

Andriol® Testocaps®

Testosterone Undecanoate

Consumer Medicine Information

Before administration of this medicine please read this leaflet carefully. If you have any questions or worries, ask your doctor or pharmacist.

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Product Description

The name of your medicine is Andriol Testocaps.

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

Each capsule contains 40 mg of the active ingredient called testosterone undecanoate. Testosterone undecanoate is turned into testosterone by your body. Testosterone is a natural male hormone known as an androgen. Andriol Testocaps belong to a group of medicines called androgens, a type of sex hormone necessary for the normal sexual development of males.

This leaflet answers some common questions about Andriol Testocaps. It does not contain all the available information.

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

Keep this information with the pack.

You may wish to read it again.

If you have further questions, please 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.

What Andriol Testocaps are used for

Andriol Testocaps are used to replace the body's natural sex hormone testosterone when not enough is made by the body.

In men testosterone is produced by the testicles. It is necessary for the normal growth, development and function of the male sex organs and for secondary male sex characteristics. It is necessary for the growth of body hair, the development of bones and muscles, and it stimulates the production of red blood cells. It also makes men's voices deepen. Andriol Testocaps is used in adult men for testosterone replacement to treat various health problems caused by a lack of testosterone (male hypogonadism). Your doctor will confirm this by blood testosterone measurements and also clinical symptoms such as inability to get or maintain an erection (impotence), infertility, low sex drive, tiredness, depressive moods, or bone loss caused by low hormone levels.

Because of problems with the pituitary or testis, the production of testosterone by the body decreases.

Men may suffer from complaints such as depression, loss of motivation or concentration, and loss of sexual desire. Andriol Testocaps can relieve these complaints. It can also relieve these symptoms in men who have had their testis removed. Relief of symptoms usually starts within a few days, but optimal results are obtained after weeks to months of treatment.

Before you use Andriol Testocaps

When you must not take it

Do not use Andriol Testocaps if

- you have or have had a tumour of your prostate or breast, or are suspected to have one of these tumours.
- you have or have had severe kidney disease
- you are allergic to testosterone undecanoate or any of the ingredients listed under Product Description, at the end of this leaflet.

Do not use Andriol Testocaps if the packaging is torn or shows signs of tampering.

Before you start to take it

Andriol Testocaps may not be suitable for you if you suffer from certain medical conditions.

Tell your doctor or pharmacist before you start using this medicine if you ever had, still have, or are suspected to have (particularly if you are elderly):

- heart disease, high blood pressure or blood vessel problems
- Diabetes mellitus, Kidney disease
- Kidney or lung cancer;
- Liver disease;
- Breast cancer which has spread to the bones;
- Epilepsy
- Migraine, headaches
- Psychiatric or emotional illness
- Prostatic complaints, such as problems with passing urine.
- any unusual or allergic reactions to androgens or anabolic steroids
- Sleep apnoea (temporarily stopping breathing during your sleep), this may get worse if you are using testosterone-containing products. Extra supervision by your doctor may be necessary in case you are overweight or suffer from chronic lung disease.
- Tell your doctor if you are on a special diet, e.g. low salt, lower sugar and you are taking any other medicines.

Caution:

Before taking Andriol Testocaps it is also important to tell your doctor if you have or have ever had too much cholesterol or other fatty substances in the blood.

Tell your doctor if you have been treated with other sex hormones recently.

During long-term treatment with Andriol Testocaps regular medical checks, including prostate examination, are recommended. Extra supervision by a doctor is necessary in the treatment of young boys.

Taking other medicines

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

buy from your pharmacy, supermarket or healthfood shop.

Other medicines may influence the effects of Andriol Testocaps, or Andriol Testocaps may affect other medicines.

Therefore you must tell your doctor or pharmacist if you are taking (or intend to take) other medicines such as:-

- barbiturates, (medicines for epilepsy or sleeplessness)
- antidiabetic drugs
- cyclosporin
- Insulin and/or other medicines to control your blood sugar levels*
- Medicines to reduce the clotting of your blood (anti-coagulants)*

* The use of androgens like Andriol Testocaps 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 androgens like Andriol Testocaps may increase the risk of water retention especially if your heart and liver are not working properly.

Andriol Testocaps may interfere with some laboratory tests (e.g for glucose tolerance, thyroid function and clotting factors).

Therefore you must tell your doctor or the laboratory staff performing the tests that you are using this medicine.

Andriol Testocaps are not intended for use in female patients. Therefore 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 Andriol Testocaps can lead to fertility disorders by repressing sperm formation.

If you are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This medicine contains Sunset Yellow which may cause allergic reactions.

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 Andriol Testocaps 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.

Drug abuse and dependence:

Always take this medicine exactly as your doctor or pharmacist has told you.

Abuse of testosterone, especially if you take too much of this medicine alone or with other anabolic androgenic steroids, 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 testosterone may become dependent and may experience withdrawal symptoms when the dosage changes significantly or is stopped immediately. You should not abuse this medicine alone or with other anabolic androgenic steroids because it carries serious health risks. (See "Side Effects".)

How to use Andriol Testocaps

Take Andriol Testocaps as directed by your doctor. You should also read the instructions on the label of your medicine. If you are not sure how to take Andriol Testocaps, ask your doctor or pharmacist.

How and when to take it

Take capsules daily, as directed by your doctor. Andriol Testocaps are to be swallowed after the morning and evening meal. Swallow the capsules

with some water or other drink. Do not chew them. If you are taking an uneven number of capsules, the larger dose should be taken in the morning.

Food allows testosterone undecanoate, the active substance of this medicine, to be taken up by your body. Therefore, Andriol Testocaps must be taken with a meal.

