Package leaflet: Information for the user

Testarzon® 20 mg/g 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 Testarzon is and what it is used for
2. What you need to know before you use Testarzon
3. How to use Testarzon
4. Possible side effects
5. How to store Testarzon
6. Contents of the pack and other information

1. What Testarzon is and what it is used for

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

Testarzon 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 Testarzon is used for
Testarzon 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 Testarzon

Who can use Testarzon
- Only men can use Testarzon.
- 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 Testarzon gel or the areas of skin where Testarzon has been applied.

Do not use Testarzon:
- 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 Testarzon and do follow-up check by carrying out periodic blood tests and prostate examinations.

Talk to your doctor before using Testarzon, if any of the following applies to you:
- 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 Testarzon may cause a rise in blood pressure
- you have severe heart, liver or kidney disease, as treatment with Testarzon may cause severe complications in the form of water retention in your body sometimes accompanied by (congestive) heart failure (fluid 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 Testarzon – using this medicine may make these conditions worse.

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

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 Testarzon, do not apply moisturisers or sunscreen products to the area where you have put the gel

How to prevent transfer of Testarzon to someone else
Testarzon can transfer to others by close skin-to-skin contact. This may result in increased testosterone levels in their body – this can be dangerous. This can happen from one contact – but it can also build up bit by bit with small amounts of contact over time.
- 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 Testarzon. If your partner is pregnant you must be careful and protect her from any contact with the medicine and the application area.

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 Testarzon 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 Testarzon
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 Testarzon 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 Testarzon
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. Testarzon 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) - Testarzon may increase the effects of these drugs
- corticosteroids or any other medicines that may increase the production of these hormones. Both corticosteroids and Testarzon 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 Testarzon. Taking SGLT-2 inhibitors (such as empagliflozin, dapagliflozin or canagliflozin) together with testosterone may increase the number of red blood cells in your blood. Your doctor may need to monitor your blood more regularly.

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

Pregnancy, breast-feeding and fertility
Testarzon 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** Testarzon **to someone else'**.

Pregnant women must avoid **any** skin contact with Testarzon 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 Testarzonapplication sites in men.

Sperm production may be reversibly suppressed with Testarzon.

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

Testarzon contains ethanol
This medicine contains 538.70 mg alcohol (ethanol) in each 1.15 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 Testarzon

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 Testarzon is 23 mg testosterone (one pump press) 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 (three pump presses).

The correct dose of Testarzon 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 Testarzon properly.

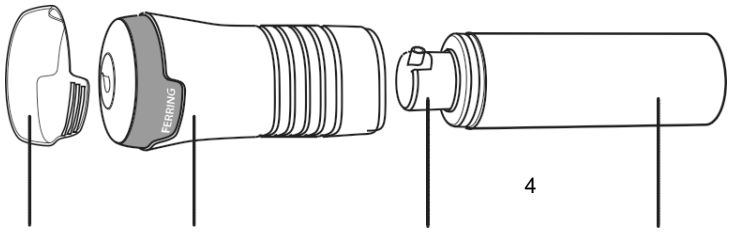
Apply Testarzon on your skin using the applicator. This is called “trans-dermal use” – the medicine goes through your skin into your body.

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

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

<u>Supplies you will need</u>

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



Lid Applicator Pump Head Pump

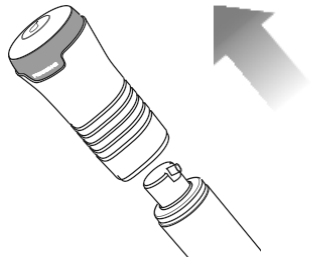
Picture A

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

Priming your gel pump – first time only

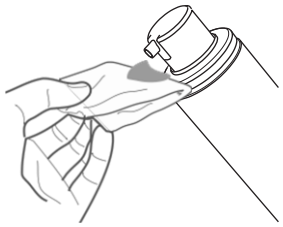
Before using a **new** Testarzon pump, you need to get it ready to use. This is called "priming" the pump:

- 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**.



