

Package leaflet: information for the patient

Testogel® 40.5 mg, gel for transdermal use in sachet  
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? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, 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 listed in this leaflet? Then contact your doctor or pharmacist.

In this leaflet, Testogel 40.5 mg, gel for transdermal use in sachet is often referred to as 'this medicine'.

Contents of this leaflet

1. What is this medicine and what is it used for?
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## 1. What is this medicine and what is it used for?

This medicine contains testosterone, a male hormone produced by your body.

This medicine is used in adult men to supplement testosterone. It is used to treat health problems caused by low testosterone (hypogonadism in men). This must be confirmed by two separate measurements of testosterone in your blood. There must also be symptoms such as:

- impotence (unable to get an erection when sexually aroused)
- infertility
- low sex drive
- fatigue
- depressive moods
- bone loss due to low hormone levels

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

Who is this medicine for?

- only men may use this medicine.
- young men under 18 years should not use this medicine
- this medicine should not be used by women of any age
- note: women (especially those who are pregnant or breastfeeding) or children should not come into contact with this medicine or the areas of skin where this medicine has been applied

When should you not use this medicine?

- You have prostate cancer
- You have breast cancer
- You are allergic to one of the substances in this medicine. You can find these substances in section 6 of this leaflet.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

Before treatment with this medicine, it must be clear that you have low testosterone. Symptoms that indicate this include: fewer male characteristics, less muscle mass, feeling weak or tired, reduced libido, difficulty achieving or maintaining an erection. Blood tests should be able to confirm this.

Your doctor will conduct the necessary tests before you can use this medicine. Your doctor will then monitor you by conducting regular blood tests.

Are you experiencing any of the symptoms listed below? Or are you unsure? Then contact your doctor before using this medicine. This medicine can worsen these symptoms.

You have difficulty urinating because your prostate is larger than normal.

You have bone cancer – your doctor will measure the amount of calcium in your blood.

You have high blood pressure or are being treated for high blood pressure, as this medicine can increase blood pressure.

You have severe heart, liver, or kidney problems, as treatment with this medicine can cause severe issues such as fluid retention and potentially lead to heart failure (fluid in the lungs).

You have a heart condition where blood does not flow properly, blocking the blood supply to the heart.

Problems with blood clotting

- (thrombophilia; a blood clotting disorder that increases the risk of a blood clot in a blood vessel (thrombosis))
- Factors that increase the risk of a blood clot: previous blood clots, smoking, obesity, cancer, prolonged immobility, a family history of blood clots in the leg, lungs, or other organs at a young age (up to 50 years), aging.
- How to recognize a blood clot. Painful swelling of a leg, or a sudden change in skin color, such as turning white, red, or blue, sudden shortness of breath, sudden unexplained coughing with or without blood, sudden chest pain severe dizziness, severe abdominal pain, sudden vision loss. Seek emergency medical help if any of these symptoms occur.

You have epilepsy.

You suffer from migraines.

You have breathing problems during sleep (this is more likely if you are obese or have long-term lung problems).

Treatment with androgens may increase the risk of an enlarged prostate gland (your prostate is larger than normal. This is not dangerous) or prostate cancer. Before starting treatment and during treatment, the prostate should be regularly examined, as recommended by your doctor.

Do you have diabetes and use insulin to control the amount of sugar in your blood? Then treatment with testosterone can change your body's response to insulin. Your diabetes medication may need to be adjusted.

Are you experiencing severe skin reactions? Then the treatment should be adjusted and may even need to be stopped.

This medicine should not be used by women because it has virilizing effects (such as growth of body or facial hair, deepening of the voice, or changes in the menstrual cycle).

Information about additional checks

Your doctor should perform the following blood tests before and during treatment:

testosterone levels in the blood, complete blood count.

During treatment, you will be regularly monitored (at least once a year and twice a year if you are older or if your doctor believes you are at risk).

If you have been on testosterone (testosterone replacement therapy) for a very long time, you may experience too many red blood cells in your blood (polycythemia). You should have regular blood tests to ensure this does not occur.

KChildren and adolescents up to 18 years

This medicine is not recommended for:

- children, because there is no clinical data available on use in boys under 18 years.

Does another person accidentally come into contact with this medicine?

With frequent or prolonged physical contact, another person may come into contact with this medicine. This can cause side effects. In women, this can cause more hair growth on the face or body, a deeper voice, or changes in menstruation. In children, it can cause rapid growth, a larger penis or vagina, and early puberty (such as developing pubic hair). The risk of this is reduced if you wash the treated skin and cover it with clothing before contact with someone.

