

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Testogel 50 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? Then contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. 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 listed in this leaflet? Then contact your doctor or pharmacist.

In this leaflet, Testogel 50 mg, gel for transdermal use in sachet is further referred to as 'this medicine'.

Contents of this leaflet:

1. What is this medicine and what is it used for?
2. When should you not use this medicine or be extra careful?
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 this medicine and what is it used for?

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

This medicine is used in adult men as testosterone replacement (supplementation) for the treatment of various health problems caused by a lack of testosterone (male hypogonadism). This must be confirmed by two separate measurements of the amount of testosterone in the blood. Additionally, there must be clinical symptoms, such as:

- impotence,
- infertility,
- low sex drive,
- fatigue,
- depressive moods,
- bone loss caused by too little hormone,
- reduction of secondary sexual characteristics,
- change in body composition,
- inability to achieve/maintain an erection.

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? If you are allergic to any of the ingredients in this medicine. These substances can be found in section 6.
- When you suffer from prostate cancer,
- When you suffer from breast cancer.

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 indicating this include: fewer male characteristics, less muscle mass, feeling weak or tired, reduced sex drive, difficulty achieving or maintaining an erection. Blood tests should 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 due to an enlarged prostate gland. The prostate is located below the bladder in men.

you have bone cancer. Your doctor will check the calcium levels in your blood.

you have high blood pressure, or you are being treated for high blood pressure. This medicine can cause an increase in blood pressure.

you have a severe heart disease, liver disease, or kidney disease. Treatment with this medicine can cause severe problems due to water retention in your body. Sometimes this can be associated with heart diseases where your heart cannot pump blood properly due to excess fluid in the heart.

you have a heart disease where there is insufficient blood flow to the heart

you have problems with blood clotting (clotting causes a scab on a

wound)thrombophilia: a problem with blood clotting. This increases the risk of a blood clot getting stuck in a blood vessel or vein (thrombosis)

- o thrombophilia: a problem with blood clotting. This increases the risk of a blood clot becoming lodged in a blood vessel or vein (thrombosis)
 - o if you have a higher risk of blood clots in a vein due to, for example: previous blood clots in a vein, smoking, overweight, cancer, prolonged sitting or lying down. Or if someone in your family has had a blood clot in the leg, lung, or another organ at a young age (for example, younger than 50 years). Or as you get older.
 - o how do you recognize a blood clot? Your leg becomes swollen and painful. Or the color of the skin suddenly changes and becomes, for example, pale, red, or blue. You suddenly have difficulty breathing. You suddenly have a cough with blood. Or suddenly have chest pain. You are very dizzy or feel like you are about to faint. You have severe stomach pain. You suddenly see less well. Do you have any of these symptoms? Then contact a doctor immediately.
- you have a brain disease (epilepsy)

- you have attacks of severe headache (migraine)
- you have difficulty breathing during sleep. This happens more often if you are overweight. Or if you have had long-term lung problems.

Androgens can increase the risk of an enlarged prostate (benign prostatic hypertrophy) or prostate cancer. The prostate should be regularly examined, before and during treatment, according to your doctor's instructions.

Do you have diabetes and use insulin to control the amount of sugar in your blood? Then treatment with testosterone can affect how your body responds to insulin. Your diabetes medications may need to be adjusted.

Do you experience severe skin reactions? Then the treatment must be adjusted and possibly even stopped.

This medicine should not be used by women. It can cause male characteristics such as: more hair growth on the face or body, a deeper voice, or changes in menstruation.

Information about additional checks

Your doctor must check your blood before and during treatment. Your doctor checks the amount of testosterone in your blood and performs a complete blood count.

You will be regularly monitored during treatment. This happens at least once a year. Are you older or does your doctor think you are at higher risk? Then you will be monitored at least twice a year.

Are you being treated for a long time with medications that replace testosterone? Then too many red blood cells can develop in your blood (polycythemia). Your blood must be frequently tested to ensure this does not happen.

Children and adolescents up to 18 years

This medicine is not recommended for children, as there is no information on its use in boys up to 18 years.

Does another person accidentally come into contact with this medicine?

With frequent or prolonged physical contact, another person can come into contact with this medicine. This can cause side effects. In women, it 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 the development of pubic hair).

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

- wash your hands very well 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 think you will come close to someone with your bare skin? Then wash the treated skin well with water and soap beforehand. This removes any remaining testosterone. Is this not possible? Then wear clothing that covers the treated skin during contact, such as a shirt or a T-shirt.

Patients using this medicine and coming close to children must be extra careful. Testosterone can pass through clothing. Do you come into direct skin contact with children? Always follow the rules regarding the use of this medicine (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.

It is preferable to wait at least 1 hour between applying the gel and taking a bath or shower.

Are you using any other medicines?

