

Package leaflet: information for the patient

Testogel® 16.2 mg/g, transdermal gel  
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? 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 mentioned in this leaflet? Then contact your doctor or pharmacist.

In this leaflet, Testogel 16.2 mg/g, transdermal gel is often 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 with it?
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 Testogel 16.2 mg/g and what is it used for?

This medicine contains testosterone, a male hormone produced by your body. Hormones are produced in different places in the body. They are important for how your body functions.

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. Also must there be symptoms such as:

- impotence (not getting an erection when sexually aroused)
- infertility are
- little desire for sex
- tired are
- depressive moods
- bone loss due to too little hormones
- fewer male characteristics
- lose weight
- unable to get or maintain an erection

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

For whom is this medicine?

- only men are allowed to use this medicine
- young men under 18 years old are not allowed to use this medicine
- this medicine must 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 or it is possible that you have it

You have breast cancer or it is possible that you have it

You are allergic to any of the ingredients in this medicine. You can find these ingredients 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 sex drive, difficulty getting or maintaining an erection. Blood tests should be able to confirm this.

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

Do you have any of the complaints listed below? Or are you unsure? Then contact your doctor before using this medicine. This medicine can make these complaints worse.

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 checks the amount of calcium in your blood.

you have high blood pressure, or you are being treated for high blood pressure. This medicine can cause a higher 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 too much fluid in the heart.

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

you have problems with blood clotting (due to clotting somewhere is a scab on a wound)

- o thrombophilia: a problem with blood clotting. This increases the risk of a blood clot getting stuck 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 at a young age (for example, younger than 50 years) has had a blood clot in the leg, lung, or another organ. Or if you get older ..
- o 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 trouble 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? 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 have impaired vision. Are you experiencing any of these symptoms? immediately contact a doctor. you have a brain disease (epilepsy)  
you have a disease of your brain (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 lung problems for a long time.

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. Prior to and during therapy, regular examination of the prostate gland should take place, as recommended by your doctor.

If you suffer from diabetes and use insulin to control your blood sugar levels, testosterone treatment can affect the response to insulin and your response to antidiabetic medication, and it may be necessary to adjust the dose of your diabetes medication.

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

This medicine should not be used by women because it has virilizing effects (such as growth of body or head 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 level 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).

Are you being treated with testosterone replacement medicines for a long time? Then too many red blood cells may develop in your blood (polycythemia). Your blood should be tested frequently 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 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, 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 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 medicine and coming close to children should be extra careful. Testosterone can pass through clothing. Do you come into direct skin contact with children? Always follow the rules about using 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 has passed, as advised. Then cover the skin again with clean clothing before coming into physical contact with children.

If you think another person (man, woman, or child) has come into contact with testosterone, this person should:

- wash the skin that has come into contact with this medicine immediately with soap and water
- contact a doctor if symptoms such as acne, changes in facial or body hair growth, deepening of the voice, or irregular menstruation occur.
- watch for symptoms in children such as early puberty or 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 medicines?

Are you using any other medicines besides Testogel 16.2 mg/g, have you recently done so, or are you planning to do so soon? Then tell your doctor or pharmacist, especially the following medicines:

oral anticoagulants (blood thinners taken by mouth)  
adrenal cortex hormones (corticosteroids, these are medicines that reduce inflammation and allergic reactions)  
insulin (medicines to control your blood sugar levels). It may be necessary to lower the insulin dose when using this medicine.

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

In particular, these medicines may require your dose of this medicine to be adjusted.

Pregnancy, breastfeeding, and fertility This medicine should not be used by women.

The production of sperm cells can be reversibly suppressed by the use of this medicine.

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 should 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 operate machines.

This medicine contains alcohol (ethanol)

This medicine contains 0.9 g of alcohol (ethanol) in each dose of 1.25 g gel.

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 to use this medicine?

This medicine 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 first use of the pump

Before using a new pump for the first time, you must prepare it as follows.

Remove the cap from the reservoir so that the plunger becomes visible.

Press the plunger three times.

The gel released by pressing three times for the first time should not be used. This dose must be safely disposed.

Your pump is now ready for use. You do not need to prepare it again.

Each time the plunger is pressed, 1.25 g of gel is delivered.

