

ANDRIOL[®] TESTOCAPS[®]

Testosterone Undecanoate (40mg)

What is in this leaflet:

1. What *ANDRIOL TESTOCAPS* are used for
2. How *ANDRIOL TESTOCAPS* work
3. Before you take *ANDRIOL TESTOCAPS*
4. How to take *ANDRIOL TESTOCAPS*
5. While you are taking *ANDRIOL TESTOCAPS*
6. Side effects
7. Storage and Disposal of *ANDRIOL TESTOCAPS*
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What *ANDRIOL TESTOCAPS* are used for

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 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.

How *ANDRIOL TESTOCAPS* work

The active substance, testosterone undecanoate is turned into testosterone by your body. Testosterone is a natural male hormone known as an androgen.

Before you take *ANDRIOL TESTOCAPS*

- *When you must not take it*

Do not take *ANDRIOL TESTOCAPS*:

- If you have or have had a tumour of your prostate or breast, or are suspected to have one of these tumours.

• If you are allergic to one or more of the ingredients of this medicine (listed in "*Ingredients*").

- Before you start to take it

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. 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:

- 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, headaches;
- Prostatic complaints, such as problems with passing urine.

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 doctor maybe necessary in case you are overweight or suffer from chronic lung cancer.

- 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.

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 using or are about to use:

- 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.

Androgens 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 *ANDRIOL TESTOCAPS* with food and drink

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 (see "**How to take *ANDRIOL TESTOCAPS***").

Pregnancy, breast-feeding and fertility

ANDRIOL TESTOCAPS are not for use in women, 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.

Important information about some of the ingredients of *ANDRIOL TESTOCAPS*

This medicine contains Sunset Yellow which may cause allergic reactions.

Improper use

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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.

How to take *ANDRIOL TESTOCAPS*

- How much to take

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 3-4 capsules daily during the first 2-3 weeks, followed by a gradual decrease to 1-3 capsules daily. You must take this medicine with a meal. Swallow the capsules whole without chewing, using some water or other fluid.

Take half of the daily dose in the morning and the other half in the evening.

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

- When to take it

Use as directed by your doctor or pharmacist.

- How long to take it

Continue taking *ANDRIOL TESTOCAPS* for as long as your doctor recommends.

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 (see "**Take special care with *ANDRIOL***").

TESTOCAPS"

Elderly People

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

- If you forget to take it

If you have forgotten to take your dose of *ANDRIOL TESTOCAPS*, do not take a double dose to make up for missed individual doses. Just skip the missed dose and take your next dose at the normal time.

- If you take too much (overdose)

If you have taken several capsules at once, there is no need for great concern. The castor oil in the capsule may cause diarrhea, nausea or stomach discomfort. In the case of an overdose, contact your doctor for medical treatment.

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 taking *ANDRIOL TESTOCAPS*

- Things you must do

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.

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 (see "**Side effects Children and adolescents**").

- Things you must not do

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.

- Things you must be careful of

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.

Side effects

Like all medicines, *ANDRIOL TESTOCAPS* can have side effects although not everybody gets them. In general side effects which are reported with testosterone therapy include:

- Itching (pruritus);
- Acne;
- Nausea;
- Changes in liver function tests;
- Changes in cholesterol levels (changes in lipid metabolism);
- Depression, nervousness, mood

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- alterations;
- Muscle pain (myalgia);
 - Fluid retention in the tissues, usually marked by swelling of ankles or feet;
 - High blood pressure (hypertension);
 - 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 (haemocrit);
 - Increased concentration of the red blood cell component that carries oxygen (haemoglobin);
 - Changes in sexual desire;
 - Prolonged abnormal, painful erection of the penis;
 - Disturbed formation of sperm;
 - Feminization (gynecomastia);
 - Prostatic growth to a size representative for the concerned age group;
 - Increased levels of a blood marker which is associated with prostate cancer (PSA increased);
 - Increased growth of a small prostate cancer which had not been detected yet (progression of a sub-clinical prostatic cancer);
 - In a few patients diarrhea and stomach pain or discomfort have been reported during use of this medicine.

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)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not

listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI)

Storage and Disposal of ANDRIOL TESTOCAPS**- Storage**

Store below 30°C. Do not refrigerate or freeze. 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

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 are soft oval glossy capsules, transparent, orange in color, coded ORG DV3 containing a yellow oily fill.

A box of ANDRIOL TESTOCAPS contains either 3, 6 or 12 sachets, each containing a blister with 10 capsules.

- Ingredient

The active substance is: Testosterone undecanoate, 40 mg, which is equivalent to 25.3 mg testosterone.

The other ingredients are:

- **Capsule contents:**
Each capsule contains about 293 mg of a mixture of castor oil and propylene glycol monolaurate
- **Capsule shell ingredients:**
Glycerin, Sunset Yellow and gelatin
- **Printing ink:**
Opacode WB®
- **Auxiliary substances:**
Medium-chain triglycerides and Lecithin

MAL number:

MAL05032535ACZ

Manufacturer

Catalent France Beinheim SA
74 Rue Principale
67930 Beinheim
France

Product Registration Holder

MERCK SHARP & DOHME
(MALAYSIA) SDN. BHD.

Lot No. B-22-1 & B-22-2,
Level 22

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47301 Petaling Jaya,
Selangor, Malaysia

Date of revision

16/02/2017 (version 072015b)

Serial Number

NPRA (R1/1) 150217 / 004