop, discontinuation of the treatment should be considered, preferably in consultation with the patient
- It is recommended to monitor patients with any of the following conditions:
  - latent or overt cardiac failure, renal dysfunction, hypertension of migraine (or a history of these conditions), since anabolic steroids may occasionally induce fluid retention
  - incomplete statural growth, since anabolic steroids in high dosages may accelerate epiphyseal closure
  - skeletal metastases of breast carcinoma. In these patients hypercalcaemia may develop both spontaneously and as a result of anabolic steroid therapy. The later can be indicative of a positive tumour response to the hormonal treatment. Nevertheless, the hypercalcaemia should first be treated appropriately and after restoration of normal calcium levels hormone therapy can be resumed
  - liver dysfunction
- The use of anabolic steroids to enhance athletic ability may carry severe risks to the user's health and should be discouraged

**Interactions**
Due to the nature of the drug, side effects cannot be quickly reversed by discontinuing medication. Injectables in general, may cause a local reaction at the injection site.

Depending on the dose, frequency and total period of administration of DECA-DURABOLIN® the following undesirable effects may occur.

- Virilism
- Hyperlipidaemia
- Increased Libido
- Hypertension
- Dysphonia
- Nausea
- Abnormal hepatic function
- Peliosis hepatis
- Acne, Rash, Pruritus, Hirsutism
- Premature fusion of Epiphyses
- Decreased urine flow
- Benign prostatic hyperplasia
- Priapism
- Enlarged penis, clitoris
- Amenorrhoea, Oligomenorrhoea
- Decreased sperm count
- Oedema, Injection site reaction
- Decreased HDL, increased Haemoglobin

**Overdosage**
The acute toxicity of nandrolone decanoate in animals is very low. There are no reports of acute over dosage with DECA-DURABOLIN® in the human.

**Storage Condition**
Store in between 8°C – 30°C, away from light. Keep out of the reach of children

**Commercial Pack**
DECA-DURABOLIN® injection : Each box contains 2 × 1 ml ampoule in Alu - PVC blister strip.

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Manufactured by:
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