

Package leaflet: Information for the patient

Deca-Durabolin 50 mg/ml Solution for Injection

(Nandrolone decanoate)

Read all of this leaflet carefully before this medicine is administered because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Deca-Durabolin is and what it is used for
2. What you need to know before Deca-Durabolin is given to you
3. How Deca-Durabolin is given to you
4. Possible side effects
5. How to store Deca-Durabolin
6. Contents of the pack and other information

1. WHAT DECA-DURABOLIN IS AND WHAT IT IS USED FOR

Deca-Durabolin is a clear yellow oily solution for injection containing 50 mg/ml of the active ingredient nandrolone decanoate. The active substance, nandrolone decanoate belongs to the group of medicines known as anabolic steroids that help to prevent bone loss. Deca-Durabolin is used in osteoporosis, when bones thin and become brittle, after the menopause.

2. WHAT YOU NEED TO KNOW BEFORE DECA-DURABOLIN IS GIVEN TO YOU

Do not receive Deca-Durabolin:

- If you are pregnant or think you may be pregnant (see section 2 "pregnancy, breast-feeding and fertility").
- If you are allergic (hypersensitive) to nandrolone decanoate or any of the ingredients of this medicine (listed in section 6 "What Deca-Durabolin contains").
- In children under the age of 3 years.
- If you have porphyria (an inherited blood disorder)

If you are allergic to peanuts or soya (see section 2 "Important information about some of the ingredients of Deca-Durabolin").

Take special care with Deca-Durabolin:

If you notice any signs of masculinization (for instance lowering of the voice or increase in body or facial hair), consult your doctor immediately.

Extra supervision by your doctor may be necessary in some cases; particularly the elderly. At regular intervals, blood tests will be done to check the oxygen-carrying substance in your red blood cells (haemoglobin). In very rare cases the number of red blood cells will increase too much leading to complications.

Medical checks may also be necessary in some other conditions.

→ Tell your doctor or pharmacist or nurse if you have ever had, still have or are suspected to have:

- breast cancer which has spread to the bones;
- Kidney or lung cancer
- heart disease
- kidney disease
- liver disease
- high blood pressure
- diabetes mellitus
- epilepsy
- migraine

Other medicines and Deca-Durabolin

Please tell your doctor or pharmacist or nurse if you are taking, have recently taken, or might take any other medicines-even those not prescribed.

Other medicines may affect how Deca-Durabolin works or Deca-Durabolin may affect how they work. Therefore you must tell your doctor or pharmacist or nurse if you are using, or about to use:

- Insulin and/or other medicines to control your blood sugar levels.
- Erythropoietin (medicine to reduce anemia);
- Medicines to reduce the clotting of your blood (anti-coagulants)

The use of anabolic steroids like Deca-Durabolin may lead to a reduction of the doses of these medicines.

Also tell your doctor or pharmacist or nurse if you are using or about to use the hormone ACTH or corticosteroids (used to treat various conditions such as rheumatism, arthritis, allergic conditions and asthma). The use of anabolic steroids like Deca-Durabolin may increase the risk of water retention especially if your heart and liver are not working properly.

Laboratory tests:

Anabolic steroids may also affect the results of some laboratory tests (e.g. thyroid gland). Therefore, you must tell your doctor or the laboratory staff performing the tests that you are using this medicine.

Using Deca-Durabolin with food and drink

This medicine can be injected without taking consideration of meals and drinks.

→ Please tell your doctor or pharmacist or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility

This medicine must not be taken by women who are pregnant or think that they are pregnant, or by women who are breast-feeding.

In women, treatment with Deca-Durabolin can lead to an irregular or absent menstrual cycle. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist or nurse for advice before taking any medicine.

Driving and using machines

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

Deca-Durabolin 50mg/ml for Injection

nandrolone decanoate

Technical information for the healthcare professional

The following information is intended for the healthcare professional only: This is an extract from the Summary of Product Characteristics (SmPC) to assist in the administration of Deca-Durabolin 50mg/ml solution for Injection.

