

TESTOGEL®

(TES-toe-gel)

testosterone

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Testogel. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Testogel against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT TESTOGEL IS USED FOR

Testogel is used to replace the body's natural hormone testosterone when not enough is made by the body.

Testosterone is a natural hormone, known as an androgen, which controls normal sexual development and function in men.

Testosterone is essential for the development and maintenance of the male reproductive organs as well as other male characteristics, such as facial and body hair growth, deep voice, sexual drive, muscle mass and body fat distribution.

Testogel is a testosterone-containing gel that is applied by the

patient daily to the skin. The testosterone passes from the gel through the skin and into the bloodstream at a steady rate.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

BEFORE YOU USE TESTOGEL

When you must not use it

Do not use Testogel if you have an allergy to:

- testosterone, the active ingredient in Testogel
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not use Testogel if you have or are suspected to have:

- prostate cancer
- breast cancer in males

Testogel must not be used by children under the age of 18 years.

The safety of Testogel in children under 18 years of age has not been established.

Testogel must not be used by women.

Do not allow women (especially women that are pregnant or breast-feeding), children or pets to come into contact with the medicine or the skin where this medicine has been applied.

Do not use this medicine after the expiry date printed on the pack.

The expiry date is printed on the carton after "EXP" (e.g. 11 18 refers to November 2018). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

Do not use this medicine if the packaging is torn or shows signs of tampering.

If the packaging is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have, or have had, any of the following medical conditions:

- high blood calcium levels associated with tumours (hypercalcaemia)
- high levels of calcium in the urine (hypercalciuria)
- high blood pressure or heart disease
- a tendency to retain fluid (signs may include swollen feet or ankles)
- liver or kidney disease
- thrombophilia (an abnormality of blood coagulation that

increases the risk of thrombosis- blood clots in blood vessels)

- epilepsy
- migraines
- diabetes
- sleep apnoea (abnormal pauses in breathing during sleep)
- polycythaemia (a blood disorder where too many red blood cells are being produced)

Testogel may quicken the growth of existing prostatic tumours and benign prostatic hyperplasia (enlargement of the prostate gland). It may also increase the risk of breast cancer in males.

Before treatment, your doctor should conduct tests to check that you do not have existing prostate or breast cancer.

If you use Testogel over long periods of time, you may develop an abnormal increase in the number of red blood cells in the blood (polycythaemia). Your doctor may organise regular blood counts to monitor this.

If you have not told your doctor about any of the above, tell them before you start using Testogel.

Athletes should note that the active substance, testosterone, may produce a positive reaction in anti-doping tests.

Misuse of androgens to enhance your physical ability in sport carries serious health risks and is discouraged. Use of androgens for reasons other than what your doctor prescribed carries a serious health risk and is strongly discouraged.

Application of sunscreen should not affect the way Testogel works.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Testogel may interfere with each other. These include:

- oral anticoagulants, medicines used to thin blood and to treat or prevent blood clots
- corticosteroids or adrenocorticotrophic hormone (ACTH), hormones used to control inflammation
- oxyphenbutazone, a medicine used to treat pain and inflammation
- insulin, a medicine used to control blood sugar levels (you may need to lower your dose of antidiabetic medicines)
- bupropion, a medicine used to aid in smoking cessation
- ciclosporin, a medicine used to suppress the immune system
- some herbal products.

These medicines may be affected by Testogel or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

HOW TO USE TESTOGEL

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions printed on the pharmacist label, ask your doctor or pharmacist for help.

How much to use

The usual starting dose for is 5g of gel per day. Your doctor or pharmacist will tell you exactly how much to use. You should not use

more than 10g of gel (100 mg testosterone) per day.

How to use it

Do not apply Testogel to the testes, scrotum or penis.

Do not let other persons (children and adults) or pets come into contact with the area of your body where you apply Testogel.

Each 1% bottle of Testogel contains 0.89g alcohol (ethanol) in each dose of 1.25g gel.

The high alcohol content may cause local skin irritation.

The product is flammable until dry. Care should be taken to avoid sources of heat/naked flames when applying the product.

Follow these steps when applying Testogel multidose pump:

1. Before using the pump for the first time it is necessary to prime the pump pack. With the pump in an upright position, slowly push down on the pump to fully depress 3 times. Do not use any of the Testogel that was dispensed during priming. Wash it down the sink or throw it in the trash can to avoid accidental exposure to others. Your Testogel pump is now ready to use.
2. Spread a thin layer of Testogel onto clean, dry, healthy skin over the upper arms, shoulders or stomach. It is not necessary to rub Testogel into the skin.
3. Allow the gel to dry for at least 3-5 minutes before dressing.
4. Wash your hands thoroughly with soap and water after applying the gel.
5. Once gel has dried, cover the application area with clean clothing (such as a T-shirt).
6. Do not shower or bathe for at least One (1) hour after applying Testogel.

