

Deca-Durabolin

Nandrolone decanoate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Deca-Durabolin.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Deca-Durabolin against the benefits they expect it will have for you.

A doctor's prescription is required to obtain this medicine.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

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

Keep this information with the pack.

You may need to read it again.

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. This includes any possible side effects not listed in this leaflet.

What Deca-Durabolin is used for

Deca-Durabolin is a clear yellow oily solution for injection containing 50 mg/ml of the active ingredient nandrolone decanoate.

It is used to treat:

- osteoporosis (loss of bone tissue)
- certain types of anaemia
- breast cancer (in women)
- patients on long term corticosteroids.

It belongs to a group of medicines known as anabolic steroids.

These medicines help to rebuild tissues that have become weak because of continuing illness or serious injury. Deca-Durabolin can be used to increase lean body mass in the case of negative nitrogen balance. It can also be used to increase bone mass and stimulate the formation of red blood cells in the bone marrow.

Your doctor may have prescribed it for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Ability to drive or operate machinery.

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

Before you use Deca-Durabolin

When you must not use it

Do not use Deca-Durabolin if:

- you are a man and have or have had cancer of the prostate or the breast, or are suspected of having one of these tumours. You also should have had an examination by your physician to exclude any abnormalities of the genital organs.
- you have kidney disease
- you have liver disease

- you have heart failure
- you are allergic to nandrolone decanoate, or any of the ingredients listed at the end of this leaflet
- you are allergic to peanuts or soya
- you are a child below the age of 3 years
- it is past the expiry date or the packaging shows signs of tampering.

Do not use this medicine if you are pregnant or think you may be pregnant.

It may give increased male characteristics to an unborn baby and should not be used during pregnancy.

Do not breastfeed if you are using this medicine.

It may have a virilising effect on your baby and the amount of active ingredient excreted in breast milk is unknown.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Medical checks may also be necessary in some other cases. Therefore, before you start using this medicine you must tell your doctor or pharmacist if you ever had, still have or are suspected to have:

- prostate disorders
- liver disease, such as jaundice
- heart disease
- high blood pressure
- kidney disorders
- Kidney or lung cancer
- high or low cholesterol
- epilepsy
- migraine, headaches
- diabetes mellitus
- heparin therapy
- breast cancer that has spread to your bones.
- Prostatic complaints, such as problems with passing urine

Deca-Durabolin should not be given to children under 3 years of age.

This is because Deca-Durabolin contains benzyl alcohol, which may cause toxic or allergic reactions in infants and children up to 3 years old.

Natural rubber latex

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

Children and adolescents

The safety and efficacy of this medicine has not been adequately determined in children and adolescents.

Extra supervision is necessary in the treatment of children since anabolic steroids in general may cause early sexual development and limits growth and the incomplete statural growth.

Improper use

If you are a patient who participates in competitions governed by the World Anti-Doping Agency (WADA), then you should consult the WADA-code before using this medicine as Deca-Durabolin can interfere with anti-doping testing.

The misuse of this medicine to enhance ability in sports carries serious health risks and is to be discouraged. These risks include testicular wasting in men and voice changes in women that may be permanent.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Other medicines may influence the effects of Deca-Durabolin, or Deca-Durabolin may affect other medicines. Therefore you must tell your doctor or pharmacist if you are using or about to use

- Anticoagulants or medicines used to prevent blood clots.
- Hypoglycaemic agents or medicines used to treat diabetes such as insulin or medicines to control your blood sugar levels
- Erythropoietin (medicine to reduce anaemia).

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 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.

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.

These medicines may be affected by Deca-Durabolin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor will advise you.

Using Deca-Durabolin with food and drink

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

In order for this medicine to work properly to rebuild tissues weakened by injury or illness, it is important that you follow strictly any possible diet measures as directed by your doctor or dietician.

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 men, treatment with Deca-Durabolin can lead to fertility disorders by repressing sperm formation.

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 for advice before taking this medicine.

How Deca-Durabolin is given

The dosage depends on the severity of your condition and the response to treatment. Your doctor will find the correct dosage for you. The doctor will also make any dose adjustments depending on your individual requirements. Usually, one injection every 2-3 weeks is sufficient

Deca-Durabolin is given as a deep injection into a muscle (such as the buttock, upper leg or upper arm). These injections should only be given by a doctor or trained nurse.

