

Package leaflet: Information for the user

TESTIM 50 mg 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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Testim GEL is and what it is used for

Testim gel is a clear gel that contains testosterone. Testosterone is a male hormone. The gel is put on to your skin (shoulders and/or upper arms) and testosterone is absorbed into your body through your skin. It then enters your bloodstream and helps to raise your testosterone to normal levels. The type of testosterone delivered into your body by Testim gel is the same as the testosterone produced by your body.

Testim Gel is used to replace testosterone in men who do not produce sufficient natural testosterone, a condition known as hypogonadism. Testosterone is made naturally in your body in your testicles. It helps produce sperm and to develop and maintain the male sexual characteristics such as a deep voice and body hair. It is also necessary for normal sexual function and sex drive. Testosterone also helps to maintain muscle size and strength.

Testim is used in adult 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 symptoms such as:

- impotence
- infertility
- low sex drive
- tiredness
- depressive moods
- bone loss caused by low hormone levels

Other medicines may be needed as well as Testim if you are being treated for infertility.

2. What you need to know before you use Testim Gel

Only men can use Testim Gel. Do not allow women or children to come into contact with the areas of skin to which Testim Gel has been applied. Males under the age of 18 years should not use this product. This product should also not be used by females of any age.

Do not use Testim Gel:

- if you have or are suspected of having prostate cancer

- if you have or are suspected of having male breast cancer (a rare condition for men)
- if you are allergic to testosterone or soy or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before using Testim Gel

- if you have difficulty in passing water (urinating) due to an enlarged prostate gland
- if you are suffering from severe heart, liver or kidney disease, treatment with Testim GEL may cause severe complications in the form of water retention in your body sometimes accompanied by (congestive) heart failure.
- if you have high calcium levels in your blood or urine caused by bone cancer you may be advised by your doctor to undergo regular blood tests
- if you have high blood pressure or if you are treated for high blood pressure, as testosterone may cause a rise in blood pressure.
- if you suffer from ischaemic heart disease (a condition that affects the supply of blood to the heart)
- if you have epilepsy
- if you suffer from migraines
- if you have breathing difficulties during sleep; these are more likely to occur if you are overweight or have chronic lung disease.
- if you have or have ever had 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.

These conditions may be aggravated when using Testim Gel. If you have any of the above conditions go back to your doctor to seek advice.

If you develop serious reactions on your skin where you applied the Testim Gel, go back to your doctor to seek advice.

If you have close skin-to-skin contact, testosterone may be transferred to someone else. For further information, please refer to section 3 (How to use).

The following blood checks should be carried out by your doctor before and during the treatment: testosterone blood level, full blood count. Testosterone treatment may accelerate the progression of pre-existing prostate cancer. Your doctor will perform the necessary tests before starting treatment and then check by carrying out periodic blood tests and prostate examinations.

If you are an athlete, be aware that this product may produce a positive reaction in anti-doping tests. Testosterone must not be used to increase muscles or improve physical strength in healthy individuals.

Children

TESTIM is not indicated in children.

Other medicines and Testim Gel

Tell your doctor if you are using, have recently used or might use any other medicines.

Testim Gel may affect how these medicines work and you may need to have your doses adjusted. This is particularly important if you are taking:

- insulin to control your blood sugar levels (in diabetes): you may need to reduce your dose of insulin when using in combination with Testim Gel
- drugs to thin your blood (anti-coagulants): Testim Gel may increase the effects of these drugs
- corticosteroids or drugs which may increase the production of these hormones (ACTH): both corticosteroids and Testim Gel may cause your body to retain more water.

Other forms of interactions: laboratory test interactions. Treatment with testosterone may alter the levels of thyroid hormones in your body. The thyroid function is not affected by these minor changes in levels of thyroid hormones. The thyroid is a gland located in the neck and is involved in the regulation of the body's metabolism and growth.

Pregnancy and breast-feeding

Testim Gel is not intended for use by women.

Pregnant women should avoid skin contact with Testim Gel application sites in men as testosterone can cause the appearance of male secondary sex characteristics in the female foetus.

Breast-feeding women should also avoid any contact with Testim Gel application sites in men.