Are you using any other medicines besides Testogel 25 mg, have you done so recently, or are you planning to do so soon? Then tell your doctor or pharmacist. Especially with the following medicines:

- oral anticoagulants (blood thinners),
- insulin. Insulin regulates the amount of sugar in the blood in diabetes. You may need to use less insulin if you are using Testogel 25 mg.
- medicines against inflammation (corticosteroids)

Does any of the above apply to you? Or are you not sure? Talk to your doctor or pharmacist before using this medicine.

These medicines may require an adjustment in your dose of this medicine.

Pregnancy, breastfeeding, and fertility

This medicine must not be used by women.

It is possible that the body produces fewer sperm cells due to this medicine. This can recover. This medicine must not be used by women who are pregnant or breastfeeding. 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.

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

Driving and using machines

This medicine does not affect the ability to drive or use machines.

This medicine contains alcohol

This medicine contains 3.6 grams of alcohol (ethanol)

It can cause a burning sensation on damaged skin.

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

3. How do you use this medicine?

This medicine for transdermal use should only be used by adult men.

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

The recommended dose is 5 grams of gel (i.e., 50 mg testosterone) to be applied once daily at approximately the same time, preferably in the morning.

Depending on the patient, the daily dose may be adjusted by your doctor, with the amount not exceeding 10 grams of gel per day.

How to apply the gel:

The gel must be applied by the patient themselves.

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

The gel should be carefully applied in a thin layer on the shoulders, arm, or abdomen. It is not necessary to rub the gel into the skin.

Allow the gel to dry for at least 3-5 minutes before getting dressed.

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

Do not apply to the genitals (penis and testicles), as the high alcohol content can cause local irritation.causes.

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.

Was the skin where you applied the gel washed 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.

Your doctor may advise you to wash the skin where you applied the gel and to stop the treatment.

Do you have the following complaints? Then contact your doctor. You may have used too much of this medicine:

- being easily angered or irritated
- being nervous
- gaining weight
- having a frequent or prolonged erection (priapism)

These complaints may mean that your dose of this medicine is too high. Your doctor may need to adjust your dose (see section 2: When should you be extra careful with this medicine?).

Did 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 discontinue treatment with this medicine unless your doctor has told you to.

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

Common (affect less than 1 in 10 users)

- problems with your emotions
- emotional complaints. For example, mood problems, emotional issues (mood disorders), anger, aggression, impatience, poor sleep, strange dreams, or increased sexual desire).
- feeling dizzy
- a tingling, prickling, or numb sensation (paresthesia)
- your memory is not working as 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 application site
- 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 normal (hirsutism). All women can have this.
- skin rash
- dry skin
- eczema with an 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 site of application
- nipple problem

- prostate problems. The prostate is located below the bladder in men and adds fluid to the sperm cells.
- 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 stiff for a long time and it hurts (priapism)
- liver cancer

Very rare (occur in less than 1 in 10,000 users) p de 10.000 gebruikers)

- jaundice. In this case, your skin and the whites of your eyes turn yellow.
- obstruction in the urinary tract

Not known (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
- shrinking of the testicles. This is because treatment with high doses of testosterone usually temporarily stops or reduces sperm production.
- you feel sick or unwell (malaise)
- fluid retention (edema)
- allergic reactions
- weight gain
- changes in the salts in the body. Your body may 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 medication (because it contains alcohol)
- more frequent fluid retention and edema

This medication 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 possible side effects not listed in this leaflet. You can also report side effects via the national reporting system: Netherlands Pharmacovigilance Centre Lareb website: www.lareb.nl

By reporting side effects, you help us obtain more information about the safety of this medication.

5. How do you store this medication?

There are no special storage conditions for this medication.

Keep out of the sight and reach of children.

Do not use this medication after the expiry date. You will find this on the box and sachet after EXP. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medications down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medications you no longer use. Proper disposal of medications ensures they are destroyed correctly and do not enter the environment.

6. Contents of the package and other information

What substances are in this medication?

- The active substance in this medication is testosterone. Each 5 g sachet contains 50 mg testosterone.
- The other excipients in this medicine are carbomer 980, isopropyl myristate, 96% ethanol, sodium hydroxide, and purified water.

What does this Testogel 50 mg look like and how much is in the package?

TESTOGEL 50 mg is a colorless gel packaged in a 5 gram sachet.

TESTOGEL 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).

It may happen that not all pack sizes are marketed.

Marketing authorization holder and manufacturer Registration holder

Besins Healthcare Netherlands B.V.
Servaasbolwerk 14
3512 NK Utrecht
The Netherlands

Manufacturers

Laboratoires Besins International
13, rue Périer
92120 Montrouge
France

or

Besins Manufacturing Belgium
Groot Bijgaardenstraat, 128
1620 Drogenbos
Belgium

Registered in the register under
RVG 27724.

This medicine is registered in EEA member states under the following names:

Belgium, Cyprus, Denmark, France, Finland, Ireland, Iceland, Luxembourg, Norway, Austria, Portugal, Spain, Sweden, Italy, TESTOGEL

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