

Package Leaflet: Information for the Patient

TESTOGEL® 40.5 mg, transdermal gel in sachet 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.

TESTOGEL® 40.5 mg, transdermal gel in sachet will be referred to as “this medicine” throughout this leaflet.

What is in this leaflet:

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

1. What TESTOGEL® is and what it is used for

This medicine contains testosterone, a male hormone produced naturally in the body.

This medicine 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

2. What you need to know before you use TESTOGEL®

Who can use TESTOGEL®

- Only men can use TESTOGEL®
- 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 TESTOGEL® or the areas of skin where TESTOGEL® has been applied.

Do not use this medicine

- if you have or are suspected of having prostate cancer
- if you have or are suspected of having breast cancer

- if you are allergic to testosterone or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Your doctor will do the necessary tests before you can use this medicine and do follow-up checks by carrying out periodic blood tests.

Talk to your doctor or pharmacist before using this medicine, 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 this medicine may cause a rise in blood pressure
- you have severe heart, liver or kidney disease, as treatment with this medicine 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 before using this medicine as using this medicine may make these conditions worse.

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

Androgens may increase the risk of an enlarged prostate gland (benign prostatic hypertrophy) or prostate cancer. Regular examinations of the prostate gland before the beginning and during therapy should be performed to follow your doctor's recommendations.

Worsening of breathing problems during sleep have been reported during treatment with testosterone in some people, particularly those who are very overweight or are already suffering from breathing difficulties.

If you have diabetes and use insulin to control your blood sugar levels, testosterone treatment may affect your response to insulin and your antidiabetics' medication might need adjustment.

In case of severe skin reactions, treatment should be reviewed and stopped if necessary.

This medicine should not be used by women due to possible virilising effects (such as growth of facial or body hair, deepening of the voice or changes in the menstrual cycle).

Information on additional monitoring

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

You will have regular check-ups (at least once a year and twice a year if you are elderly or if your doctor considers you as a risk patient) during treatment.

If you receive testosterone replacement treatment over long periods of time you may develop an abnormal increase in the number of red blood cells in your blood (polycythaemia). You will need regular blood tests to check that this is not happening.

Children and adolescents

This medicine is not recommended for children, as no clinical information is available for boys under 18 years

Possible transfer of testosterone

During close skin-to-skin contact testosterone may be transferred to another person and could result in the other person showing signs of increased testosterone (see below).

The following precautions are recommended to protect against transfer:

For the patient:

- wash your hands with soap and water after applying the gel
- cover the application area with clothing once the gel has dried
- wash the application area before making close skin-to-skin contact with another person or if not possible wear clothing such as a shirt or a T-shirt covering the application site during the contact period
- wear clothing (such as a sleeved shirt) covering the application site during contact periods with children

If you believe testosterone has been transferred to another person (man, woman or child), this person should:

- wash the area of skin onto which may have been affected immediately with soap and water
- contact a doctor if they get signs such as acne, changes in the growth or pattern of hair on their body or face, deepening of the voice, changes in their menstrual cycle.
- For children signs of early puberty and genital enlargement should also be looked out for.

You should preferably wait at least 1 hour before showering or bathing after applying this medicine.

Other medicines and this medicine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, particularly the following:

- oral anticoagulants (medicines used to thin the blood)
- corticosteroids (medicines used to reduce inflammation)
- insulin (medicines used to control your blood sugar levels in diabetes). You may need to reduce your dose of insulin when using this medicine.

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

These particular medicines may lead to your dose of this medicine being adjusted.

Pregnancy, breast-feeding and fertility

This medicine is not to be used by women.

Sperm production may be reversibly suppressed with this medicine.

If your partner is or becomes pregnant or is planning to have a baby you **must** follow the advice regarding avoiding transfer of the testosterone gel (see “Possible transfer of testosterone” above).

Pregnant women must avoid **any** contact with this medicine’s application sites. This medicine may cause damage to the unborn baby.

