

ANDRIOL® TESTOCAPS™

40 MG CAPSULES

Read all of this leaflet carefully before you start using 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 are and what they are used for
2. Before you take Andriol Testocaps
3. How you take 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: castor oil and propylene glycol laurate (E477), glycerin, Sunset Yellow (E110, FD&C Yellow no. 6) and gelatin.

Marketing Authorisation Holder:

N.V. Organon, Postbus 20, 5340 BH Oss,
The Netherlands

Manufacturer:

N.V. Organon, Postbus 20, 5340 BH Oss,
The Netherlands

1. What Andriol Testocaps are and what they are used for

The active substance of Andriol Testocaps is turned into testosterone by your body. Testosterone is the natural male hormone, necessary for the normal growth, development and function of the male sex organs and for secondary male sex characteristics. Preparations containing testosterone are usually prescribed to replace the hormone if the body is unable to produce enough on its own. Andriol Testocaps are soft oval glossy capsules, transparent, orange in colour, with a yellow oily fill.

2. Before you take Andriol Testocaps

Do not take Andriol Testocaps

- if you have a tumour of the prostate or the breast
- if you are pregnant
- if you are breast-feeding
- if you are hypersensitive (allergic) to testosterone undecanoate or any of the other ingredients of Andriol Testocaps

Take special care with Andriol Testocaps:

Extra supervision by a doctor is necessary in the treatment of young boys, since testosterone supplementation may cause early sexual development and disturb growth. Extra supervision by a doctor is also necessary in the treatment of elderly men, since male hormones may increase the size of the prostate gland.

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
- high blood pressure
- epilepsy
- migraine headaches
- prostatic complaints, such as problems with passing urine

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

Do not take Andriol Testocaps if you are pregnant or think that you may be pregnant.

Breast-feeding

Do not take Andriol Testocaps if you are breast-feeding.

Driving and using machines

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

Using other medicines

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 using (or intend to use) rifampicin (an antibiotic) or medicines for epilepsy or sleeplessness.

3. How you take 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 the daily dose is an uneven number of capsules, take the larger number in the morning.

If you have the impression that the effect of Andriol Testocaps is too strong or too weak, inform your doctor immediately.

If you take more 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 diarrhoea.

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.

In general:

- increased sexual desire
- fluid retention in the tissues, usually marked by swelling of ankles or feet

In men:

- prolonged abnormal, painful erection of the penis
- disturbed formation of sperm
- decreased amount of sperm with seminal discharge

In elderly men:

- problems with passing urine

In young boys:

- early sexual development
- erections occurring more often than normal
- enlarged penis
- disturbed growth

Tell your doctor as soon as possible if any side-effect becomes troublesome or continues. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. Storing Andriol Testocaps

Keep Andriol Testocaps out of reach and sight of children.
Store at 15 °C–30 °C.

Store in the original package in order to protect from light.

Do not use Andriol Testocaps after the expiry date stated on the package, sachet and blister. This leaflet was last revised/approved in July 2001

In correspondence please quote packing number.
