HCP-MEPPO
Publishers of MEPPO and MODERN MEDICINE

DECA-DURABOLIN® IV
ORGANON

1. NAME OF THE MEDICINAL PRODUCT
Deca-Durabolin® 25 mg/ml. Solution for injection
Deca-Durabolin® 50 mg/ml. Solution for injection
Deca-Durabolin® 100 mg/ml. Solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
For 25 and 50 mg/ml pre-filled syringe:
Each pre-filled syringe contains 1 ml of 25 or 50 mg/ml nandrolone decanoate.

For 25, 50 and 100 mg/ml ampoule:
Each ampoule contains 1 ml of 25, 50 or 100 mg/ml nandrolone decanoate.

For 25 and 50 mg/ml vial:
Each vial contains 1 ml of 25 or 50 mg/ml nandrolone decanoate.

For 100 mg/ml vial:
Each vial contains 2 ml of 100 mg/ml nandrolone decanoate.

3. PHARMACEUTICAL FORM
Solution for injection.
Clear, yellow, oily solution

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
- Treatment of osteoporosis
- As an adjunct to specific therapies and dietary measures in pathologic conditions characterized by a negative nitrogen balance
- Treatment of anemia of chronic renal failure, aplastic anemia and anemia due to cytotoxic therapy

NB: Treatment with Deca-Durabolin does not substitute for other therapeutic measures.

4.2 Posology and method of administration
Deca-Durabolin should be administered by deep intramuscular injection. For treatment of osteoporosis: 50 mg once every 3 weeks

As an adjunct to specific therapies and dietary measures in pathologic conditions characterized by a negative nitrogen balance: 25-50 mg every 2 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.

For the treatment of anemia due to:
- Chronic renal failure: 100-200 mg once every week
- Aplastic anemia: 50-150 mg once every week
- Cytotoxic therapy: 200 mg once every week, starting 2 weeks prior to the course of cytotoxic therapy. This treatment should be continued throughout cytotoxic therapy and thereafter during the recovery period until the blood count has returned to normal

After a satisfactory improvement or a normalization of the red blood picture has been obtained, treatment should be withdrawn gradually on the basis of regular monitoring of the hematological parameters.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

N.B.:
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.

Pediatric patients:
Since Deca-Durabolin contains benzyl alcohol as excipient, Deca- Durabolin should not be used in children younger than 3 years.

No sufficient data on the use of Deca-Durabolin in children are available. Safety and efficacy have not been determined.

4.3 Contraindications
- Pregnancy (see Section 4.6)
- Known or suspected carcinoma of the prostate or breast in the male
- Hypersensitivity to the active substance or to any of the excipients

4.4 Special warnings and precautions for use
If signs of virilization develop, discontinuation of the

treatment should be considered 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
- Diabetes mellitus; Deca-Durabolin can improve the glucose tolerance and thus decrease the need for insulin or other anti-diabetic medicines in diabetics
- Skeletal metastases of breast carcinoma. In these patients hypercalcemia may develop spontaneously, also during anabolic steroid therapy. The latter can be indicative of a positive tumor 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
- Liver dysfunction
- The misuse of anabolic steroids to enhance ability in sports carries serious health risks and is to be discouraged

4.5 Interaction with other medicinal products and other forms of interaction

Anabolic steroids may improve glucose tolerance and decrease the need for insulin or other anti-diabetic medicines in diabetic subjects (see section 4.4).

High doses of Deca-Durabolin may enhance the anticoagulant action of coumarin type agents allowing a reduction of the dose of these agents.

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

4.6 Pregnancy and lactation

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 (see Section 4.3).

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

4.7 Effects on ability to drive and use machines

As far as is known Deca-Durabolin has no effect on driving and using machines.

4.8 Undesirable effects

Dependent on the dose, frequency and total period of administration of Deca- Durabolin the following undesirable effects may occur (see also Section 4.4):

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
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
General disorders and administration site conditions	Oedema Injection site reaction
Investigations	High density lipoprotein decreased Sperm count decreased Haemoglobin increased
Injury, poisoning and procedural complications	Intentional misuse

* MedDRA version 8.0.

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

4.9 Overdose

The acute toxicity of nandrolone decanoate in animals is very low. There are no reports of acute overdose with Deca-Durabolin in the human.