The following precautions are advised to ensure that another person does not come into contact with this medicine:

- wash your hands thoroughly with water and soap after using the gel
- cover the treated skin with clothing after the gel has dried. For example, with a T-shirt. Wait at least 1 hour before showering or bathing after using this medicine.
- Do you expect to come into close contact with someone with your bare skin? Then wash the treated skin well with water and soap beforehand. This removes any remaining testosterone. If this is not possible, wear clothing that covers the treated skin during contact, such as a shirt or a T-shirt.

Patients using this medication and who may come into physical contact with children should be extra cautious. Testosterone can penetrate clothing. Do you come into direct skin contact with children? Always follow the rules for using this medication (see section 3 of this leaflet). Cover the treated skin with clean clothing once the gel has dried. Also wash the treated skin with soap after at least 1 hour, as advised. Then cover the skin again with clean clothing before coming into physical contact with children.

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

- wash the skin that came into contact with this medication immediately with soap and water,
- contact a doctor if there are complaints such as: pimples (acne), changes in facial or body hair, deepening of the voice, changes in the menstrual cycle.
- in children, also watch for signs of early puberty and enlargement of the penis or vagina.

Preferably wait at least 1 hour after applying the gel before showering or bathing.

Are you using any other medications?

Are you using any other medications besides this one, have you recently done so, or are you planning to do so soon? Then tell your doctor or pharmacist, especially if you are using the following medications:

- blood thinners taken orally (oral anticoagulants)
- adrenal cortex hormones (corticosteroids, these are medications that reduce inflammation and allergic reactions)
- insulin (medications to control the amount of sugar in your blood). It may be necessary to lower the insulin dose when using this medication.

If any of the above points apply to you (or if you are unsure), contact your doctor or pharmacist before using this medication.

Especially these medications may require your medication dose to be adjusted.

Pregnancy, breastfeeding, and fertility This medication should not be used by women. If you use this medication, it may cause your body to temporarily produce less sperm.

Is your partner pregnant? Then you must follow the advice on how to ensure that others do not come into contact with the testosterone gel (see section above: "Does another person accidentally come into contact with this medication?").

Pregnant women should avoid any contact with areas where this medication has been applied. This medication can be harmful to the unborn baby because male characteristics may develop. If skin contact accidentally occurs, wash the contact area thoroughly with soap and water as soon as possible.

Driving and using machines

This medication does not affect the ability to drive or operate machines.

This medication contains alcohol (ethanol)

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

On damaged skin, this medicine may cause a burning sensation.

This product is flammable until it is dry. Therefore, be careful with heat and fire when using this medicine.

### 3. How to use this medicine?

This medicine should only be used by adult men.

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

The recommended dose is 1 sachet (or 2.5 grams of gel containing 40.5 mg testosterone) once daily, at approximately the same time preferably in the morning.

The daily dose can be adjusted by your doctor, per patient. Never use more than 2 sachets per day (5 grams of gel containing 81 mg testosterone).

How to apply the gel?

The patient should apply the gel themselves to clean, dry, healthy skin on both shoulders or both arms.

After opening the sachet, the entire contents must be squeezed out and immediately applied to the skin.

The gel should be gently spread in a thin layer over the skin. Do not rub the gel into the skin.

Allow the gel to dry for at least 3 to 5 minutes before dressing.

Wash hands thoroughly with water and soap after applying the gel.

Do not apply the gel to the genitals (penis and testicles), as the large amount of alcohol in the gel can cause local irritation.

Patients should be aware that other people (adult or child) should not come into contact with the area of the body where the gel has been applied.

Cover the skin where the gel has been applied with clean clothing (such as a T-shirt) after the gel has dried.

Wash the skin where you have applied the gel with water and soap before having physical contact with someone else (adult or child). Do this after the prescribed time of at least 1 hour has passed. Then cover the skin again with clean clothing.

Have you used too much of this medicine?

Ask your doctor or pharmacist for advice. You may be advised to wash the application site immediately, and your doctor may advise you to stop the treatment.

The following signs may indicate that you might be using too much of this medicine and you should contact your doctor:

you are easily angered or irritated

you are nervous

you are gaining weight

your penis becomes erect more often or stays erect longer (frequent or prolonged erections)

These complaints may mean that your dose of this medicine is too high and your doctor needs to adjust your dose (see section 2).

Have you forgotten 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 the treatment with this medicine unless your doctor has told you to do so.