If you have the impression that the effect of this medicine is too strong or too weak, talk to your doctor or 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 forget to take it

If you forget to take a capsule, take it as soon as you remember. If you do not remember to take the dose until the next dose is due, then just take one dose, do not double up.

If you take too much (overdose)

It is not a medical emergency if someone has taken several capsules at once. However, you should consult a doctor, or the Australian Poisons Information Centre (telephone 131 126) or the New Zealand National Poisons Centre (telephone 0800 POISON or 0800 764 766) if you think you or anyone else may have taken too much Andriol Testocaps. Symptoms that may arise are nausea and vomiting and oily bowel motions. The oily substance in the capsule may cause diarrhea.

If you stop taking Andriol Testocaps: 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.

While you are using Andriol Testocaps

Things you must do

Stop taking Andriol Testocaps if you develop jaundice (yellowing of the eyes or skin).

Ability to drive or operate machinery.

As far as is known, this medicine has no influence on driving and using machines. If you are unsure of any of the aspects of this product, please discuss with your doctor or pharmacist.

Take special care with Andriol Testocaps

Treatment with male hormones like testosterone 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.

Your doctor will measure testosterone blood levels before and during your treatment. Based on the blood test results, your doctor may adjust the dose of ANDRIOL TESTOCAPS.

Medical checks may also be necessary in some other conditions.

If you have sleep apnea (temporarily stopping breathing during your sleep), this may get worse if you are using testosterone-containing products. Let your doctor know if you are worried about this. Extra supervision by your doctor may be necessary in case you are overweight or suffer from chronic lung disease.

Children and adolescents:

The safety and efficacy of this medicine has not been adequately

determined in children and adolescents.

Extra supervision by your doctor is necessary in the treatment of children and adolescents since testosterone administration in general may cause early sexual development and limits growth.

Elderly People:

There is limited experience on the safety and efficacy of the use of ANDRIOL TESTOCAPS in patients over 65 years of age.

Side Effects

Andriol Testocaps are generally well tolerated.

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

In general side effects which are reported with testosterone therapy include:

- stomach or bowel complaints: oily bowel motions, abdominal or stomach pain, black, tarry or light coloured stools or dark coloured urine, vomiting, nausea, diarrhoea
- acne, itching (pruritus) skin irritation: pimply spotty rash, hives
- sleeplessness, chills, generalised tingling, unusual tiredness
- headache, anxiety, mental depression, excitation, confusion, dizziness, nervousness, mood alterations
- muscle pain (myalgia)
- prolonged abnormal, painful irreversible erection, inflamed testis, bladder irritability
- sexual dysfunction, changes in sexual desire, disturbed sperm formation
- Feminization (gynecomastia)
- prostatic growth to a size representative for the concerned age group
- high blood pressure (hypertension)

- blood disorders, Increase in the number of red blood cells (the cells which carry the oxygen in your blood),
- Increase in percentage of red blood cells relative to the total blood volume (haematocrit);
- Increased concentration of the red blood cell component that carries oxygen (haemoglobin);
- increased levels of a blood marker which is associated with prostate cancer (PSA increased)
- changes in cholesterol levels (changes in lipid metabolism)
- shortness of breath
- fluid retention in the tissues, usually marked by swelling of ankles, feet or lower legs (oedema)
- breast enlargement
- increased growth of a small prostate cancer which had not been detected yet (progression of a sub-clinical prostatic cancer)
- changes in liver function tests

These symptoms usually go away when treatment is stopped for a short while. Your doctor will then probably advise you to start at a lower dosage.

In a few patients diarrhoea and stomach pain or discomfort have been reported during the use of this medicine.

Drug abuse and dependence:

Abuse of this medicine can cause serious health problems, especially if you take too much testosterone alone or with other androgenic anabolic steroids.

Some of these health problems include significant side effects on the heart and blood vessels (that can lead to death), mental health and/or the liver. (See "Before you use Andriol Testocaps").

Children and adolescents:

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

- early sexual development;
- penis enlargement;

- an increased frequency of erections;
- growth limitation (limited body height)

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After Using Andriol Testocaps

Storage

Store Andriol Testocaps below 30°C. Do not refrigerate or freeze. Store in the original package and keep the blister in the outer carton in order to protect from light.

Keep this medicine out of 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.

Disposal

Return any unused medicine to your pharmacist.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Product Description

What it looks like

Andriol Testocaps packs are available in 3, 6# or 12 sachets, each containing a blister pack with 10 capsules. Andriol Testocaps capsules are soft oval, glossy, transparent orange coloured capsules with DV3

ORG printed in white. They contain a yellow oil.

commercially available pack.

Ingredients

Each Andriol Testocap capsule consists of 40 mg of testosterone undecanoate (equivalent to 25.3 mg testosterone) in castor oil and propylene glycol monolaurate. The capsule shells contain the following inactive ingredients: gelatin, glycerol, medium chain triglycerides, lecithin, sunset yellow FCF CI15985 and printed with Opacode WB monogramming ink (ARTG proprietary ingredient 3883).

If you have any further questions or require the full prescribing information for this medicine, please consult your doctor or pharmacist.

Supplier

Andriol Testocaps is supplied:

In Australia by:

Merck Sharp & Dohme (Australia) Pty Limited
Level 1 Building A, 26 Talavera Road, Macquarie Park, NSW 2113 Australia

In New Zealand by:

Merck Sharp & Dohme (New Zealand) Ltd
PO Box 99 851
Newmarket
Auckland 1149
New Zealand

Australian Registration Number:

AUST R 92904

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

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