

DECA-DURABOLIN

Presentation

Each pre-filled syringe contains 1 mL of 25 mg/ mL nandrolone decanoate.

Each pre-filled syringe contains 1 mL of 50 mg/ mL nandrolone decanoate.

Each pre-filled syringe is affixed with a needle **closed by a needle shield of natural rubber latex** (See warnings and precautions for use).

Each ampoule contains 1 ml of 50 mg/ml nandrolone decanoate.

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 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 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

Adults including elderly

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.

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

Paediatric population:

Safety and efficacy have not been adequately determined in children and adolescents. Pre-pubertal children treated with Deca-Durabolin should be treated with caution.

Method of administration:

Deca-Durabolin should be administered by deep intramuscular injection.

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**).

Effects on Fertility:

In men, treatment with Deca-Durabolin can lead to fertility disorders by repressing sperm-formation. In women treatment with Deca-Durabolin can lead to an infrequent or repressed menstrual cycle.

Use During Pregnancy And Breast-Feeding

Deca-Durabolin is contra-indicated in women who are pregnant.

Pregnancy:

This medicine is contraindicated during pregnancy because of possible masculinization of the foetus. There are no adequate data from the use of Deca-Durabolin in pregnant women. In view of the risk of virilization of the fetus, Deca-Durabolin should not be used during pregnancy. Treatment with Deca-Durabolin should be discontinued when pregnancy occurs.

Lactation:

There are no adequate data from the use of Deca-Durabolin during lactation. Therefore, Deca-Durabolin should not be used during lactation.

Effects On Ability To Drive And Use Machines

Deca-Durabolin has no influence on the ability to drive and use machines

Warnings And Precautions

Virilization:

Patients should be informed about the potential occurrence of signs of virilization. In particular singers and women with speech professions should be informed about the risk of deepening of the voice.

If signs of virilisation develop, the risk/benefit ratio has to be newly assessed with the individual patient.

Medical examination:

Physicians should consider monitoring patients receiving Deca-Durabolin before the start of treatment, at quarterly intervals for the first 12 months and yearly thereafter for the following parameters:

- Digital rectal examination (DRE) of the prostate and PSA to exclude benign prostate hyperplasia or a sub-clinical prostate cancer,
- Hematocrit and hemoglobin to exclude polycythemia.

Conditions that need supervision:

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

- **Tumours** – Mammary carcinoma, hypernephroma, bronchial carcinoma and skeletal metastases. In these patients hypercalcemia may develop spontaneously, also during anabolic steroid therapy. The latter can be indicative of a positive tumour response to the hormonal treatment. Nevertheless, the hypercalcemia should first be treated appropriately and after restoration of normal calcium levels, hormone therapy can be resumed.
- **Pre-existing conditions** – In patients with pre-existing cardiac, renal or hepatic insufficiency/disease anabolic steroid treatment may cause complications characterized by edema 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 or reoccurrence of disease. In such cases treatment must be stopped immediately.

- **Diabetes mellitus** – Deca-Durabolin can improve the glucose tolerance in diabetic patients.
- **Anti-coagulant therapy** – Deca-Durabolin can enhance the anti-coagulant action of coumarin-type agents.

Adverse events:

If anabolic steroid-associated adverse reactions occur, treatment with Deca-Durabolin should be discontinued and, upon resolution of complaints, resumed with a lower dose.

(Mis)use in sports:

Patients who participate in competitions governed by the World Anti-Doping Agency (WADA) should consult the WADA-code before using this product as Deca-Durabolin can interfere with anti-doping testing. 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**).

The packaging of this medicinal product contains natural rubber latex which may cause allergic reactions.

Paediatric Population:

In pre-pubertal children statural growth and sexual development should be monitored since anabolic steroids in general and Deca-Durabolin in high dosages may accelerate epiphyseal closure and sexual maturation.

Interactions

Enzyme-inducing agents may decrease and enzyme-inhibiting drugs may increase nandrolone levels. Therefore, adjustment of the dose of Deca-Durabolin may be required.

Insulin and other anti-diabetic medicines:

Anabolic steroids may improve glucose tolerance and decrease the need for insulin or other antidiabetic medicines in diabetic patients. Patients with diabetes mellitus should therefore be monitored especially at the beginning or end of treatment and at periodic intervals during Deca-Durabolin treatment.

Anti-coagulant therapy:

High doses of Deca-Durabolin may enhance the anti-coagulant action of coumarin-type agents. Therefore close monitoring of prothrombin time and if necessary a dose reduction of the anti-coagulant is required during therapy.

ACTH or corticosteroids:

The concurrent administration of anabolic steroids with ACTH or corticosteroids may enhance oedema formations; thus these active substances should be administered cautiously, particularly in patient with cardiac or hepatic disease or in patient predisposed to oedema.

Laboratory test interactions

Anabolic steroids may decrease levels of thyroxine-binding globulin resulting in decreased total T4 serum levels and increase resin uptake of T3 and T4. Free thyroid hormone levels remain unchanged, however, and there is no clinical evidence of thyroid dysfunction

Recombinant Human Erythropoietin:

Combination of Deca-Durabolin (50-100 mg/week) with rhEPO (recombinant human erythropoietin), especially in females, may enable a reduction of the erythropoietin dose to reduce anaemia.

Adverse Effects

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

Dependent on the dose, frequency and total period of administration of Deca-Durabolin the following undesirable effects may occur.

System Organ Class	MedDRA term *
Endocrine disorders	Virilism
Metabolism and nutrition disorders	Hyperlipidaemia
Psychiatric disorders	Libido increased
Vascular disorders	Hypertension
Respiratory, thoracic and mediastinal disorders	Dysphonia
Gastrointestinal disorders	Nausea

System Organ Class	MedDRA term *
Hepatobiliary disorders	Hepatic function abnormal Peliosis hepatis
Skin and subcutaneous tissue disorders	Acne Rash Pruritus Hirsutism
Musculoskeletal and connective tissue disorders	Epiphyses premature fusion
Renal and urinary disorders	Urine flow decreased
Reproductive system and breast disorders	Benign prostatic hyperplasia Priapism Penis enlarged Enlarged clitoris Oligomenorrhoea Amenorrhoea Sperm count decreased
General disorders and administration site conditions	Oedema Injection site reaction
Investigations	High density lipoprotein decreased Haemoglobin increased
Injury, poisoning and procedural complications	Intentional misuse

* MedDRA version 15.0.

The terms used to describe the undesirable effects above are also meant to include synonyms and related terms.

Paediatric population:

The following undesirable effects have been reported in pre-pubertal children using androgens: precocious sexual development, an increased frequency of erections, phallic enlargement and premature epiphyseal closure.

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; 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. Keep container in the original carton.

Since an opened ampoule cannot be resealed in such a way to further guarantee the sterility of the contents, the solution should be used immediately.

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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