

TESTAVAN[®]

Transdermal Gel 2% w/w

testosterone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TESTAVAN. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you using TESTAVAN against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What TESTAVAN is used for

TESTAVAN is used 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.

Testosterone is essential for the development and maintenance of the male reproductive organs as well as other male characteristics, such as facial and body hair growth, deep voice, sexual drive, muscle mass and body fat distribution.

TESTAVAN is a testosterone-containing gel that is applied daily by the patient to the skin of the upper arm and shoulder. The testosterone passes from the gel through the skin and into the bloodstream at a steady rate.

The testosterone in TESTAVAN is identical to the naturally-occurring testosterone present in the body.

A doctor's prescription is required to obtain the medicine.

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

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

Your doctor may have prescribed it for another reason.

Before you 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.

When you must not use it

Do not use TESTAVAN if you have an allergy to:

- testosterone, the active ingredient in TESTAVAN
- any of the ingredients listed at the end of this leaflet.

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

Do not use TESTAVAN if you have or are suspected to have:

- prostate cancer
- breast cancer in males.

TESTAVAN should not be used in men desiring fertility.

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

The safety of TESTAVAN in children under 18 years of age has not been established.

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

Pregnant women must avoid any contact with the TESTAVAN treated skin.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- high blood calcium levels associated with tumours (hypercalcaemia)

- high levels of calcium in the urine (hypercalciuria)
- high blood pressure or heart disease
- a tendency to retain fluid (signs may include swollen feet or ankles)
- liver or kidney disease
- epilepsy
- migraines
- sleep apnoea (abnormal pauses in breathing during sleep)
- a blood disorder where too many red blood cells are being produced
- thrombophilia (an abnormality of blood coagulation that increases the risk of thrombosis - blood clots in blood vessels).

Before treatment with TESTAVAN your doctor will need to check that you do not have 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.

If you have not told your doctor about any of the above, tell him/her before you start using TESTAVAN.

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

Taking other medicines

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

Some medicines and TESTAVAN may interfere with each other. These include:

- oral anticoagulants, medicines used to thin blood and to treat or prevent blood clots
- corticosteroids or adrenocorticotrophic hormone (ACTH), hormones used to control inflammation
- insulin, a medicine used to control blood sugar levels.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use TESTAVAN

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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.

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.

How to use it

Use TESTAVAN exactly as your doctor tells you to use it. Apply your dose correctly by following the detailed instructions for use contained in the package insert.

TESTAVAN is for use by adult men only.

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 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	Application Method
Dose	
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.
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When to use it

Apply TESTAVAN once daily at approximately the same time each day, preferably in the morning.

Using it at the same time each day helps maintain a steady level of testosterone in the blood. It will also help you remember when to apply it.

How long to use it

TESTAVAN helps control the symptoms of your condition, but does not cure it. Therefore, you must use TESTAVAN every day.

Continue taking your medicine for as long as your doctor tells you.

If you forget to use it

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 (overdose)

Wash the skin with soap and water. Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much TESTAVAN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using TESTAVAN

Things you must do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking 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.

Things you must 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.

If you stop using it suddenly, your condition may worsen or you may have unwanted side effects.

Things to be careful of

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, first wash the area well with soap and water.

Unwanted transfer of testosterone to another person can be substantially reduced by wearing a shirt or similar. You should have a shower or bath before having intimate physical contact.

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 makes contact with the

application area, the contact area on the woman or child should be washed well with soap and water immediately.

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 and the development or worsening of acne.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using TESTAVAN.

Ask your doctor or pharmacist to answer any questions you may have.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- skin reactions such as rash, redness, itching, dryness, and/or irritation
- high triglyceride levels in the blood

- increased levels of an enzyme, prostate-specific antigen (PSA), in the blood
- easy bruising and/or blood clot formation
- headaches
- high levels of haemoglobin, the oxygen carrying substance in the blood
- high blood pressure.

These are the common side effects of TESTAVAN.

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. You may not experience any specific symptoms.

Side effects associated with high doses or long term treatment include:

- increased tendency to retain fluid (signs may include swollen feet or ankles)
- decreased sperm count, which may affect fertility
- unwanted, frequent or prolonged and painful erections
- severe stomach pain or tenderness, which do not disappear within a short time.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using TESTAVAN

Storage

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

Store TESTAVAN in the original container and do not use after 60 days of opening.

Do not store TESTAVAN or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

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, return any medicine that is left over to your pharmacy for disposal.

Product description

What it looks like

TESTAVAN is a translucent to slightly opalescent gel presented in a non-aerosol metered-dose pump.

Each metered-dose pump contains 85.5 g gel and is capable of dispensing 56 metered individual doses of 1.15 g gel (1.25 mL), each dose containing 23 mg of testosterone.

Ingredients

TESTAVAN contains 23 mg of testosterone per 1.15 g gel as the active ingredient.

Inactive ingredients:

- ethanol
- water - purified
- propylene glycol
- diethylene glycol monoethyl ether
- carbomer 980
- trolamine
- disodium edetate.

Supplier

TESTAVAN is supplied in Australia by:

Ferring Pharmaceuticals Pty Ltd

Suite 2, Level 1, Building 1

20 Bridge Street

Pymble NSW 2073, Australia.

AUST R 277958 - TESTAVAN

testosterone 2% w/w gel in a metered-dose dispenser with a cap applicator

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