

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

Package leaflet: Information for the patient

(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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Nandrolone decanoateis and what it is used for

Nandrolone decanoateis 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.

Nandrolone decanoateis used in osteoporosis, when bones thin and become brittle, after the menopause.

2. What you need to know before Nandrolone

decanoateis given to you

Do not receive Nandrolone decanoate:

- If you are pregnant or think you may be pregnant (see section 2 "pregnancy, breast-feeding and fertility").
- If you are allergic to nandrolone decanoate or any of the ingredients of this medicine (listed in section 6).
- 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 "Nandrolone decanoatecontains Arachis oil (peanut oil) and Benzylalcohol").

Warnings and precautions



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.

Talk to your doctor, pharmacist or nurse before Nandrolone decanoateis given to you 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 Nandrolone decanoate

Tell your doctor, 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 Nandrolone decanoateworks or Nandrolone decanoatemay affect how they work. Therefore; you must tell your doctor, 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 (anticoagulants)

The use of anabolic steroids like Nandrolone decanoatemay lead to a reduction of the doses of these medicines.

Also, tell your doctor, 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 Nandrolone decanoatemay 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.



Nandrolone decanoatewith food and drink

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

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 Nandrolone decanoatecan 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, pharmacist or nurse for advice before taking any medicine.

Driving and using machines

As far as is known, Nandrolone decanoatehas no influence on driving and using machines.

Nandrolone decanoatecontains Arachis oil (peanut oil) and Benzyl alcohol

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 Nandrolone decanoate").
- **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.

Drug abuse and dependence

This medicine should only be given by a doctor or nurse and used exactly as your doctor has told you. Abuse of anabolic androgenic steroids, especially if you use too much of this medicine alone or with testosterone, can cause serious health problems to your heart and blood vessels (that can lead to death), mental health and/or the liver. Individuals who have abused anabolic androgenic steroids may become dependent and experience withdrawal symptoms when the dosage changes significantly or is stopped immediately. You should not abuse this medicine alone or with testosterone because it carries serious health risks.

3. How Nandrolone decanoateis 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 Nandrolone decanoatethan 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 Nandrolone decanoate

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.

If you stop treatment with Nandrolone decanoate

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 reoccur within a few weeks.

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

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them. Dependent on

the dose, frequency and total period of administration of Nandrolone decanoatethe 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
- Masculinization
- Abnormal blood tests

Nandrolone decanoatemay affect some liver tests or may cause liver tumours, although very rarely. Due to the nature of Nandrolone decanoate, side effects cannot be quickly reversed by discontinuing medication.



Injectables, in general, may cause local reaction at the injection site.

Reporting of side effects

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

5. How to store Nandrolone decanoate

Keep this medicine out of the sight and reach 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 Nandrolone decanoatecontains

• The active substance is Nandrolone decanoate, 50 mg per ml fluid.

The other ingredients are 100mg/ml benzyl alcohol and Arachis oil.

What Nandrolone decanoatelooks like and contents of the pack

Nandrolone decanoate50 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

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