

Package leaflet: information for the user

Testavan 20 mg/g transdermal gel
testosterone

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm others, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

1. What is Testavan and what is this medicine used for?
2. When should you not use this medicine or be extra careful with it?
3. How do you use this medicine?
4. Possible side effects
5. How do you store this medicine?
6. Contents of the package and other information

1. What is Testavan and what is this medicine used for?

What is Testavan?

This medicine is a clear gel that contains testosterone, a male hormone that the body naturally produces.

This medicine is used to replace testosterone in adult men who do not produce enough natural testosterone, which is called 'hypogonadism'. The medicine helps bring your testosterone levels to a normal level.

What does testosterone do?

Testosterone is naturally produced in your body by the testicles.

It helps in the production of sperm and the development and maintenance of male characteristics such as a deep voice and body hair.

It is necessary to be able to function normally sexually and become sexually aroused.

It also helps to maintain muscle mass and strength.

What is this medicine used for?

This medicine is used in men as a replacement for testosterone to treat various health problems caused by a deficiency of testosterone (male hypogonadism). This deficiency must be demonstrated by two separate measurements of the testosterone level in the blood. There must also be clinical signs and symptoms such as:

Impotence (erectile problems)
infertility

low libido fatigue
depressive
mood bone loss
, caused by a low hormone levelpartial
partial loss of secondary sexual characteristics such as changes in your voice or
changes in fat distribution
loss of part of your facial and body hair.

2. When should you not use this medicine or be extra careful with it?

Who can use this medicine?

Only men may use this medicine.
Children and adolescents under 18 years should not use this medicine.
Women should not use this medicine, regardless of age.
Do not let women (especially those who are pregnant or breastfeeding) or children
come into contact with Testavan gel or skin areas where this medicine has been
applied.

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these
ingredients in section 6.
If you have prostate cancer or there is a suspicion of it.
If you have breast cancer (this is rare in men) or there is a suspicion of it.

When should you be extra careful with this medicine?

Treatment with testosterone can accelerate the development of pre-existing prostate cancer.
Your doctor will perform the necessary tests before you can use this medicine. Follow-up
checks will also take place through regular blood tests and prostate examinations.

Contact your doctor before using this medicine if you suffer or have ever suffered from any of
the following conditions: .

- You may have difficulty urinating due to an enlarged prostate gland.
 - You suffer from bone cancer: your doctor checks your calcium levels.
 - You have high blood pressure or are being treated for high blood pressure, as this
medicine can lead to an increase in blood pressure.
 - You suffer from a severe heart, liver, or kidney disease, as treatment with this medicine
can lead to serious problems in the form of retained fluid in your body. This is
sometimes associated with (congestive) heart failure (fluid accumulation in the heart).
 - You suffer from ischemic heart disease (heart disease where the blood supply to the
heart is impaired).
- Blood clotting disorders
- o thrombophilia (a clotting disorder that increases the risk of thrombosis (blood
clots in the blood vessels).
 - o factors that increase the risk of blood clots in a blood vessel: previous blood
clots in a blood vessel, smoking, obesity, cancer, prolonged sitting, if one of your

close relatives had a blood clot at a young age (for example, younger than about 50) in a leg, lung, or other organ, or as you get older.

- o How do you recognize a blood clot? By a painful swelling in one leg or sudden change in skin color such as becoming pale, red, or blue, sudden shortness of breath, sudden unexplained cough possibly with blood, or sudden chest pain, severe lightheadedness or dizziness, severe abdominal pain, sudden loss of vision. Immediately alert a doctor if you experience any of these symptoms.

You suffer from epilepsy.

You have migraine.

You have breathing difficulties during sleep, which is more likely if you are overweight or have long-term lung problems.

If any of the above situations apply to you (or if you are unsure), contact your doctor or pharmacist before using this medicine. The use of this medicine may worsen these conditions. Return to your doctor for advice if you experience skin reactions at the site where you applied this medicine. It may be necessary to stop treatment with this medicine.

Before and/or during treatment, your doctor should perform the following blood tests: testosterone level in the blood, complete blood count (test that detects abnormalities in the blood). At the time of and immediately after daily application of this medicine, you should not apply moisturizing agents or sunscreen products to the area where you applied the gel.

How can you prevent transfer of this medicine to another person?

This medicine can be transferred to other people through direct skin-to-skin contact. This can lead to an increased testosterone level in their body, which can be dangerous. Such an increase can occur after one contact, but can also slowly build up over time through short contact moments.

This is especially important for women and children. Normally, they have only a low testosterone level in their body.

Pregnant women should not come into contact with this medicine. If your partner is pregnant, you must be careful and protect her from any contact with the medicine and the application site.