The prescriber should be familiar with the full SmPC in order to determine the appropriateness of the use of the product in a particular patient. The full SmPC can be found on the electronic Medicines Compendium (eMC) website: <http://www.medicines.org.uk/emc/>.

The Patient Information Leaflet provided (see the other half of this leaflet) should be given to the patient.

Deca-Durabolin 50mg/ml solution for injection contains nandrolone decanoate. Each vial contains 1 ml of solution. Each 1 ml of solution contains 50 mg nandrolone decanoate.

PREPARATION AND OTHER HANDLING INSTRUCTIONS

Deca-Durabolin should be administered by deep intramuscular injection.

DOSAGE AND ADMINISTRATION

Dosage

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.

CONTRAINDICATIONS

- Pregnancy (see section 4.6 of the full SmPC)
- 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 of the full SmPC)

WARNINGS

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

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Important information about some of the ingredients of Deca-Durabolin

This medicine also contains:

- **Arachis oil (peanut oil)** - If you are allergic to peanut or soya, you should not be given this medicine (see "Do not receive Deca-Durabolin").
- **Benzyl alcohol** (100 mg per ml solution) - Products containing benzyl alcohol must not be given to premature babies or neonates. Benzyl alcohol may cause toxic reactions and allergic reactions in infants and children up to 3 years old.

Improper use

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

3. HOW DECA-DURABOLIN IS GIVEN TO YOU

This medicine should only be given by a doctor or a nurse. The injections are given deeply into a muscle (for instance in the buttock, upper leg or upper arm.)

The dose depends on your illness and how bad it is. Your doctor will decide the dose.

If you receive more Deca-Durabolin than you should:

Your doctor or nurse will inject this medicine into you. If you have the impression that the effect of this medicine is too strong then please talk to your doctor or nurse immediately.

If you forgot to get your injection of Deca-Durabolin:

Your doctor or nurse will inject this medicine into you. Should you miss a scheduled injection then please talk to your doctor or nurse as soon as possible. No double dose should be injected to make up for forgotten individual doses.

Effects when treatment with Deca-Durabolin is stopped:

The effects of this medicine do not stop immediately after discontinuation, but gradually subside.

When treatment with this medicine is stopped, complaints such as those experienced before treatment may re-occur within a few weeks.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines Deca-Durabolin can cause side effects, although not everybody gets them. Dependent on the dose, frequency and total period of administration of Deca-Durabolin the following undesirable effects may occur:

- Fluid retention in the tissues, usually marked by swelling of the ankles or feet or increased blood pressure
- An increase in male characteristics in women; your voice may get deeper and you may notice some hair growth or acne
- Acne
- Increased sexual desire
- Nausea
- Itching
- Increased haemoglobin
- Changes in blood lipids
- Abnormal liver function
- Liver anatomy changes
- Hoarseness
- Change of the voice
- Increased body or facial hair
- Enlargement of the clitoris



- 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 of the full SmPC), 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.

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 of the full SmPC).

OVERDOSE

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

Store below 30°C

Do not refrigerate or freeze.

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

- Masculinization
- Abnormal blood tests

Deca-Durabolin may affect some liver tests or may cause liver tumours, although very rarely. 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.

→ If you get any side effects talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE DECA-DURABOLIN

Keep this medicine out of the reach and sight of children.

Do not use this medicine after the expiry date stated on the carton or label after the term "exp." (expiry date). The expiry date refers to the last day of that month.

Store below 30°C.

Do not refrigerate or freeze.

Store in the original package in order to protect from light. Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Deca-Durabolin contains

- The active substance is Nandrolone decanoate, 50 mg per ml fluid.
- The other ingredients are: 100mg/ml benzyl alcohol and Arachis oil.

What Deca-Durabolin looks like and contents of the pack

Deca-Durabolin 50 mg solution for injection is a slightly yellow, oily solution filled in a 1ml clear glass ampoule and sold in packs of 1, 3 or 6 ampoules.

Marketing Authorisation Holder

Aspen Pharma Trading Limited,
3016 Lake Drive,
Citywest Business Campus,
Dublin 24,
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Manufacturer:

Ever Pharma Jena GmbH,
Otto-Schott-Str. 15, 07745, Germany

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