

Andriol® Testocaps®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Andriol Testocaps?

Andriol Testocaps contains the active ingredient Testosterone Undecanoate. Andriol Testocaps is used in adult men for testosterone replacement to treat various health problems caused by lack of testosterone.

For more information, see Section [1. Why am I using Andriol Testocaps?](#) in the full CMI.

2. What should I know before I use Andriol Testocaps?

Do not use if you have ever had an allergic reaction to Andriol Testocaps or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Andriol Testocaps?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Andriol Testocaps and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Andriol Testocaps?

- Take the capsules daily, as directed by your doctor. Andriol Testocaps are to be swallowed after the morning and evening meal.
- Swallow the capsules whole with some water or other drink. Do not chew them.

More instructions can be found in Section [4. How do I use Andriol Testocaps?](#) in the full CMI.

5. What should I know while using Andriol Testocaps?

Things you should do	<ul style="list-style-type: none">• Stop taking Andriol Testocaps if you develop jaundice (yellowing of the eyes or skin).• Keep your appointments with your doctor to regularly examine your prostate gland.• Keep your appointments with your doctor to do blood tests to check your red blood cells (haemoglobin) and testosterone blood levels
Things you should not do	<ul style="list-style-type: none">• Do not give Andriol Testocaps to anyone else, even if they have the same condition as you. Remember that your doctor has prescribed this medicine only for you.• Do not stop taking your medicine or lower the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Andriol Testocaps affects you.• As far as is known, this medicine Andriol Testocaps has no influence on driving and using machines.
Looking after your medicine	<ul style="list-style-type: none">• 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.• Follow the instructions on the carton on how to take care of your medicine properly.

For more information, see Section [5. What should I know while using Andriol Testocaps?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, Andriol Testocaps can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of using Andriol Testocaps.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Andriol® Testocaps®

Active ingredient: *Testosterone Undecanoate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Andriol Testocaps. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Andriol Testocaps.**

Where to find information in this leaflet:

- [1. Why am I using Andriol Testocaps?](#)
- [2. What should I know before I use Andriol Testocaps?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Andriol Testocaps?](#)
- [5. What should I know while using Andriol Testocaps?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Andriol Testocaps?

Andriol Testocaps contains the active ingredient Testosterone Undecanoate.

Testosterone undecanoate is turned into testosterone by your body. Testosterone is a natural male hormone known as an androgen, a type of sex hormone necessary for the normal sexual development of males.

Andriol Testocaps is used in adult men for testosterone replacement to treat various health problems caused by lack of testosterone.

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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

2. What should I know before I use Andriol Testocaps?

Warnings

Do not use Andriol Testocaps if:

- **you are allergic to Testosterone Undecanoate, or any of the ingredients listed at the end of this leaflet.**
- **Always check the ingredients to make sure you can use this medicine.**
- **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**
- **The packaging is torn or shows signs of tampering.**
- **You are pregnant or breastfeeding**

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.

Check with your doctor if you:

- **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
 - Factors that increase your risk for blood clots in a vein i.e. previous blood clots in a vein; smoking; obesity; cancer; immobility; family history of a blood clot in the leg, lung or other organ at a young age (below the age of 50); older age.
 - Sleep apnoea (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.
- **are on a special diet, e.g. low salt, lower sugar and you are taking any other medicines.**
- **have or ever had high cholesterol or high levels of other fatty substances in the blood.**
- **have been treated with other sex hormones recently.**
- **are planning for a baby**

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Andriol Testocaps and affect how it works.

- Barbiturates (medicines for epilepsy or sleeplessness)
- Ciclosporin
- Insulin and/or other medicines to control your blood sugar levels (antidiabetic drugs)*
- 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Andriol Testocaps.

4. How do I use Andriol Testocaps?

How much to take

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

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

Follow the instructions provided and use Andriol Testocaps until your doctor tells you to stop.

How to take Andriol Testocaps

- Swallow the capsules whole 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.

When to take Andriol Testocaps

Take Andriol Testocaps exactly 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.

If you forget to use Andriol Testocaps

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 use too much Andriol Testocaps

If you think that you have used too much Andriol Testocaps, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Andriol Testocaps?

Things you should do

- **Stop taking Andriol Testocaps if you develop yellowing of the eyes or skin (jaundice).**
- **Keep your appointments with your doctor to regularly examine your prostate gland at regular intervals by digital rectal examination (DRE) and blood tests for prostate-specific antigen (PSA)**

Treatment with male hormones like testosterone may increase the size of the prostate gland, especially in elderly men.

- **Keep your appointments with your doctor to do blood tests to check your red blood cells (haemoglobin) and testosterone blood levels.**

Your doctor will do blood tests to check the oxygen-carrying substance in your red blood cells (haemoglobin). 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.

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

- **Tell your doctor or the laboratory staff performing the tests that you are using this medicine.**

Remind any doctor, dentist or pharmacist you visit that you are using Andriol Testocaps.

Things you should not do

- Do not give Andriol Testocaps to anyone else, even if they have the same condition as you. Remember that your doctor has prescribed this medicine only for you.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Andriol Testocaps affects you.

As far as is known, this medicine has no influence on driving and using machines.

Looking after your medicine

- 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.

Follow the instructions on the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

When to discard your medicine

Discard this medicine after the expiry date stated on the carton or label after the term "Expiry date". The expiry date refers to the last day of that month.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

General side effects

General side effects	What to do
<ul style="list-style-type: none">• 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• high blood pressure (hypertension)	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

General side effects	What to do
<ul style="list-style-type: none">• 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• 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• changes in liver function tests• weight gain• blood clot in the deep vein (venous thromboembolism)	

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.

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)

Fertility

In men, treatment with Andriol Testocaps can lead to fertility disorders by reducing sperm formation. If you are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Andriol Testocaps contains

Active ingredient (main ingredient)	testosterone undecanoate
Other ingredients (inactive ingredients)	Gelatin Glycerol Medium chain triglycerides Lecithin Sunset yellow FCF printed with Opacode WB water based monogramming ink NSP-78-18022 White

Do not take this medicine if you are allergic to any of these ingredients.

What Andriol Testocaps looks like

Andriol Testocaps capsules are soft oval, glossy, transparent orange coloured capsules marked with ORG DV3 printed in white. They contain a yellow oil. (AUST R 92904).

Who distributes Andriol Testocaps

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

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

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