In the event of contact, your partner must wash the area of contact as soon as possible with soap and water.

Driving and using machines

This medicine has no influence on the ability to drive or use machines.

This medicine contains alcohol (ethanol)

This medicine contains 1.81 g alcohol (ethanol) in each sachet.

It may cause burning sensation on damaged skin.

This product is flammable until dry.

3. How to use TESTOGEL®**This medicine is for use by adult men only.**

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.

The recommended dose is 1 sachet (i.e. 2.5g of gel which contains 40.5 mg of testosterone) applied once daily at approximately the same time, preferably in the morning.

The daily dose may be adjusted by your doctor, on an individual patient basis, not exceeding 2 sachets (i.e. 5 g of gel which contains 81 mg of testosterone) per day.

How to apply this gel:

- After opening the sachet, the entire contents should be taken out of the sachet and applied immediately onto the skin.
- The gel must be gently spread onto clean, dry, healthy skin.
- Apply as a thin layer on the right and left upper arms and shoulders.
- Allow the gel to dry for at least 3-5 minutes before dressing.
- Wash your hands with soap and water after applying.

Do not apply to the genital areas (penis and testes) as the high alcohol content may cause local irritation.



If you use more of this medicine than you should

Seek advice from your doctor or pharmacist. You may be advised to wash application site immediately and your doctor may advise you to stop treatment.

The following signs may indicate you may be taking too much of the product and you should contact your doctor:

- Irritability
- nervousness
- weight gain
- frequent or prolonged erections

These symptoms may mean that your dose of this medicine is too high and your doctor may need to adjust your dose (see Warnings and Precautions, section 2).

If you forget to use this medicine

Do not use a double dose to make up for a forgotten individual dose. Apply the next dose at the usual time.

If you stop using this medicine

You should not stop therapy with this medicine unless told to do so by your doctor.

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)

- Because of the alcohol this medicine contains, frequent applications to the skin may cause:
 - irritation
 - skin dryness
 - acne

Uncommon (may affect up to 1 in 100 people)

This medicine may cause:

- headaches
- hair loss
- development of painful, tender or enlarged breasts
- changes to your prostate gland
- diarrhoea
- dizziness
- an increase in blood pressure

- changes to your mood
- increase 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, changes in lipid levels, skin hypersensitivity, stinging and loss of memory.

Other side effects have been observed during treatment with oral or injectable testosterone: weight gain, changes of the salt in the blood, muscular pain, nervousness, depression, hostility, breathing problem during sleep, yellowing of the skin (jaundice), changes in the results of tests that check how the liver is working seborrhoea, sex drive changes, reduction in the number of sperm, frequent or prolonged erections, blockages that may make it difficult to pass urine, water retention, hypersensitivity reactions.

Reporting of side effects

United Kingdom

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store TESTOGEL®

This medicinal product does not require any special storage conditions.

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 sachet. 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 this medicine contains

- The active substance is testosterone. One sachet of 2.5 g contains 40.5 mg of testosterone.
- The other ingredients are carbomer, isopropyl myristate, ethanol, sodium hydroxide, water.

What this medicine looks like and contents of the pack

This medicine is a colourless transdermal gel presented in a 2.5 g sachet.

This medicine is available in boxes of 1, 2, 7, 10, 14, 28, 30, 50, 60, 90 or 100 sachets (not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Besins Healthcare (UK) Ltd
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**This medicinal product is authorised in the Member States of the EEA
under the following names:**

Belgium, Ireland, Luxembourg: **Testogel 40,5 mg transdermal gel in sachet**
The Netherlands: **Testogel 40,5 mg transdermale gel in sachet**
Germany: **Testogel 40,5 mg transdermales Gel im Beutel**
Denmark, Iceland, Finland, Sweden, Norway: **Testogel**

For information in large print, tape, CD or Braille, telephone
+44(0)203862 0920.

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