If your partner is or becomes pregnant, you must follow the advice under the heading 'How to prevent transfer of Testim Gel to someone else' on the other side of this leaflet

Testim Gel contains propylene glycol

This medicine contains 250 mg propylene glycol in each tube, which is equivalent to 250mg/ 5g.

Testim Gel contains ethanol

This medicine contains 3680 mg alcohol (ethanol) in each tube (73.60% w/w). It may cause burning sensation on damaged skin.

Warning: Testim gel is flammable and should not be used near an open flame, lit cigarette or some devices (e.g. hairdryers).

3. How to use Testim Gel

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

Testim Gel is intended for transdermal use, which means application on the skin (shoulders and/or upper arms).

Before you start to use Testim Gel, your doctor will check that you have low testosterone levels in your blood. Always use Testim Gel exactly as your doctor has told you. Check with your doctor if you are not sure. Each 5g tube contains 50mg of testosterone. The usual starting dose of Testim Gel is one tube of gel (5g) each day. Some patients may require a higher dose and your doctor may prescribe two tubes of gel every day. The correct dose of Testim Gel that you need will be decided by regularly measuring the levels of testosterone that are in your blood, as well as by assessing the clinical response to Testim Gel treatment. If you have the impression that the effect of T Gel is too strong or too weak, you should talk to your doctor. Signs of irritability, nervousness, weight gain and prolonged or frequent erections may be suggestive of excessive use.

It is important that you read and follow these directions on how to use Testim Gel properly. Apply Testim Gel only to healthy, normal skin. Never apply Testim Gel to your genitals (penis and testes) or to skin that is broken or damaged and avoid contact with open sores, wounds or irritations.

1. Apply Testim Gel at the same time each day (preferably every morning).
2. Apply the contents of one (1) or two (2) tube(s) of gel on the shoulders and/or upper arms, every morning as instructed by your doctor. If you take a bath or shower in the morning, use Testim Gel after your bath or shower.
3. Make sure that your shoulders and/or upper arms are clean and completely dry before putting on the gel.



4. Open the Testim Gel aluminium tube by piercing the end of the tube with the top part of the cap.

5. Squeeze the entire contents of the tube into the palm of your hand. Squeeze the gel out from the bottom of the tube towards the top.



6. Apply Testim Gel only to your shoulders and/or upper arms as a thin layer. In this way your body will absorb the right amount of testosterone.



7. Use a circular motion to rub the gel in to your skin for several seconds. Do this until no gel is left on the skin area. This process should be repeated with a second tube of Testim Gel by patients who have been prescribed a daily dose of testosterone 100mg. It is suggested that patients who require two tubes of gel each day use both shoulders (one tube per shoulder) and/or upper arms as application sites.

8. Thoroughly wash your hands with soap and water immediately after application. This will also reduce the chance that the medicine will spread from your hands to other people.



9. Let Testim Gel dry for a few minutes before you dress. This prevents your clothing from wiping the gel off your skin and ensures that your body will absorb the correct amount of testosterone.



10. If you wash the application site within 6 hours after applying Testim Gel you may lower the amount of testosterone that is absorbed by your body. Therefore, wait at least 6 hours after applying the gel before showering or swimming to ensure that the greatest amount of Testim Gel is absorbed into your body.

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

How to prevent transfer of Testim Gel to someone else

It is important that you do not spread the medicine to others, especially women and children. If you do not take appropriate precautions, you can transfer testosterone gel to other persons by close skin-to-skin contact. This may result in increased testosterone serum levels in the other person. If the contact is repeated or prolonged, this may cause unwanted side effects such as the growth of facial and/or body hair, *acne*, deepening of the voice or changes in the menstrual cycles of women. Similarly, children have naturally low concentrations of testosterone and could be harmed by higher levels.

To stop the gel being transferred from your skin to someone else, the following precautions are recommended:

- wash your hands thoroughly with soap and water after applying the gel

- cover the application site with clothing once the gel has dried
- have a bath or shower, or wear clothing *to cover the gel application site* (e.g. a T-shirt), before having close skin-to-skin contact with anyone
- leave a long period of time between putting on the gel and having sex or making close skin to skin contact with anyone.

What to do if someone else is exposed to Testim Gel

If someone else is exposed to Testim Gel either as a result of contact with the gel itself or because of contact with the application area on your skin, the person should wash their area of skin contact 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. This is particularly important for women, especially pregnant or breast-feeding women, and children.

