

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 TESTAVAN?

TESTAVAN contains the active ingredient, testosterone. TESTAVAN is used only in adult men, to replace the body's natural hormone, testosterone, when not enough is made by the body.

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

2. What should I know before I use TESTAVAN?

Do not use if you have ever had an allergic reaction to testosterone, propylene glycol 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 TESTAVAN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TESTAVAN 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 TESTAVAN?

- The usual starting dose is 23 mg testosterone (one pump actuation) per day.
- Read the package leaflet before use.

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

5. What should I know while using TESTAVAN?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using TESTAVAN. • Keep all of your doctor's appointments.
Things you should not do	• Do not stop using TESTAVAN or lower the dosage without first checking with your doctor.
Driving or using machines	• This medicine is not expected to affect your ability to drive a car or operate machinery.
Looking after your medicine	• Keep TESTAVAN in a cool dry place where the temperature stays below 25°C. • Store TESTAVAN in the original container. • Store TESTAVAN away from moisture, heat or sunlight

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

6. Are there any side effects?

Common side effects are headaches, skin reactions, prostatic disorders, painful, tender or enlarged breasts, dizziness, feeling of "pins and needles" or tingling sensation, memory loss, heightened senses, mood changes, anxiety, easy bruising, and high blood pressure, diarrhoea, hair loss, changes in laboratory tests (polycythaemia, lipids).

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.

TESTAVAN[®]

Active ingredient: testosterone

Consumer Medicine Information (CMI)

This leaflet provides important information about using TESTAVAN. **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 TESTAVAN.**

For detailed instructions on how to apply TESTAVAN, please read the package insert before use.

Where to find information in this leaflet:

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

1. Why am I using TESTAVAN?

TESTAVAN contains the active ingredient testosterone.

TESTAVAN is used only in adult men, to replace the body's natural hormone, testosterone, when not enough is made by the body.

Testosterone is a natural male hormone, known as an androgen, which controls normal sexual development and function in men.

2. What should I know before I use TESTAVAN?

Warnings

Do not use TESTAVAN if:

- you are allergic to testosterone, propylene glycol, 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 are a woman or a child.
- you have or are suspected to have prostate cancer.
- you have or are suspected to have breast cancer in males.

Check with your doctor if you:

- have or have had any other medical conditions including the following:
 - o high blood calcium levels associated with tumours (hypercalcaemia)
 - o high levels of calcium in the urine (hypercalciuria)
 - o high blood pressure or problems with your heart
 - o a tendency to retain fluid (signs may include swollen feet or ankles)
 - o problems with your liver
 - o problems with your kidneys

- o epilepsy
- o migraines
- o diabetes
- o sleep apnoea (problems with breathing during sleep)
- o a blood disorder where your body produces too many red blood cells
- o thrombophilia (a condition where you have an increased risk of blood clots in your blood vessels)
- o thrombosis (blood clots) in the deeper veins of the body such as in your legs (deep-vein thrombosis), in the lungs (pulmonary embolism) or in the veins of the eye (ocular thrombosis)

Before treatment with TESTAVAN your doctor will organise tests for prostate or breast cancer.

TESTAVAN may increase the risk of benign prostatic hyperplasia (enlargement of the prostate gland) and/or prostate cancer. It may also increase the risk of breast cancer in males.

If you use TESTAVAN over long periods of time, you may develop an abnormal increase in the number of red blood cells in the blood (polycythaemia). Your doctor may organise regular blood counts to monitor this.

Athletes should note that the active ingredient, testosterone, may produce a positive reaction in anti-doping tests.

Tell your doctor if you take any medicines for any other condition.

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?](#)

Women

TESTAVAN must not be used by women, particularly if they are, or anticipate becoming, pregnant or are breastfeeding.

Pregnant women must avoid any contact with TESTAVAN treated skin.

Men capable of fathering children

TESTAVAN should not be used by men desiring fertility.

Children

TESTAVAN must not be used by children under the age of 18 years.

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 TESTAVAN and affect how it works. These include:

- oral anticoagulants, such as warfarin, medicines used to thin blood and to treat or prevent blood clots
- corticosteroids such as prednisone or hydrocortisone, or adrenocorticotrophic hormone (ACTH), hormones used to control inflammation
- insulin, a medicine used to control blood sugar levels (you may need to lower your dose of antidiabetic medicines).
- bupropion, a medicine used to aid in smoking cessation
- ciclosporin, a medicine used to suppress the immune system
- some herbal products

These medicines may be affected by TESTAVAN, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

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

4. How do I use TESTAVAN?

How much to use

- The usual starting dose is 23 mg testosterone (one pump actuation) per day. You should not use more than 69 mg testosterone per day (which is equivalent to three pump actuations). Your doctor will tell you the dose of TESTAVAN that is right for you.

