Package leaflet: Information for the user

Testavan® 4.6 mg/actuation transdermal gel
testosterone

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Testavan is and what it is used for
2. What you need to know before you use Testavan
3. How to use Testavan
4. Possible side effects
5. How to store Testavan
6. Contents of the pack and other information

1. What Testavan is and what it is used for

What Testavan is
Testavan is a clear gel that contains testosterone, a male hormone produced naturally in your body.

Testavan is used to replace testosterone in adult men when you do not produce enough natural testosterone – this is called "hypo-gonadism". The medicine helps to raise your testosterone to normal levels.

What testosterone does
Testosterone is made naturally in your body in your testicles.
- It helps produce sperm and to develop and maintain male features such as a deep voice and body hair.
- It is necessary for normal sexual function and sex drive.
- It also helps to maintain muscle size and strength.

What Testavan is used for
Testavan is used in men for testosterone replacement to treat various health problems caused by a lack of testosterone (male hypogonadism). This should be confirmed by two separate blood testosterone measurements and also include clinical signs and symptoms such as:
- impotence
- infertility
- low sex drive
- tiredness
- depressive moods
- bone loss caused by low hormone level
- partial loss of secondary sex characteristics, such as changes in your voice, changes in the fat distribution and partial loss of face and body hair

2. What you need to know before you use Testavan

Who can use Testavan
- Only men can use Testavan.
- Young men under the age of 18 years should not use this medicine.
- This medicine should not be used by females of any age.
- Do not allow women (especially women that are pregnant or breast-feeding) or children to come into contact with Testavan gel or the areas of skin where Testavan has been applied.

Do not use Testavan:
- if you are allergic to testosterone or any of the other ingredients of this medicine (listed in section 6)
- if you have or are suspected of having prostate cancer
- if you have or are suspected of having breast cancer (a rare condition for men).

Warnings and precautions
Testosterone treatment can speed up the progress of pre-existing prostate cancer. Your doctor will do the necessary tests before you can use Testavan and do follow-up check by carrying out periodic blood tests and prostate examinations.

Talk to your doctor before using Testavan, if you have or ever had any of the following:
- you have difficulty in passing water (urinating) due to an enlarged prostate gland
- you have bone cancer - your doctor will check your calcium levels
- you have high blood pressure, or if you are treated for high blood pressure, as Testavan may cause a rise in blood pressure
- you have severe heart, liver or kidney disease, as treatment with Testavan may cause severe complications in the form of water retention in your body sometimes accompanied by (congestive) heart failure (overload in the heart)
- you have ischaemic heart disease (which affects the supply of blood to the heart)
- blood clotting problems
    - thrombophilia (an abnormality of blood coagulation that increases the risk of thrombosis – blood clots in blood vessels)
    - factors that increase your risk for blood clots in a vein: previous blood clots in a vein; smoking; obesity; cancer; immobility; if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50); or as you get older.
    - How to recognise a blood clot: 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. Seek urgent medical attention if you experience one of these symptoms.
- you have epilepsy
- you have migraines
- you have breathing difficulties when you sleep – these are more likely to happen if you are overweight or have long term lung problems

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Testavan – using this medicine may make these conditions worse.

If you develop reactions on your skin where you applied the Testavan, go back to your doctor to seek advice. It may be necessary to stop the treatment with Testavan.

The following blood checks should be carried out by your doctor before and/or during the treatment: testosterone blood levels, full blood count.

At the time of, and just after, the daily application of Testavan, do not apply moisturisers or sunscreen products to the area where you have put the gel

How to prevent transfer of Testavan to someone else

During repeated or prolonged periods of physical contact, this medicine may be transferred to another person. This may cause side-effects such as growth of facial or body hair, deepening of the voice or changes in the menstrual cycle of women, or accelerated height, genital enlargement, and early puberty (including development of pubic hair) in children. Wearing clothes covering the application area or washing the application area before contact may reduce this risk.
- This is especially important for women and children – they normally only have low levels of testosterone in their bodies
- Pregnant women must not come into contact with Testavan. If your partner is pregnant you must be careful and protect her from any contact with the medicine and the application area.

Additional care should be taken by patients using this product who may be in close physical contact with children as testosterone may pass through clothing. Please make sure you follow the application technique (see section 3 of this leaflet) when in physical contact with children, including covering the application site with clean clothing once the gel has dried. Additionally, please wash the application site with soap once the recommended time period (at least 2 hours) has passed and cover again with clean clothing before physical contact with children.