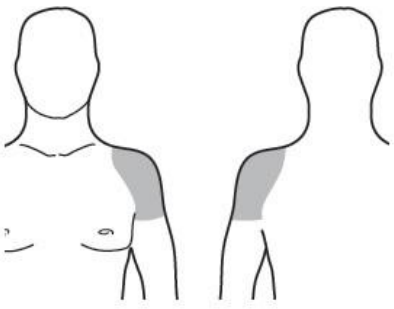
Picture C

- **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 Testarzon pump is now ready to use.

For daily dosing follow steps 1-4

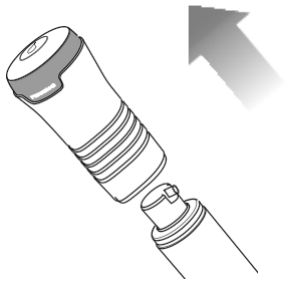
Step 1: Preparing to apply your Testarzon gel

- 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 Testarzon gel **only** on the upper arm and shoulder.



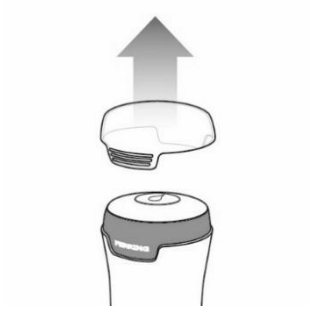
Picture D

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



Picture E

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



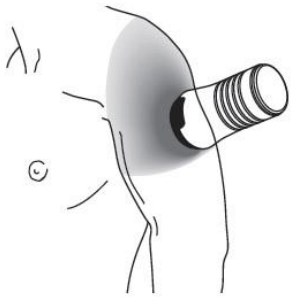
Step 2: Applying your Testarzon gel

- Hold the pump with the nozzle facing the applicator surface.
- Press the pump head all the way down **once**. **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**.
- 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 (1 pump press)	Apply one pump press as shown in **Step 2 – do this once**.
46 mg (2 pump presses)	**Apply one pump press as shown in Step 2.** **Repeat** to apply another pump press – put on the opposite upper arm and shoulder.
69 mg (3 pump presses)	**Apply one pump press as shown in Step 2.** **Repeat** to apply one pump press – put on the opposite upper arm and shoulder. **Repeat** again to apply the third pump press to the first upper arm and shoulder that you used.

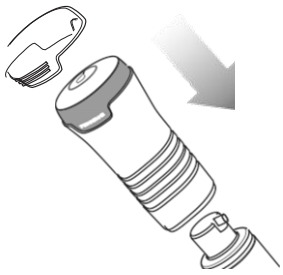
Step 3: Cleaning your Testarzon applicator

- 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 Testarzon

- **Wash your hands with soap and water straight away, if you got gel on them.**
- Testarzon gel is flammable until dry. Let the Testarzon 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 other persons as well as pets.
- **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 Testarzon 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 Testarzon
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 Testarzon
Talk to your doctor before you stop taking 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, 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 HPRA Pharmacovigilance,

Earlsfort Terrace, IRL – Dublin 2. Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; Email: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Testarzon

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 Testarzon 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, purified water.

One gram of gel contains 20 mg testosterone. Each pump press delivers 1.15 g gel (1.25 ml) containing 23 mg of testosterone.

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

The following pack sizes are available with or without a cap applicator and hygiene lid:
Single pack containing 1 metering pump.
Multipacks containing 3 metering pumps.

Each pump contains 85.5 g Testarzon gel and is capable of dispensing 56 metered doses.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Androlabs, Marcel Broodthaersplein 8, Sint-Gillis, Brussels-Capital Region, 1060, Belgium

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

 CAP applicator:
The Simple Pharma Company Limited, Ground Floor, 71 Lower Baggot St, Dublin D02 P593, Ireland
CE

This medicine is authorised in the Member states of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:
Austria, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Germany, Iceland, Italy, Liechtenstein, Lithuania, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Spain, Sweden, United Kingdom (Northern Ireland): **Testavan**
Belgium, Croatia, Greece, Hungary, Ireland Latvia, Luxembourg, Slovenia: **Testarzon**

This leaflet was last revised in August 2026.

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