Nandrolone decanote Injection USP 50mg/1ml, 200mg/5ml, 250mg/10ml

1. Name of the medicinal product

Nandrolone decanote Injection USP 50mg/1ml Taj Pharma

Nandrolone decanote Injection USP 200mg/5ml Taj Pharma

Nandrolone decanote Injection USP 250mg/10ml Taj Pharma

2. Qualitative and quantitative composition

a) Nandrolone decanote Injection USP 50mg/1ml

Each ml Contains:	
Nandrolone Deconoate	**50mg**
Benzyl Alcohol	**1.5%v/v**
Arachis Oil	**q.s**

b) Nandrolone decanote Injection USP 200mg/5ml

Each ml Contains:	
Nandrolone Deconoate	40mg
Benzyl Alcohol	1.5%v/v
Arachis Oil	q.s

c) Nandrolone decanote Injection USP 250mg/10ml

Each ml Contains:	
Nandrolone Deconoate	25mg
Benzyl Alcohol	1.5%v/v
Arachis Oil	q.s

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Solution for injection

Clear, yellow, oily solution

4. Clinical particulars

4.1 Therapeutic indications

For use in osteoporosis in post-menopausal women.

Established osteoporosis should have been diagnosed by the following parameters:

i) crush or wedge fractures of the vertebrae

ii) other osteoporotic fractures

iii) established reduction in bone mineral content as measured by accepted BMC measurements.

4.2 Posology and method of administration

Posology:

Post-menopausal women

50mg every three weeks

The duration of treatment depends on the clinical response and the possible occurrence of side-effects.

We would recommend that the effectiveness of therapy be monitored with the appropriate methods for osteoporosis on a 6-12 monthly basis.

Method of administration:

Deca-Durabolin should be administered by deep intramuscular injection

4.3 Contraindications

Pregnancy (see section 4.6).

Breast-feeding

Porphyria

Hypersensitivity to the active substance or to any of the excipients, including arachis oil. Deca-Durabolin is therefore contraindicated in patients allergic to peanuts or soya (see section 4.4).

4.4 Special warnings and precautions for use

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:

• 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 hypercalcaemia or hypercalciuria may develop spontaneously, and also during androgen therapy. Nevertheless, the hypercalcaemia or hypercalciuria should first be treated appropriately and after restoration of normal calcium levels, if judged necessary and taking into account the risks and benefits on a case by case basis, hormone therapy can be resumed, with caution.

• **Pre-existing conditions**-In patients with pre-existing cardiac, renal or hepatic insufficiency/disease or epilepsy or migraine anabolic steroid treatment may cause complications characterized by oedema 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 of or reoccurrence of disease. In such cases treatment must be stopped immediately.

• **Diabetes mellitus –** Deca-Durabolin can improve glucose tolerance in diabetic patients (see section 4.5).

• **Anti-coagulant therapy –** Deca-Durabolin can enhance the anti-coagulant action of coumarin-type agents (see also section 4.5).

• **Liver dysfunction** - caution should be used in patients with severe hepatic impairment and Deca-Durabolin 50mg/ml should only be used if the benefits outweigh the risks.

Adverse events:

If anabolic steroid-associated adverse reactions occur (see section 4.8), treatment with Deca-Durabolin should be discontinued and, upon resolution of complaints, treatment can be resumed.

Virilisation:

Patients should be informed about the potential occurrence of signs of virilisation. 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.

(Mis) use in sports:

Nandrolone is classified as a prohibited substance under the Olympic Movement Anti- doping Code (OMAC 1999). The misuse of Nandrolone and other anabolic steroids to enhance ability in sports carries serious health risks and is to be discouraged.

Drug abuse and dependence:

Anabolic androgenic steroids have been subject to abuse, typically at doses higher than recommended for the approved

indication(s) and in combination with testosterone. Abuse of anabolic androgenic steroids including testosterone can lead to serious adverse reactions including: cardiovascular (with fatal outcomes in some cases), hepatic and/or psychiatric events. Anabolic androgenic steroid abuse may result in dependence and withdrawal symptoms upon significant dose reduction or abrupt discontinuation of use. The abuse of anabolic androgenic steroids including testosterone carries serious health risks and is to be discouraged.

Excipients:

Deca-Durabolin contains arachis oil (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 section 4.3).

Deca-Durabolin 50mg/ml contains 100 mg benzyl alcohol per ml solution and must not be given to premature babies or neonates. Benzyl alcohol may cause anaphylactoid reactions in infants and children up to 3 years old.

Paediatric Population:

Safety and efficacy have not been adequately determined in children and adolescents. 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.