To stop the gel being transferred from your skin to someone else, you should:
- use the applicator to apply the medicine rather than your fingers
- wash your hands with water and soap straight away if you do get any Testavan on your hands
- cover where you have put the gel with clothing - once the gel has dried
- have a bath or shower, or wear clothing to cover the gel application site (such as a T-shirt), before having close skin-to-skin contact with anyone

In order to improve the safety of your partner you should wash the area with soap for instance during a shower before having sexual intercourse or, if not possible, wear a T-shirt that covers the application site at the time of contact.

What to do if someone else is exposed to Testavan
If someone touches the gel or has skin-to-skin contact where you have put the gel, they should wash their area of skin with soap and water as soon as possible. The longer that the gel is in contact with the skin before washing, the greater the chance that the person will absorb some testosterone.

If Testavan has been transferred to someone else, then look out for any changes in the body or behaviour of people close to you. If anyone close to you gets any of the following signs, they should see their doctor:
- acne
- deepening of the voice
- growth of facial or body hair
- changes in their monthly period
- early puberty, genital enlargement or changes in level of sexual behaviour of children

Other medicines and Testavan
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This includes medicines obtained without a prescription and herbal medicines. Testavan may affect how these medicines work and you may need to have your doses adjusted.

In particular, tell your doctor or pharmacist if you are taking:
- Medicines to thin your blood (anti-coagulants) - Testavan may increase the effects of these drugs
- corticosteroids or any other medicines that may increase the production of these hormones. Both corticosteroids and Testavan may cause your body to hold on more water
- insulin to control your blood sugar levels (in diabetes); you may need to reduce your dose of insulin when you are in treatment with Testavan .

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Testavan.

Pregnancy, breast-feeding and fertility
Testavan is not intended for use by pregnant or breastfeeding women.

If your partner is or becomes pregnant, you **must** follow the advice above under the heading **'How to Prevent transfer of Testavan to someone else'**.

Pregnant women must avoid **any** skin contact with Testavan application sites in men. This medicine may cause damage to the unborn baby. In the event of contact, the area should be washed as soon as possible with soap and water.

Breast-feeding women must avoid **any** contact with Testavan application sites in men.

Sperm production may be reversibly suppressed with Testavan.

Testavan contains propylene glycol
This medicine contains propylene glycol, which may cause skin irritation.

Testavan contains ethanol
This medicine contains 107.74 mg alcohol (ethanol) in each 0.23 g dose which is equivalent to 468.40 mg/g (46.84 %w/w). It may cause burning sensation on damaged skin.

3. How to use Testavan

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to use

- The recommended starting dose of Testavan is 23 mg testosterone (five pump presses) applied once daily at approximately the same time each day preferably in the morning - but some patients may require a higher dose.
- The maximum recommended dose is 69 mg testosterone daily (fifteen pump presses).

The correct dose of Testavan that you need will be decided by your doctor – they will do this by measuring two things regularly:
- the levels of testosterone in your blood
- How well the medicine is working for you.

Talk to your doctor if you feel that the effects of the medicine is too strong or too weak.

Using this medicine
It is important that you read and follow these directions on how to use Testavan properly.

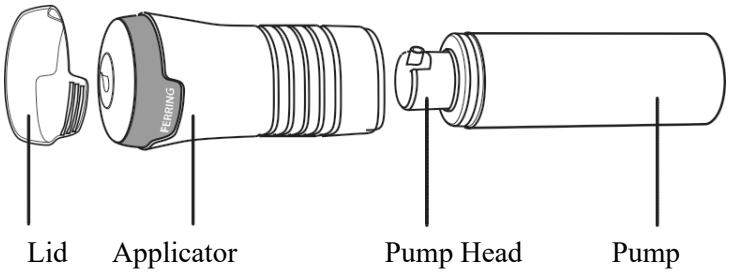
Apply Testavan on your skin using the applicator. This is called "trans-dermal use" – the medicine goes through your skin into your body.

Apply the medicine only to clean, dry, normal healthy skin on your shoulders or upper arms.

Never apply Testavan to:
- your penis and testicles
- to skin that is broken or damaged
- open sores, wounds or irritations.