If you have the impression that the effect of this medicine is too strong or too weak, talk to your doctor or a nurse immediately.

Use in children and adolescents

The safety and efficacy of this medicine have not been adequately determined in children and adolescents. Pre-pubertal children using this medicine will be monitored by your doctor.

If you are given too much

These injections are given under medical supervision and it is very unlikely that you will be given too much.

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 several doses are given at once it is not a medical emergency. However you should consult your doctor as side-effects are dependent on dosage, dose interval and your individual sensitivity.

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.

While you are given Deca-Durabolin

Things you must do

If you become pregnant while taking this medicine, tell your doctor.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Deca-Durabolin.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

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

Treatment with anabolic steroids may increase the size of the prostate gland, especially in elderly men. Therefore your doctor will examine your prostate gland at regular intervals by digital rectal examination (DRE) and blood tests for prostate-specific antigen (PSA).

Additionally, at regular intervals, blood tests will be done to check the oxygen-carrying substance in your red blood cells (hemoglobin). In very rare cases the number of red blood cells will increase too much leading to complications.

Things you must not do

Do not use Deca-Durabolin to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things that may help your condition

Some self help measures may help your condition. Your doctor or pharmacist can give you more information.

Your doctor may advise you to change your diet. This is because Deca-Durabolin works best in helping to repair and replace your damaged tissue, bone or red blood cells when you are eating a high protein, and nutritious diet.

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Do not be alarmed by the following list of side effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

In general:

- pain at the injection site
- fluid retention e.g. swelling of the ankles or feet
- increased blood pressure
- oily skin, greasy hair
- acne, rash
- itching
- nausea
- increased blood fats
- abnormal liver function
- increased or decreased sexual desire
- liver anatomy changes
- incomplete statural growth.

In males:

- enlargement of the penis
- enlargement of the breast
- difficulty to urinate (growth of the prostate)
- disturbed formation of sperm
- painful erections
- testicular atrophy
- impotence.

In females:

- hoarseness or changes of the voice, which may be long-lasting or permanent
- increased body or facial hair
- irregular periods (or complete absence of periods)
- enlargement of the clitoris
- masculinisation.

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.

Children and adolescents:

The following side effects have been reported in pre-pubertal children using anabolic steroids:

- early sexual development;
- penis enlargement;
- an increased frequency of erections;
- growth limitation (limited body height)

Some side effects have no symptoms. These side effects e.g. increased blood fats, abnormal liver function, liver anatomy changes or increased blood pressure can only be found when your doctor does tests to check your progress.

Tell your doctor if you notice any other side effects.

Other side effects not listed in this leaflet also occur in some people.

After Using Deca-Durabolin

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.

Storage

Keep Deca-Durabolin in the original box, the outer carton, in a safe place out of reach and sight of children.

Keep it in a cool dark place where the temperature stays below 30°C.

Do not refrigerate as this makes the product difficult to inject.

Do not use Deca-Durabolin after the expiry date stated on the label after the term 'exp.'.

Disposal

Return any unused medicine to your pharmacist.

Product Description

What it looks like

Deca-Durabolin solution for injection is a slightly yellow, oily solution.

Deca-Durabolin comes in a transparent 1 mL pre-filled syringe with a fixed needle.

Ingredients

Deca-Durabolin contains 50 mg/mL of nandrolone decanoate as the active ingredient.

It also contains:

- Arachis (peanut) oil (base)
- Benzyl alcohol (preservative).

Supplier

This medicine is supplied in Australia by:
Merck Sharp & Dohme (Australia) Pty Limited
54-68 Ferndell Street
South Granville NSW 2142
Australia

This medicine is supplied in New Zealand by:
Merck Sharp & Dohme (New Zealand) Ltd
PO Box 99 851
New Market
Auckland 1149
New Zealand

Australian Registration Number:
Deca-Durabolin Orgaject 50mg/mL solution for injection
(AUST R 10655)

Leaflet prepared: July 2013

The information supplied relates only to Deca-Durabolin and should not be used in relation to any other product which may also contain the same active ingredients.

For further information please ask your doctor or pharmacist.