If they develop signs such as acne or changes in the growth or pattern of hair on their face or body, they should see their doctor.

If you use more Testim Gel than you should

If you have applied too much Testim Gel by mistake, wash the application area with soap and water as soon as you realise. For further information about any possible side effects, please refer to section 4 (Possible side effects).

If you forget to use Testim Gel

If you miss a dose, do not double your dose the next day to catch up. If your next dose is less than 12 hours away, do not take the missed dose but continue with 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 have any further questions on the use of this product, ask your doctor.

4. Possible side effects

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

Important side effects or symptoms to look out for - and what to do if you are affected

If you have been told after a clinical examination or periodic blood test that you have developed any of the following side effects, see a doctor immediately. Your doctor may review or discontinue your treatment.

The following are common side effects, probably affecting up to 1 in every 10 people taking Testim Gel:

- worsening of hypertension (increase of blood pressure above the normal range)
- increased Prostatic Specific Antigen (PSA), identified by periodic blood tests. PSA is a protein produced by the prostate, which can be used to detect prostate disease
- increased in red blood cell count, haematocrit (percentage of red blood cells in blood) and haemoglobin (the component of red blood cells that carries oxygen), identified by periodic blood tests.

If you think you have any of the following side effects, see your doctor as soon as possible. Depending on your doctor's decision and/or in the case of a severe reaction, your treatment may be reviewed or discontinued.

The following are common side effects. They probably affect up to 1 in every 10 people taking Testim Gel:

- redness, rash or other application site reaction
- acne
- headache

The following are uncommon side effects. They probably affect fewer than 1 in every 100 people taking Testim Gel:

- breast enlargement in males.
- Hot flushes or flushing
- Itching

- Water retention

Azoospermia (no sperm count) may occur very rarely (in fewer than 1 in 10,000 people taking Testim Gel)

Tell your doctor as soon as possible if you notice any of the following symptoms while taking Testim Gel. Your doctor may decide to adjust your treatment:

- too frequent or persistent erections of the penis
- any changes in skin colour
- swelling of the ankles
- unexplained nausea (feeling sick) or vomiting
- any breathing abnormalities including those during sleep

Other possible side effects

The following side effects have not been reported with Testim Gel, but may occur as with any other testosterone treatment:

- prostate cancer
- liver problems (which may be associated with altered liver function tests and/or jaundice (yellowing of the skin/eyes))
- prostate abnormalities (enlargement of the prostate gland, that may cause problems with urination)
- emotional instability
- generalised pins & needles
- altered blood lipid levels
- anxiety
- decreased sexual desire
- hair loss
- skin seborrhoea (oily skin)
- increased body hair
- feeling sick
- muscle cramps

In case of prolonged use or excessive dose:

- changes to salt (electrolyte) levels (such as sodium, chloride, potassium, calcium, inorganic phosphates) in blood may clinically result in oedema (swelling), hypertension (increase of blood pressure above the normal range) or behavioural disturbances such as anxiety
- frequent and/or prolonged erections of the penis

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any side effects not listed in this leaflet. You can also report side effects directly via;

UK: The Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard

Ireland: 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 Testim Gel

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

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

Do not store above 25°C.

Keep the tubes of Testim Gel away from direct heat and direct sunlight as the contents are flammable. Not to be used or stored near an open flame, lit cigarette or some devices (e.g. hairdryers).

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 Testim Gel contains

- The active substance is testosterone. Each single dose container of 5g contains testosterone 50 mg.
- The other ingredients are ethanol, carbomers (980 and copolymer), propylene glycol, glycerol, macrogol 1000, trometamol, pentadecalactone and purified water. The ethanol content is approximately 74%.

What Testim Gel looks like and contents of the pack

This medicinal product is presented as a gel in a single dose container, the gel is a clear to translucent gel. Testim Gel is provided in single dose aluminium tubes with screw caps, each containing 5g gel. Testim Gel is available in cartons containing 7, 14, 30 or 90 single dose containers. Not all pack sizes may be available in the country where it is purchased.

Marketing Authorisation Holder and Manufacturer

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UK: PL 43808/0018

IE: PA 2311/001/001

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