

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.

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.

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.

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 a tumour (e.g. a breast tumour or enlarged prostate)
- 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 before you start to take Andriol Testocaps if:

- you have or have had heart disease or blood vessel problems
- you are a diabetic
- you have or have had kidney disease
- you have epilepsy
- you have migraines
- you have or have had a psychiatric or emotional illness
- you have had any unusual or allergic reactions to androgens or anabolic steroids
- you are on a special diet, e.g. low salt, lower sugar
- 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.

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

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

Andriol Testocaps may interfere with laboratory tests for glucose tolerance, thyroid function and clotting factors.

Andriol Testocaps are not intended for use in female patients.

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.

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.

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, Andriol Testocaps have no adverse effect on alertness and concentration.

If you are unsure of any of the aspects of this product, please discuss with your doctor or pharmacist.

Side Effects

Andriol Testocaps are generally well tolerated.

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

- stomach or bowel complaints: oily bowel motions, abdominal or stomach pain, black, tarry or light coloured stools or dark coloured urine, vomiting, nausea
- skin irritation: pimply spotty rash, hives
- sleeplessness, chills, generalised tingling, unusual tiredness

- headache, anxiety, mental depression, excitation, confusion, dizziness
- painful irreversible erection, inflamed testis, bladder irritability
- sexual dysfunction, disturbed sperm formation
- blood disorders
- increase in cholesterol levels
- shortness of breath
- swelling of feet or lower legs (oedema)
- breast enlargement

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 Andriol Testocaps.

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. Keep the blister in the outer carton in order to protect from light.

Disposal

Return any unused medicine to your pharmacist.

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 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).

Supplier

Andriol Testocaps is supplied:

In Australia by:

Merck Sharp & Dohme (Australia)
Pty Limited
54-68 Ferndell Street
South Granville NSW 2142
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

This leaflet was prepared July 2011.

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.