The recommended amount is to apply 2 pumps once daily at approximately the same time, preferably in the morning. The dose may be adjusted by your doctor and should not exceed 4 pumps per day.

Your doctor will tell you how often to press the plunger to get the right dose of gel for you. The table below provides more information about this.

Number of times pressed	Amount of gel (g)	Amount of testosterone applied to the skin (mg)
1	1.25	20.25
2	2.5	40.5
3	3.75	60.75
4	5.0	81.0

The gel should be carefully spread in a thin layer over a clean, dry, and healthy area of skin on both shoulders and upper arms. Do not rub the gel into the skin. Allow the gel to dry for at least 3-5 minutes before dressing. Wash your hands with water and soap after applying the gel.

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

Have you primed the pump as described above? Then the gel is ready for use.

#### How do you apply the gel?

The patient must apply the gel themselves.

1. Press the plunger down once to dispense the gel into the palm of your hand.
2. Choose a clean, dry, and healthy skin area on the shoulder and upper arm (see marked areas in the photo below).
3. Spread the gel gently and evenly over one shoulder and upper arm with your fingers. Do not rub it into the.
4. Are you using 2 pumps? Then repeat steps 1, 2, and 3 on the other shoulder and upper arm.
5. If you use 3 or more pumps, apply a maximum of 2 pumps to the first shoulder and upper arm and a maximum of 2 pumps to the other shoulder and upper arm.
6. Wash your hands with water and soap after applying the gel.
7. Allow the gel to dry completely before dressing.

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

Patients should be aware that other persons (adult or child) should not come into contact with the body part 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.

The gel must be applied by the patient themselves to clean, dry, healthy skin of both shoulders or both arms.

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 discontinue the treatment.

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

- rapid anger or irritation being
- 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 section 2: When should you be extra careful with this medicine?).

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 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 cause side effects. Not everyone will experience 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, mood problems, emotional issues (mood disorders), anger, aggression, impatience, poor sleep, strange dreams, or increased sexual desire).
- dizzy being
- 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)
- rash on the skin with pink bumps and severe itching (urticaria)
- swelling of the breasts in men. Or of one breast (gynecomastia).
- application site reactions
- 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
- thicker/swollen abdomen
- pimples (acne)
- you have more hair than usual (hirsutism). Only women can have this.
- skin rash
- dry skin
- eczema with oily and scaly skin (seborrhea)
- wounds on the skin
- itchy rash on your skin (contact dermatitis)
- changes in your hair color
- sensitive react when applying application
- itching at the site of application
- problem with the nipple

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 erect for a very long time and it is painful (priapism)
- liver cancer

Very rare (occur in less than 1 in 10,000 users)

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

Unknown (cannot be determined from the available data)

- prostate cancer
- you are very tired and have little energy (asthenia)
- nervous are
- depression
- angry and aggressive are
- your breathing stops briefly during sleep (sleep apnea)
- constipation 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 you feel unwell (malaise)
- fluid retention (edema)
- allergic reactions
- heavier become
- changes in the salts in the body. Your body can 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 often moisture retain and edema

This medicine contains alcohol. Frequent use can 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 label after EXP. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. If you dispose of medicines correctly, they are destroyed properly and do not enter the environment.

## 6. Contents of the package and other information

What substances are in this medicine?

The active substance in this medicine is testosterone.

The other substances in this medicine are carbomer 980, isopropyl myristate, 96% ethanol, sodium hydroxide, purified water.

What does this medicine look like and what is in a package?

Testogel 16.2 mg/g is a colorless gel delivered in a multi-dose gel pump, equipped with a dosing pump, containing 88 g of gel and delivering a minimum of 60 doses.

This medicine is available in boxes with one, two, three, or six packages.

It is possible that not all pack 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

of

Besins Manufacturing Belgium

Groot-Bijgaardenstraat 128

1620 - Drogenbos

Belgium

Registered under:

RVG 126594

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

Denmark: Testogel

Cyprus: Testogel 16.2 mg/g transdermal gel

Greece: Testogel 16.2 mg/g transdermal gel

Finland: Testogel 16.2 mg/g transdermal gel

Iceland: Testogel 16.2 mg/g transdermal gel

Malta: Testogel 16.2 mg/g transdermal gel

Norway: Testogel 16.2 mg/g transdermal gel

Sweden: Testogel

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Transtoyou