To prevent transferring the gel from your skin to another person, you must:

apply the medicine with the applicator (the tool for applying the medicine) and not with your fingers.

immediately wash your hands with water and soap if your hands have come into contact with this medicine.

cover the area where you applied the gel with clothes once the gel has dried.

one take a bath or shower or wear clothes to cover the application site (such as a T-shirt) before having direct skin-to-skin contact with another person.

To increase the safety of your partner, you should wash the application site with soap before intercourse, for example in the shower, or, if that is not possible, wear a T-shirt that covers the application site during the contact period.

What if another person is exposed to this medication?

If another person touches the gel or has skin-to-skin contact with the area where you applied the gel, they should wash the contact area with soap and water as soon as possible. The

longer the gel is in contact with the skin before washing, the greater the chance that the person will absorb some testosterone.

If this medication has been transferred to another person, you should watch for any physical or behavioral changes in people around you. If someone around you develops any of the following symptoms, they should see a doctor:

- acne (pimples)
- deepening of the voice
- growth of facial- or body hair
- changes in the menstrual cycle
- early puberty, enlargement of the genitals or changes in the level of sexual behavior in children

Are you using any other medicines?

Are you using Testavan in addition to other medicines, have you recently done so or is there a possibility that you will use other medicines in the near future? If so, tell your doctor or pharmacist. This also applies to medicines you can obtain without a prescription and herbal medicines. Testavan can affect the action of these medicines and you may need to have your doses adjusted.

Especially tell your doctor or pharmacist if you are taking the following:

- medicines to thin your blood (anticoagulants): Testavan can enhance the effect of these medicines.
- corticosteroids (hormones used to suppress inflammation) or other medicines that can increase the production of these hormones: both corticosteroids and Testavan can cause the body to retain more fluid.
- insulin to control blood sugar levels (in diabetes): you may need to lower your insulin dose if you are treated with Testavan.

If any of the above situations apply to you (or if you are in doubt), contact your doctor or pharmacist before using Testavan .

Pregnancy, breastfeeding and fertility

This medicine is not intended for use by pregnant women or women who are breastfeeding.

If your partner is pregnant or becomes pregnant, you must follow the advice under the section "How to prevent transfer of this medicine to another person?".

Pregnant women should avoid any skin contact with application sites of men using this medicine. This medicine can cause harm to the unborn baby. In case of contact, the contact area should be washed with soap and water as soon as possible.

Women who are breastfeeding should avoid any skin contact with application sites of men using this medicine.

This medicine suppresses sperm production. This process is reversible.

Testavan contains propylene glycol

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

Testavan contains ethanol

This medicine contains 538.70 mg of alcohol (ethanol) per each dose of 1.15 g, which is equivalent to 468.40 mg/g (46.84 w/w). It may cause a burning sensation on irritated skin.

3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

How much are you allowed to use?

The recommended starting dose of this medicine is 23 mg testosterone (press the pump once). The dose should be applied once a day at approximately the same time and preferably in the morning. Some patients may require a higher dosage ..
Your doctor will determine the exact dosage of this medicine that you need.

Your doctor determines the exact dosage of this medication that you need. For this measure he/she regularly two things:

- the testosterone level in your blood
- the extent to which the medicine works for you.

Contact your doctor if you think the medicine has too strong or too weak an effect.

Use of this medicine

It is important that you read and follow these instructions for proper use of this medicine.

Apply this medicine to your skin using the applicator (the tool for applying the medicine). Applying it to the skin is called "transdermal use." The medicine enters the body through the skin.

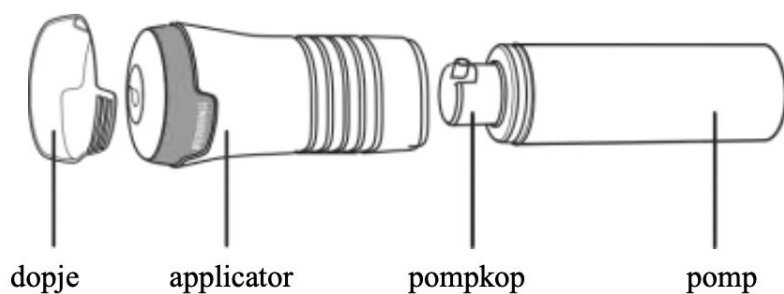
Apply the medicine only to clean, dry, and normally healthy skin on the shoulders or upper arms.

Never apply this medicine to:

- the penis and testicles
- cracked or damaged skin
- open skin ulcers, wounds, or irritated skin.

Accessories that you need have

- Pump kit with the gel. See figure A.
- Box with wipes.