When to use TESTAVAN

- Apply TESTAVAN once daily at approximately the same time each day, preferably in the morning.
- TESTAVAN helps control the symptoms of your condition but does not cure it. Continue taking your medicine for as long as your doctor tells you.

How to use TESTAVAN

Before beginning therapy and each time you get a new pack, you should read the package insert, which contains detailed instructions for use.

Prior to using TESTAVAN you should read the package insert, which contains detailed instructions for use.

If you do not understand the instructions printed on the pharmacist label or in the package insert, ask your doctor or pharmacist for help.

Use TESTAVAN exactly as your doctor tells you to use it.

TESTAVAN is to be applied to the skin of the upper arm and shoulder only.

Before applying TESTAVAN, make sure the skin is clean, dry and that there is no broken skin.

Apply TESTAVAN to the skin using the applicator. Do not apply TESTAVAN with fingers or hands.

Hands should be washed well with soap and water after TESTAVAN has been applied.

Avoid swimming or showering for at least two (2) hours after applying TESTAVAN.

TESTAVAN contains ethanol which may cause local skin irritation.

TESTAVAN is flammable until dry. Avoid fire, flame or smoking until the gel has dried.

Follow these steps when using TESTAVAN multi-dose pump:

1. Before using the pump for the first time, prime the pump by pressing the pump head all the way down over a tissue paper until gel appears.
2. Repeat (4) four more times by pressing the pump head all the way down into a tissue. Do not use the gel that appears.
3. Throw the used tissue into a rubbish bin to avoid accidental exposure to others.
4. Your TESTAVAN pump is ready to use.
5. The content of only one pump actuation should be applied to the applicator at a time.
6. The applicator should be used to spread the gel evenly across the skin of one upper arm and shoulder. Do not get any gel on your hands.
7. Allow the gel to dry completely before getting dressed.
8. When more than one pump actuation is needed, the procedure is repeated to the other arm and shoulder (as described in Table 1).

Table 1: Dosing Information for TESTAVAN 2% w/w Gel

Testosterone Dose	Application Method
23 mg (1 pump actuation)	Apply one pump actuation to an upper arm and shoulder.
46 mg (2 pump actuations)	Apply one pump actuation to an upper arm and shoulder. Repeat to apply one pump actuation to the opposite upper arm and shoulder.
69 mg (3 pump actuations)	Apply one pump actuation to an upper arm and shoulder. Repeat to apply one pump actuation to the opposite upper arm and shoulder. Repeat again to apply the third pump actuation to the initial upper arm and shoulder.

If you forget to use TESTAVAN

TESTAVAN should be used regularly at the same time each day.

If you forget to apply a dose, apply it as soon as you remember.

If you do not remember to apply the dose until the next dose is due, then just apply one dose.

Do not apply a double dose to make up for the dose that you missed.

If you use too much TESTAVAN

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

- **Wash the skin with soap and water and 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 TESTAVAN?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking TESTAVAN.

Remind any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

Keep all of your doctor's appointments. Your doctor may monitor your blood pressure, examine your prostate, and conduct other tests (including blood tests) from time to time, particularly if you are elderly. This is to make sure the medicine is working and to check for unwanted side effects.

The use of TESTAVAN may affect the results of certain laboratory tests. If you are about to have any tests, tell your doctor that you are using this medicine.

Athletes should note that the active ingredient, testosterone, may produce a positive reaction in anti-doping tests.

Things you should not do

- Do not use TESTAVAN to treat any other complaints unless your doctor tells you to.
- Do not give your TESTAVAN to anyone else, even if they have the same condition as you.
- Do not stop using TESTAVAN or lower the dosage without first checking with your doctor.

Unwanted transfer of TESTAVAN to others

- TESTAVAN can transfer from your body to others. This can happen if other people come into contact with the area where TESTAVAN was applied.
- If you expect another person to have direct skin-to-skin contact with the application area, wash the contact area well with soap and water.
- **Unwanted transfer of testosterone to another person can be avoided by wearing clothes which cover the application area and/or by showering before contact.**

- You need to ensure that your partner, children and pets are not put at risk of receiving testosterone by accident.
- You should leave a gap of 6 hours between applying TESTAVAN and having intimate physical contact. You should also wear clothing such as a T-shirt to cover the gel application area and/or have a shower or bath beforehand washing the application area thoroughly with soap and water.
- **You should also follow these precautions before coming into close contact with women, children and pets.**
- **Women and children should avoid contact with the unwashed or unclothed area where TESTAVAN has been applied. If your partner is pregnant, it is particularly important that you take care to protect her from testosterone. If a woman or child contacts the application area, the contact area on the woman or child should be washed well with soap and water immediately.**

If contact occurs a number of times or for long periods of time this could cause the other person to show signs of increased testosterone such as more hair on the face and body and a deepened voice.