4.5 Interaction with other medicinal products and other forms of interaction

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 anti-diabetic drugs in diabetic patients (see section 4.4). 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 (see section 4.4). 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 edema formations; thus these active substances should be administered cautiously, particularly in patients with cardiac or hepatic disease or in patient predisposed to edema (see section 4.4).

Laboratory test interactions:

Anabolic steroids may decrease levels of thyroxine-binding globulin resulting in decreased total T4 serum levels and increases 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 with rhEPO (recombinant human erythropoietin), especially in females, may enable a

reduction of the erythropoietin dose to reduce anemia.

4.6 Pregnancy, lactation and fertility
Deca-Durabolin is contra-indicated in women who are pregnant (see section 4.3).

Pregnancy

There are no adequate data for the use of Deca-Durabolin in pregnant women. In view of the risk of virilisation of the foetus, Deca-Durabolin should not be used during pregnancy. Treatment with Deca-Durabolin should be discontinued when pregnancy occurs.

Lactation:

There are no adequate data for the use of this medicine during lactation to assess potential harm to the infant or a possible influence on milk production. Therefore, Deca-Durabolin should not be used during lactation.

Fertility:

In men treatment with Deca-Durabolin can lead to fertility disorders by repressing sperm-formation. In women treatment with androgens can lead to an infrequent or repressed menstrual cycle (see section 4.8).

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

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

Deca-Durabolin at the recommended dosages is unlikely to produce virilising effects. High dosages, prolonged treatment and/or too frequent administration may cause:

System Organ Class	MedDRA term
Endocrine disorders	Virilism
Metabolism and nutrition disorders	Lipids abnormal[1]
Psychiatric disorders	Libido increased
Vascular disorders	Hypertension
Respiratory, thoracic and mediastinal disorders	Dysphonia
Gastrointestinal disorders	Nausea
Hepatobiliary disorders	Hepatic function abnormal Peliosis hepatis Liver tumours
Skin and subcutaneous tissue disorders	Acne Pruritus Hirsutism
Renal and urinary disorders	Urine flow decreased
Reproductive system and breast disorders	Enlarged clitoris
General disorders and administration site conditions	Oedema Injection site reaction Sodium retention
Investigations	Haemoglobin increased

[1.] Decrease in serum LDL-C, HDL-C and triglycerides.

Virilisation which appears in sensitive women as hoarseness, acne, hirsutism and increase of libido. Hoarseness may be the first symptom of vocal change which may end in long-lasting, sometimes irreversible deepening of the voice.

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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important.

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

5. Pharmacological properties

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Anabolic steroids.

Nandrolone is chemically related to testosterone and shows enhanced anabolic and a reduced androgenic activity.

In humans Deca-Durabolin has been shown to positively influence calcium metabolism and to increase bone mass in osteoporosis.

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.

5.2 Pharmacokinetic properties
Absorption

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

Distribution

The ester is rapidly hydrolysed to nandrolone in the blood 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.

Biotransformation 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.

5.3 Preclinical safety data
Toxicity studies in animals after repeated dosing did not indicate a safety risk for humans. No formal studies to assess reproduction toxicity, genotoxicity and carcinogenicity have been conducted by the company. As a class, anabolic steroids are considered to be probably carcinogenic to humans (IARC Group 2a).

The use of androgens in different species has resulted in virilisation of the external genitals of female foetuses. Investigations into the genotoxic potential of nandrolone showed it to be positive in an in vitro micronucleus assay and an in vivo micronucleus assay in mouse but not rat, and in the comet assay of mouse and rat. The clinical relevance of these findings is unknown, therefore the risk to patients cannot be ruled out.

6. Pharmaceutical particulars

6.1 List of excipients
Benzyl alcohol Arachis oil

6.2 Incompatibilities
None known

6.3 Shelf life
3 years

6.4 Special precautions for storage
Store below 30°C

Do not refrigerate or freeze.

Store in the original package in order to protect from light.

6.5 Nature and contents of container
Deca-Durabolin 50 mg/ml solution for injection: 1 ml type I ampoules sold in packs of 1, 3 or 6 ampoules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling
No special requirements for disposal.

7.Manufactured in India by:
TAJ PHARMACEUTICALS LTD.
Mumbai, India
Unit No. 214.Old Bake House,
Maharashtra chambers of Commerce Lane,
Fort, Mumbai - 400001
at:Gujarat, INDIA.
Customer Service and Product Inquiries:
1-800-TRY-FIRST (1-800-222-434 & 1-800-222-825)
Monday through Saturday 9:00 a.m. to 7:00 p.m. EST
E-mail: tajgroup@tajpharma.com