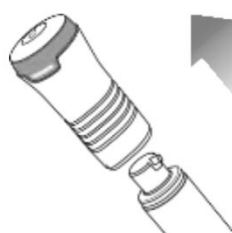
figuur A

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

The gel pump priming – only for first use

Before using a new pump, you must prepare it for use. This is called priming the pump called.

Remove the applicator (the tool for applying the product) from the pump in case of a single package or remove the cap from the pump in case of a multiple package. See figure B.



figuur B

Prime the pump by the pump head completely. Hold a tissue underneath when you do this. Repeat this step until the gel appears. See figure C.



figuur C

Do not use gel that has come out of the pump during priming as it may not be the correct dose.

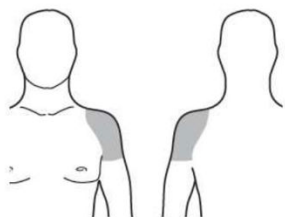
Dispose of used tissues safely to prevent the product from being transferred to others, including children or pets.

Your pump is now ready for use.

Follow steps 1 to 4 for the daily dosage

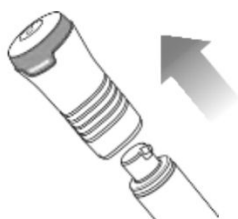
Step 1: Preparing to apply your gel

Choose a clean, dry, and normally healthy skin area on the upper arm and shoulder that can be covered with a T-shirt with short sleeves. See figure D.
Apply the gel only to the upper arm and shoulder.



figuur D

Remove the applicator from the pump. See figure E.



figuur E

Remove the cap from the applicator. See figure F.



figuur F

Step 2: Your gel apply

Hold the pump with the nozzle aimed at the applicator head.
Press the pump head fully once. See figure G.



figuur G

Use the applicator to evenly distribute the gel on one upper arm and shoulder. Ensure your hands do not come into contact with the gel. See figure H.



figuur H

Use a tissue to clean up any spilled gel. Dispose of used tissues safely to prevent the product from being transferred to others, including children or pets.

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

Dose	How to apply the gel apply
23 mg (press pump once press)	Press the pump once, as indicated in step 2. Do this once.
46 mg (press pump twice press)	Press the pump once, as indicated in step 2. Repeat to apply a second pump dose and apply the gel to the other upper arm and shoulder.
69 mg (pump three times press)	Press the pump once, as indicated in step 2. Repeat to apply a second pump dose and apply the gel to the other upper arm and shoulder. Repeat again to apply a third pump dose and apply the gel to the upper arm and shoulder you used first.

Step 3: Your applicator cleaning

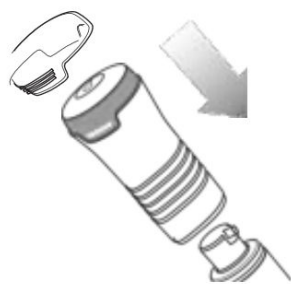
Clean the applicator with a wipe after use. See figure I.



figuur I

Dispose of the used wipe safely to prevent the product from being transferred to others, including children or pets.

REMEMBER to place the cap back on the applicator and place the applicator back on the pump. See figure J.



figuur J

Keep the product safely out of the reach of children.

Step 4: After applying your gel

Wash your hands immediately with soap and water if there is gel on them.
The gel is flammable until it dries. Allow the gel to dry before smoking or going near an open flame.
Allow the application site to dry completely before dressing.
Wear clothes that cover the application site at all times to prevent the product from being unintentionally transferred to others.
Wait at least 2 hours before showering, swimming, or bathing.
Wash the application site with soap and water before any situation where there is a high chance of skin-to-skin contact between the application site and another person.

Have you used too much of this medicine?

If you accidentally applied too much of this medicine, wash the application site with soap and water as soon as you remember.

Use only the amount of medication prescribed by your doctor. If you feel irritated or nervous, gain weight, or have prolonged or frequent erections, you may be using too much.

If you have used or taken too much of this medicine, contact your doctor or pharmacist immediately.

Did you forget to use this medicine?

Do not take a double dose to make up for a forgotten dose.

If you need to apply the next dose within 12 hours, skip the missed dose. Go further with the next usual dose.

If it is more than 12 hours until the next dose, apply the missed dose. Continue the next day with the usual dose.

If you stop using this medicine

Contact your doctor before stopping the use of this medicine.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can have side effects, although not everyone gets them.