Signs of increased testosterone in children include enlarged penis or clitoris, early development of pubic hair, increased erections or sex drive, and aggressive behaviour.

In women, this may include changes in body hair, the development or worsening of acne, and changes in the menstrual cycle.

Driving or using machines

This medicine is not expected to affect your ability to drive a car or operate machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep TESTAVAN in a cool dry place where the temperature stays below 25°C.
- Store TESTAVAN in the original container.

Store TESTAVAN away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

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

Keep it where young children cannot reach it.

When to discard your medicine (as relevant)

Discard the medicine, if your doctor tells you to stop using this medicine, the expiry date has passed, or more than 60 days have passed since you first opened the dispenser bottle.

Getting rid of any unwanted medicine

Take it to any pharmacy for safe disposal.

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.

Less serious side effects

Less serious and common effects	What to do
General disorders and administration site conditions: - Headaches Nervous system disorders: - dizziness - feeling of “pins and needles” or tingling sensation - memory loss - heightened senses Psychiatric disorders: - mood changes - anxiety Gastro-intestinal disorders: - diarrhoea Skin-related: - skin reactions such as rash/hives, redness, itching, dry or stinging skin, and/or irritation - hair loss Blood or heart-related: - high levels of haemoglobin, the substance that carries oxygen in the blood (polycythaemia) high triglyceride (fat/lipid) levels in the blood - increased levels of an enzyme, prostate-specific antigen (PSA), in the blood - easy bruising and/or the formation of blood clots - high blood pressure Reproductive system and breast disorders: - prostatic disorders such as difficulty or pain while urinating, frequent urination - painful, tender or enlarged breasts	Speak to your doctor if you have any of these less serious side effects and they worry you.
Side effects due to high doses or long-term treatment	What to do
increased tendency to retain fluid (signs may include swollen feet or ankles)	Speak to your doctor if you have any of

Less serious and common effects	What to do
- decreased sperm count, which may affect fertility and reduce the size of the testicles - unwanted, frequent or prolonged and painful erections - severe stomach pain or tenderness, which do not disappear within a short time - weight gain - electrolyte changes	these less serious side effects and they worry you.

Your doctor may need to conduct blood tests to monitor red blood cell counts and increased haemoglobin which can be affected by use of testosterone.

Serious side effects

Serious side effects	What to do
Allergic reaction Some of the symptoms of an allergic reaction may include: - shortness of breath - wheezing or difficulty breathing - swelling of the face, lips, tongue, or other parts of the body. - rash, itching or hives on the skin Liver-related: - yellowing of the skin and eyes, also called jaundice Blood or heart-related: - painful swelling of one leg or sudden change in colour of the skin e.g. turning pale, red or blue, sudden breathlessness, sudden unexplained cough which may bring up blood, or sudden chest pain, severe light headedness or dizziness, severe pain in your stomach, sudden loss of vision which can all be signs of a blood clot.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Other side effects that have been observed in rare or very low frequency

- benign liver tumours
- nervousness
- depression
- hostility
- breathing problems during sleep (sleep apnoea)
- muscle cramps
- balding
- acne
- urinary obstruction
- libido changes
- nausea
- reduction in good cholesterol levels (HDL)
- increased PSA levels

- hot flushes/flushing

Your doctor may need to monitor your blood pressure and conduct blood tests, as Testavan can increase your blood pressure and affect your liver function or profile.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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 TESTAVAN contains

Active ingredient (main ingredient)	23 mg of testosterone per 1.15 g of gel.
Other ingredients (inactive ingredients)	• ethanol • purified water • propylene glycol • diethylene glycol monoethyl ether • carbomer 980 • trolamine disodium edetate

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

Each metered-dose pump contains 85.5 g of gel. Each pump can dispense 56 metered individual doses of 1.15 g of gel (1.25 mL). Each dose contains 23 mg of testosterone.

What TESTAVAN looks like

TESTAVAN is a clear to slightly rainbow-like gel in a non-aerosol metered-dose pump dispenser with a cap applicator. (Aust R 277958).

Who distributes TESTAVAN

Clinect Pty Ltd
120-132 Atlantic Drive
Keysborough VIC 3173
Telephone: 1800 899 005

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