

DECA-DURABOLIN

nandrolone decanoate 25mg or 50mg

Presentation

Each ml of the yellow, oily solution contains:
25 or 50 mg nandrolone decanoate.

Uses

Actions

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 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 C17 α -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 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

DECA-DURABOLIN can be used for the treatment of osteoporosis; for the palliative treatment of selected cases of disseminated mammary carcinoma in women and as an adjunct to specific therapies and dietary measures in pathologic conditions characterized by a negative nitrogen balance.

Dosage And Administration

Osteoporosis

50 mg every 3 weeks.

For The Palliative Treatment Of Selected Cases Of Disseminated Mammary Carcinoma In Women

50 mg every 2-3 weeks.

As An Adjunct To Specific Therapies And Dietary Measures In Pathologic Conditions Characterized By A Negative Nitrogen Balance

25-50 mg every 3 weeks.

DECA-DURABOLIN should be administered by deep intramuscular injection.

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.

Known or suspected carcinoma of the prostate or breast in the male.

Hypersensitivity to the active substance or to any of the excipients, including arachis oil. Deca-Durabolin is therefore contraindicated in patients allergic to peanuts and soya (see **Warnings and Precautions**).

Use During Pregnancy And Breast-Feeding

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

Effects On Ability To Drive And Use Machines

Up to now no reference has been made to any influence on alertness and powers of concentration, during the use of DECA-DURABOLIN.

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 or 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 latter 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.

Deca-Durabolin contains 100 mg benzyl alcohol per mL solution and must not be given to premature babies or neonates. Benzyl alcohol may cause toxic reactions and anaphylactoid reactions in infants and children up to 3 years old.

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**).

Interactions

Anabolic steroids may improve glucose tolerance and decrease the need for insulin or other antidiabetic medicines in diabetics.

Adverse Effects

High dosages, prolonged treatment and/or too frequent administration may cause:

Virilisation which appears in sensitive women as hoarseness, acne, hirsutism and increase of libido; in prepubertal boys as an increased frequency of erections and phallic enlargement, and in girls as an increase of pubic hair and clitoral hypertrophy. Hoarseness may be the first symptom of vocal change which may end in a long-lasting, sometimes irreversible deepening of the voice.

Amenorrhoea.

Inhibition of spermatogenesis.

Premature epiphyseal closure.

Fluid retention.

Overdosage

The acute toxicity of nandrolone decanoate in animals is very low. There are no reports of acute overdosage with DECA-DURABOLIN in the human.

Pharmaceutical Precautions

List of Excipients

The ampoules and orgajects contain, apart from the active ingredient, benzyl alcohol and arachis (peanut) oil.

Incompatibilities

In view of the prescribed way of administration, chemical interaction of the active ingredient with other substances can be left out of consideration.

Shelf-Life

DECA-DURABOLIN may be used until the expiration date indicated on the package.

Orgajects 3 years

Ampoules 5 years

Special Precautions For Storage

DECA-DURABOLIN should be stored at 8°C to 25°C, protected from light.

Medicine Classification

Prescription Medicine.

Package Quantities

Orgajects containing 1ml of oily solution with 25 mg* or 50 mg nandrolone decanoate.

Ampoules containing 1ml of oily solution with 50 mg* nandrolone decanoate.

**Not commercially available*

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