<u>Supplies you will need</u>

- Testavan gel pump kit. **See Picture A**.
- Box of tissues.



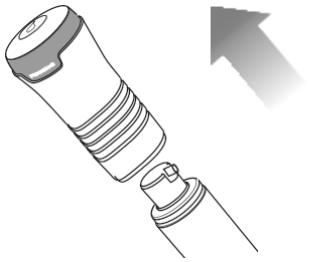
Picture A

Note: Multipacks contain a lid on top of each pump head

<u>Priming your gel pump – first time only</u>

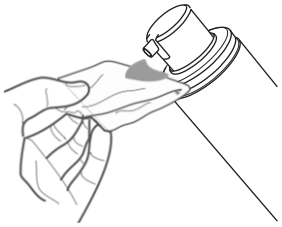
Before using a **new** Testavan pump, you need to get it ready to use. This is called "priming" the pump:

- Take off the applicator from the pump in the case of the single pack or take off the lid from the pump in the case of the multipack - **See Picture B**.



Picture B

- Prime the pump by pressing the pump head all the way down over a tissue. Repeat until gel appears. **See Picture C**.



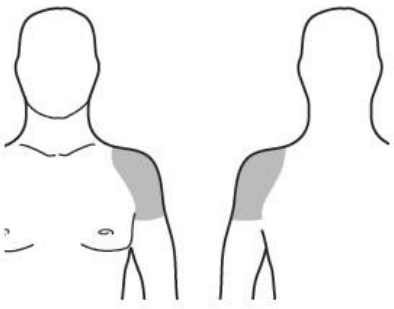
Picture C

- **Do not use any gel from priming because it might not be the right dose.**
- Safely throw away the used tissues to prevent transferring to others including children or pets.
- Your Testavan pump is now ready to use.

For daily dosing follow steps 1-4

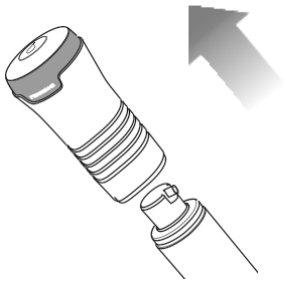
Step 1: Preparing to apply your Testavan gel

- Select a clean, dry, normal healthy area of the skin on the upper arm and shoulder that would be covered by a short sleeve t-shirt. **See Picture D**.
- Use Testavan gel **only** on the upper arm and shoulder.



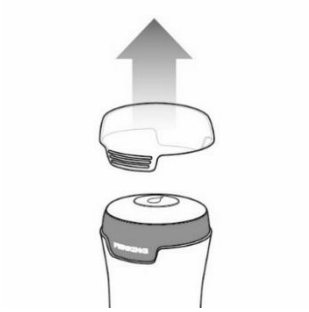
Picture D

- Take off the applicator from the pump **See Picture E**.



Picture E

- Take off the lid from the applicator **See Picture F**.



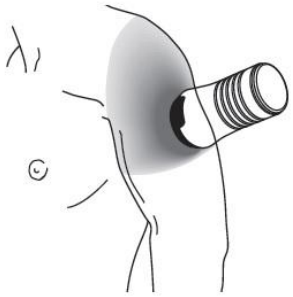
Step 2: Applying your Testavan gel

- Hold the pump with the nozzle facing the applicator surface.
- Press the pump head all the way down up to **five times**. **See Picture G**.



Picture G

- Use the applicator to spread the gel evenly across one upper arm and shoulder, making sure not to get any gel on your hands. **See Picture H**.
- Once the gel has dried, cover the application site with clean clothing (such as a t-shirt)
- Before close physical contact with another person (adult or child), wash the application site with soap and water once the recommended time period (at least 2 hours) has passed and cover again with clean clothing
- Clean up any spills with a tissue. Safely throw away used tissues to prevent transfer to others including children or pets.



Picture H

Find your dose as prescribed by your doctor in the table below.

Dose	**How to apply**
23 mg (5 pump presses)	Apply five pump presses as shown in **Step 2 – do this once**.
Up to 46 mg (up to 10 pump presses)	**Apply five pump presses as shown in Step 2.** **Repeat** to apply the remaining up to five pump presses – put on the opposite upper arm and shoulder.
Up to 69 mg (Up to 15 pump presses)	**Apply five pump presses as shown in Step 2.** **Repeat** to apply five pump presses – put on the opposite upper arm and shoulder. **Repeat** again to apply the remaining up to five pump presses to the first upper arm and shoulder that you used.