Common (occur in less than 1 in 10 users)

- skin irritation where the gel is applied (including rash, dryness, and redness)
- high fat content (triglycerides) in the blood
- increased blood pressure
- elevated prostate-specific antigen (PSA). PSA is a protein produced by the prostate and can be used to detect a prostate condition.
- increased percentage of red blood cells in the blood (hematocrit), which is determined by regular blood tests

Sometimes (occur in less than 1 in 100 users)

- elevated hemoglobin (component of red blood cells that carries oxygen), which is determined by regular blood tests
- headache

Other known side effects associated with testosterone treatment include:

(youth) acne, skin condition with oily flakes on the skin due to excessive sebum production (seborrhea), baldness, sweating, increased body hair growth, tingling or numbness of the skin, headache, dizziness, nausea, hot flashes, fluid retention (such as swelling of the ankles), weight gain, temporary cessation of breathing during sleep (sleep apnea), shortness of breath, hypersensitivity reactions, feeling sick/unwell, mood changes (such as aggression, hostility, nervousness, anxiety, depression), insomnia, muscle pain or cramps, breast development, increased number of red blood cells, decreased number of red blood cells, blood clots, jaundice (liver problems sometimes accompanied by yellowing of the skin and whites of the eyes), unusual results of tests that measure how well your liver is working (liver function tests).

Changed interest in sex, more frequent erection, prolonged and painful erections (priapism), disorder of the testis (male sex gland), decreased amount of semen, difficulty urinating, changes in the prostate gland, prostate cancer (there is no convincing evidence that testosterone replacement in hypogonadal men (men with a testosterone deficiency) causes prostate cancer; however, testosterone therapy should be avoided in men who are known or suspected to have prostate cancer).

Prolonged administration of testosterone can lead to changes in the levels of salts (electrolytes) and water in the body.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website www.lareb.nl. 5. How to store this medicine?

Keep out of the sight and reach of children.

There are no special storage conditions for this medicine.

Do not use this medicine after the expiry date. This can be found on the label of the pump and the outer packaging after "EXP". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

The active substance in this medicine is testosterone.

The other excipients in this medicine are ethanol 96%, propylene glycol (E 1520),
The other excipients in this medicine are ethanol 96%, propylene glycol (E 1520), diethylene glycol monoethyl ether, carbomer 980, trolamine, disodium edetate and purified water.

One gram of gel contains 20 mg testosterone. Pressing the pump once delivers 1.15 g (1.25 ml) gel with 23 mg testosterone.

What does this medicine look like and how much is in a package?

Testavan is a uniform, translucent to nearly translucent gel.

The following packages are available with or without cap applicator and hygiene lid:

Single package with 1 dosing pump.

Multiple package with 3 dosing pumps.

Each pump contains 85.5 g Testavan gel and can deliver 56 measured doses. Not all mentioned package sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

The Simple Pharma Company Limited, Ground Floor, 71 Lower Baggot St, Dublin D02 P593, Ireland Manufacturer

Copea Pharma Europe Limited, Medici House, Unit 2, Ashbourne Manufacturing Park, Ashbourne, Co. Meath, A84 KH58, Ireland

Applicator with cap:

The Simple Pharma Company Limited, Ground Floor, 71 Lower Baggot St, Dublin D02 P593, Ireland Number of the authorization for placing on the market RVG 120624

RVG 120624

This medicine is registered in member states of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Testarzon Bulgaria	20 mg/g transdermal gel/gel transdermique //transdermal Gel Testavan 20 mg/g ttransdermal gel
Denmark	Testavan 20 mg/g transdermal gel
Germany	Testavan 20 mg/g transdermal Gel
Estonia	Testavan
Finland	Testavan 20 mg/g transdermal gel
France	Testavan 20 mg/g gel transdermal
Greece	Testarzon 20 mg/g diadermal gel
Hungary	Testarzon 20 mg/g transdermal gel
Ireland	Testarzon 20 mg/g transdermal gel
Iceland	Testavan 20 mg/g gel for use on skin
Italy	Testavan 20 mg/g gel transdermal
Croatia	Testarzon 20 mg/g transdermal gel
Latvia	Testavan 20 mg/g transdermal gel
Liechtenstein	Testavan 20 mg/g transdermal Gel
Lithuania	Testavan 20 mg/g transdermal gel
Luxembourg	Testarzon 20 mg/g transdermal gel/gel transdermal/transdermal Gel
Netherlands	Testavan 20 mg/g gel for transdermal use
Norway	Testavan 20 mg/g transdermal gel
Austria	Testavan 20 mg/g transdermal Gel
Poland	Testavan
Portugal	Testavan 20 mg/g gel transdermic
Romania	Testavan 20 mg/g gel transdermic
Slovenia	Testarzon 23 mg/pressure transdermal gel
Slovakia	Testavan 20 mg/g transdermal gel
Spain	Testavan 20 mg/g gel transdermic
Czech Republic	Testavan
United Kingdom (Northern Ireland)	Testavan 20 mg/g transdermal gel
Sweden	Testavan 20 mg/g transdermal gel

This leaflet was last approved in August 2023