

INFORMATION FOR THE USER

ANDRIOL® TESTOCAPS™ 40 MG CAPSULES

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What Andriol testocaps is and what it is used for
2. Before you take Andriol, Andriol testocaps
3. How you take Andriol, Andriol testocaps
4. Possible side effects
5. Storing Andriol testocaps

Andriol® Testocaps™ 40 mg capsules

- **The active substance is:** Testosterone undecanoate.
- **The other ingredients are:**
Each capsule contains a mixture of castor oil and propylene glycol laurate (E477). Capsule shell ingredients are glycerin, Sunset Yellow (E110, FD&C Yellow no. 6) and gelatin

1. WHAT ANDRIOL TESTOCAPS IS AND WHAT IT IS USED FOR

The active substances of Andriol Testocaps are turned into testosterone by your body. Testosterone is the natural male hormone produced by the testicles, 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 voice deepen. Preparations containing testosterone are used to replace testosterone in a person who has low or no natural testosterone (a condition known as hypogonadism).

2. BEFORE YOU TAKE ANDRIOL, ANDRIOL TESTOCAPS

Do not take Andriol testocaps if:

- You have or have had a tumor of your prostate or breast
- You are allergic to one or more of the ingredients of the product

Take special care with Andriol testocaps
Extra supervision by a doctor is necessary, in the treatment of young boys, since testosterone administration may cause early sexual development and disturb growth. Extra supervision by a doctor is also necessary in elderly men since male hormones may increase the size of the prostate gland. Furthermore, 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. Medical checks may also be necessary in some other conditions. Therefore, tell your doctor if you have, or have ever had:

- heart disease;
- kidney disease;
- liver disease;
- high blood pressure;
- 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.

Taking Andriol testocaps with food and drink.

Food allows testosterone undecanoate to be taken up by your body. Therefore, Andriol Testocaps must be taken with a meal.

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine. If you are pregnant, or think that you may be pregnant: do not use Andriol testocaps.

Breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. If you are breast-feeding: do not use Andriol testocaps.

Driving and using machines

As far as is known Andriol testocaps have no adverse effect on alertness and concentration.

Important information about some of the ingredients of Andriol testocaps

Not applicable.

Using other medicines

Other medicines may influence the effects of Andriol testocaps, or Andriol testocaps may affect other medicines. Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicine – even those not prescribed. You must tell your doctor or pharmacist if you are using (or intend to use) anti-diabetic or anti-clotting medicines.

3. HOW YOU TAKE ANDRIOL, ANDRIOL TESTOCAPS

Usually, the dosage is 3-4 capsules daily during the first 2-3 weeks, followed by a gradual decrease to 1-3 capsules daily. You must take Andriol testocaps 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 Andriol testocaps is too strong or too weak, talk to your doctor immediately.

If you take more Andriol, Andriol testocaps than you should:

If you have taken several capsules at once, there is no need for great concern. However, you should consult your doctor. The oily substance in the capsule may cause diarrhea.

If you forgot to take Andriol testocaps:

Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with Andriol testocaps is stopped:

When treatment with Andriol Testocaps is stopped, complaints as those before treatment may re-occur within a few weeks.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Andriol Testocaps can have side effects. The side effects which are reported with

testosterone therapy in general are:

- itching (pruritus);
- acne;
- nausea;
- changes in liver function tests;
- changes in cholesterol levels (changes in lipid metabolism);
- depression, nervousness, mood disturbances;
- 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).
- 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 the use of Andriol Testocaps.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING ANDRIOL TESTOCAPS

Keep Andriol Testocaps in the original container to protect from light. Store below 30 °C; do not refrigerate or freeze

Do not use Andriol testocaps after the expiry date stated on the carton or label. Keep Andriol testocaps out of reach and sight of children.

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

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This leaflet was last revised/approved in September 2009

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
 - Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
 - Do not by yourself interrupt the period of treatment prescribed.
 - Do not repeat the same prescription without consulting your doctor.
 - Keep all medicaments out of reach of children.
- Council of Arab Health Ministers & Union of Arab Pharmacists

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