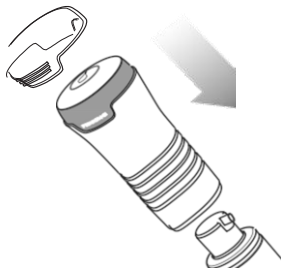
Step 3: Cleaning your Testavan applicator

- After use, clean the applicator with a tissue. **See Picture I.**



Picture I

- Safely throw away used tissue. Be careful to prevent transfer to others including children or pets.
- **REMEMBER** to put the lid back on the applicator and put the applicator back on the pump. **See Picture J**.



Picture J

- Store the product safely and out of reach of children.

Step 4: After applying your Testavan

- **Wash your hands with soap and water straight away, if you got gel on them.**
- Testavan gel is flammable until dry. Let the Testavan gel dry before smoking or going near an open flame.
- Let the application site dry completely before getting dressed.
- Wear clothing that covers the application site at all times to prevent accidental transfer to others.
- **Wait at least 2 hours** before showering, swimming or bathing.
- Wash the application site with soap and water before any situation where skin-to-skin contact of the application site with another person is likely.

If you use more Testavan than you should
If you have applied too much medicine by mistake, wash the application area with soap and water as soon as you realise.
Only use the amount of medicine prescribed by your doctor. If you feel irritable, nervous, gain weight, get long lasting or frequent erections – these may be signs that you are using too much.

If you forget to use Testavan
Do not use a double dose to make up for a forgotten dose.
- If your next dose is less than 12 hours away, do not take the missed dose. Then take your next dose as normal.
- If it is more than 12 hours until your next dose, take the dose that you have missed. Continue as normal the following day.

If you stop using Testavan
Talk to your doctor before you stop this medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common (may affect up to 1 in 10 people)
- skin irritation where the gel has been applied (including rash, dryness and redness)
- high levels of fats (triglycerides) in the blood
- increased blood pressure
- increased Prostatic Specific Antigen (PSA). PSA is a protein produced by the prostate, which can be used to detect prostate disease
- increased haematocrit (percentage of red blood cells in blood), identified by periodic blood tests

Uncommon (may affect up to 1 in 100 people)
- Increased haemoglobin (the component of red blood cells that carries oxygen), identified by periodic blood tests
- Headache

Other known undesirable effects associated with testosterone treatment include:
acne, seborrhoea, baldness, sweating, increased body hair growth, skin tickling or numbness, headache, dizziness, nausea, hot flushes, fluid retention (such as swelling of ankles), weight gain, sleep apnoea, shortness of breath, hypersensitivity reactions, feeling sick/unwell, changes to your mood (such as aggression, hostility, nervousness, anxiety, depression), sleeplessness, muscular pain or cramp, development of breasts, increase in red blood cell count, decrease in red blood cells, blood clots, jaundice (liver problems which sometimes may be associated with yellowing of the skin and the whites of the eyes), abnormal liver function tests.
Sex drive changes, erection increased, priapism (prolonged and painful erections), testis disorder, reduced number of sperm, difficulty passing urine, changes to your prostate gland, prostate cancer (there is no convincing evidence that testosterone replacement in hypogonadal men induces prostate cancer; however, testosterone therapy is to be avoided in men already known or thought to have prostate cancer).

Prolonged testosterone administration may cause changes in the levels of salts (electrolytes) and water in the body.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly

via Yellow Card scheme, Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Testavan

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the pump label and the outer carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Testavan contains
The active substance is testosterone.
The other excipients are: ethanol 96%, propylene glycol (E 1520), diethylene glycol monoethyl ether, carbomer 980, trolamine, disodium edetate, water.

One gram of gel contains 20 mg testosterone. Each pump press delivers 0.23 g gel (0.25 ml) containing 4.6 mg of testosterone.

What Testavan looks like and contents of the pack
Testavan is a homogenous, translucent to slightly opalescent gel.

The pump is available in packs containing a metering pump and a cap applicator with a hygiene lid. Each pump contains 85.5 g Testavan gel and is capable of dispensing 280 metered doses.

Marketing Authorisation Holder and Manufacturer

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