Chronic overdose to enhance athletic abilities carries severe risks to the abuser's health.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group (ATC code): A14A B01

Deca-Durabolin contains the decanoate ester of nandrolone. This decanoate ester gives the preparation a duration of action of about three weeks after injection. In the circulation the decanoate ester is hydrolyzed to nandrolone. Nandrolone is chemically related to the male hormone, testosterone. Compared to testosterone, it has an enhanced anabolic and a reduced androgenic activity. This has been demonstrated in animal bioassays and can be explained by its metabolism to 5α-dihydronandrolone, which has reduced binding capacity to the androgen receptor, in contrast to 5α- dihydrotestosterone, which displays enhanced binding. The low androgenicity of nandrolone is confirmed in clinical use. The risk on virilization increases with higher dosages and frequency of administration and the length of treatment.

Deca-Durabolin has been shown to positively influence calcium metabolism and to increase bone mass in osteoporosis. 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, burns and severe trauma. In these conditions, Deca-Durabolin serves as a supportive adjunct therapy to specific treatments and dietary measures including parenteral nutrition.

In animals, nandrolone decanoate possesses an erythropoiesis-stimulating

effect probably by directly stimulating the hematopoietic stem cells in the

bone marrow and by increasing the release of erythropoietin. It also affords protection against the bone marrow depression caused by cytotoxic agents. In the human, Deca-Durabolin stimulates erythropoiesis as demonstrated by rises in the red blood cell mass, and in the hemoglobin and hematocrit values. This effect is utilized therapeutically in the treatment of anemia due to a decreased production of erythropoietin, bone marrow depression induced by chemotherapy, or hypoplasia of the stem cells in the bone marrow. In the latter condition (e.g. aplastic anemia) the erythropoietic response is frequently accompanied by a positive effect on leukopoiesis and thrombopoiesis.

Androgenic effects (e.g. virilization) are relatively uncommon at the recommended dosages. Nandrolone lacks the C17α-alkyl group, which is associated with the occurrence of liver dysfunction and cholestasis.

5.2 Pharmacokinetic properties

Absorption

After deep intramuscular injection of Deca-Durabolin a depot is formed and nandrolone decanoate is slowly released from the injection site into the blood with a half-life of 5-15 days.

Distribution

In the blood, the ester is rapidly hydrolyzed 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 metabolized by the liver. The main excretion products in the urine are 19-norandrosterone and 19-noretiocholanolone. It is not known whether these metabolites display a pharmacological action.

5.3 Preclinical safety data

Pharmacological studies in animals on the toxicity after repeated dosing, genotoxicity and carcinogenicity did not indicate a safety risk for humans. No animal data on reproduction are available. The use of androgens in different species has demonstrated to result in masculinization of the external genitals of female fetuses.

6. PHARMACEUTICALPARTICULARS

6.1 List of excipients

For pre-filled syringe 25 and 50 mg/ml:
Arachis oil, 100 mg/ml benzyl alcohol

For 25 and 50 mg/ml ampoules and vials:
Arachis oil, 100 mg/ml benzyl alcohol

For 100 mg/ml ampoules and vials:
Arachis oil, 50 mg/ml benzyl alcohol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

For pre-filled syringe 25 and 50 mg/ml:
3 years

For 25, 50 and 100 mg/ml ampoules:
5 years

For 25, 50 and 100 mg/ml vials:
3 years

6.4 Special precautions for storage

Store 8-30°C; protect from light

6.5 Nature and contents of container

For pre-filled syringe 25 and 50 mg/ml:
Deca-Durabolin 25 or 50 mg/ml Solution for injection: 1 ml in a disposable glass syringe.

For 25, 50 and 100 mg/ml ampoules:
Deca-Durabolin 25, 50 or 100 mg/ml Solution for injection: 1 ml in 1 ml type I glass ampoules.

For 25 and 50 mg/ml vials:
Deca-Durabolin 25 or 50 mg/ml Solution for injection: 1 ml in 2 ml type I glass vials.

For 100 mg/ml vials:
Deca-Durabolin 100 mg/ml solution for injection: 2 ml in 2 ml type I glass vials.

6.6 Instructions for use and handling <and disposal>

Any unused product or waste material should be disposed of in accordance with the local requirements.

10. DATE OF REVISION OF THE TEXT

February 2008