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. Not everyone experiences them. This medicine can cause the following side effects:

Common (occur in less than 1 in 10 users)

- problems with your emotions
- emotional complaints. For example, problems with your mood, problems with emotions (mood disorders), anger, aggression, impatience, poor sleep, strange dreams, or increased sexual desire).
- dizziness
- a tingling, prickling, or numb feeling (paresthesia)
- your memory works less well (amnesia)
- being very sensitive when something or someone touches you (hyperesthesia)
- headache
- high blood pressure (hypertension)
- diarrhea
- hair loss (alopecia)
- skin rash with pink bumps and severe itching (urticaria)
- swelling of the breasts in men. Or of one breast (gynecomastia).
- complaints at the site of application
- changes in blood test results. Such as too many red blood cells in the blood (polycythemia) or fats in the blood (lipids).
- increased hematocrit. Hematocrit is the number that shows how many red blood cells are in your blood.
- increased hemoglobin. This is a protein in the red blood cells. This protein carries oxygen throughout the body.
- more red blood cells

Sometimes (occur in less than 1 in 100 users)

- severe high blood pressure
- hot flashes
- inflammation of a vein (phlebitis)
- pain in the mouth
- bloated/swollen abdomen
- pimples (acne)
- you have more hair than usual (hirsutism). All women can experience this.
- skin rash
- dry skin
- eczema with oily and scaly skin (seborrhea)
- sores on the skin
- itchy rash on your skin (contact dermatitis)
- changes in your hair color
- sensitive reaction upon application
- itching at the application site

- nipple problem
- prostate problems. The prostate is located below the bladder in men and adds fluid to the sperm.
- pain in the epididymis. The epididymis is located against the testicle in the scrotum.
- more frequent erections
- fluid in the skin where you see dimples when you press on it (pitting edema)
- elevated PSA. This is a substance in the blood that indicates if there are problems with the prostate.

Rare (occur in less than 1 in 1,000 users)

- the penis remains erect for a very long time and that hurts (priapism)
- liver cancer
- Very rarely (occurs in less than 1 in 10,000 users)

jaundice. This causes your skin and the whites of your eyes to turn yellow. obstruction in the urinary tract

- Unknown (cannot be determined from the available data)
- prostate cancer

you are very tired and have little energy (asthenia)

- being nervous
- depression
- being angry and aggressive
- your breathing stops briefly during sleep (sleep apnea)
- obstruction in the urinary tract
- muscle cramps
- having more or less interest in sex
- muscle cramps
- you feel sick or unwell (malaise)
- fluid retention (edema)
- you feel sick or you feel unwell (malaise)
- fluid retention (edema)
- allergic reactions
- weight gain
- changes in the salts in the body. Your body may then retain sodium, chloride, potassium, calcium, inorganic phosphate, and water. This occurs with a high dose and/or long treatment.
- skin irritation and dry skin with frequent use of this medicine (because it contains alcohol)
- more frequent fluid retention and edema

This medicine contains alcohol. Frequent use may cause skin irritation and dry skin.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How do you store this medicine?

There are no special storage conditions for this medicine.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the box and the label after EXP. It includes a month and a year. The last day of that month is the expiry date.

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

## 6. Contents of the package and other information

What substances are in this medicine?

- The active substance in this medicine is testosterone. One sachet of 2.5 grams contains 40.5 mg of testosterone.
- The other substances in this medicine are carbomer, isopropyl myristate, ethanol, sodium hydroxide, water.

What does Testogel 40.5 mg look like and what is in a package?

Testogel 40.5 mg is a colorless gel for the skin in a sachet of 2.5 grams.

This medicine is available in boxes with 1, 2, 7, 10, 14, 28, 30, 50, 60, 90, or 100 sachets. It may occur that not all packaging sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder  
Besins Healthcare Netherlands BV  
Servaasbolwerk 14  
3512 NK Utrecht  
Netherlands

Manufacturers

Laboratoires Besins International  
13, rue Périer  
92120 Montrouge  
France

or

Besins Manufacturing Belgium  
Groot-Bijgaardenstraat 128  
1620 - Drogenbos  
Belgium

Registered under:

RVG 126707

This medicine is registered in member states of the European Economic Area under the following names:

Netherlands: Testogel 40.5 mg, gel for transdermal use in sachet

Belgium, Luxembourg, Germany: Testogel 40.5 mg transdermal gel in sachet

Denmark, Iceland, Finland, Sweden, Norway: Testogel

Ireland, United Kingdom: Testogel 40.5 mg transdermal gel in sachet

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