Table 1 : Dosing Information for Testogel 1%

Amount of Testosterone	Number of Pump Actuations
50 mg	4 (once daily)
75 mg	6 (once daily)
100 mg	8 (once daily)

When to use it

Apply Testogel once per day at approximately the same time each day, preferably in the morning.

Using it at the same time each day helps maintain a steady level of testosterone in the blood. It will also help you remember when to apply it.

How long to use it

Testogel helps control the symptoms of your condition, but does not cure it. Therefore you must use Testogel every day.

When you have finished a pack, start the next pack on the following day. Never leave a break between packs.

Continue using Testogel for as long as your doctor tells you to.

If you forget to use it

If you forget to apply a dose, apply it as soon as you remember.

If you do not remember to apply the dose until the next dose is due, then just apply one dose.

Do not apply a double dose to make up for a forgotten individual dose.

If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre on 13 11 26 for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much Testogel. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE USING TESTOGEL

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Testogel.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

Keep all of your doctor's appointments.

Your doctor may monitor your blood pressure, examine your prostate and conduct other tests (including blood tests) at least annually and more often if you are elderly. This is to make sure the medicine is working and to check for unwanted side effects.

The use of Testogel may affect the results of certain laboratory tests.

If you are about to have any tests, tell your doctor that you are using this medicine.

Things you must not do

Do not use Testogel to treat any other complaints unless your doctor tells you to.

Do not give Testogel to anyone else, even if their symptoms seem similar to yours.

Do not stop using Testogel, or change the dosage, without checking first with your doctor.

If you stop using it suddenly, your condition may worsen or you may have unwanted side effects.

Things to be careful of

Testosterone may be transferred to another person during close physical contact at any time after dosing.

If contact occurs a number of times or for long periods of time this could cause the other person to show signs of increased testosterone such as more hair on the face and body and a deepened voice. In women, this may also cause changes in the menstrual cycle. In

children this may cause premature puberty and genital enlargement.

If these signs or symptoms of accidental exposure occur in children you should consult a doctor.

Unwanted transfer of testosterone to another person can be avoided by wearing clothes which cover the application area and/or by showering before contact.

You need to ensure that your partner, children and pets are not put at risk of receiving testosterone by accident.

You should leave a gap of 6 hours between applying Testogel and having intimate physical contact. You should also wear clothing such as a T-shirt to cover the gel application area and/or have a shower or bath beforehand washing the application area thoroughly with soap and water.

You should also follow these precautions before coming into close contact with women, children and pets.

If a woman or child does come into contact with Testogel, thoroughly wash the area of skin exposed to the gel with soap and water.

Pregnant women must avoid any contact with this medicine because the product may have adverse virilising effects on the foetus. In the event of accidental skin-to-skin contact your partner must thoroughly wash the area of contact as soon as possible with soap and water.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Testogel.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- skin reactions such as irritation, redness, dry or stinging skin and/or hives
- headaches
- prostatic disorders such as difficulty or pain while urinating, frequent urination
- painful, tender or enlarged breasts
- dizziness
- feeling of “pins and needles” or tingling sensation
- memory loss
- heightened senses
- mood changes
- anxiety
- high blood pressure
- diarrhoea
- hair loss
- changes in laboratory tests (polycythaemia, lipids)

These are the common side effects of Testogel.

Your doctor may need to conduct blood tests to monitor red blood cell counts and increased haemoglobin which can be affected by use of testosterone.

Tell your doctor immediately, or go to Accident and Emergency department at your nearest hospital if you notice any of the following:

- yellowing of the skin and eyes, also called jaundice
- 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 which can all be signs of a blood clot.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation if you experience one of these symptoms.

Other side effects that have been observed in rare or very low frequency

- benign liver tumours
- nervousness
- depression
- hostility
- breathing problems during sleep (sleep apnoea)
- muscle cramps
- balding
- acne
- urinary obstruction
- libido changes
- nausea
- reduction in good cholesterol levels (HDL)
- increased PSA levels
- hot flushes/flushing

Your doctor may need to monitor your blood pressure and conduct blood tests, as Testogel can increase your blood pressure and affect your liver function or profile.

You may not experience any specific symptoms.

Side effects associated with high doses or long term treatment include:

- increased tendency to retain fluid (signs may include swollen feet or ankles)
- weight gain
- electrolyte changes
- decreased sperm count, which may affect fertility and reduce the size of the testicles
- unwanted, frequent or prolonged and painful erections
- severe stomach pain or tenderness, which do not disappear within a short time.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

AFTER USING TESTOGEL

Storage

Keep Testogel in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave it in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

Testogel is a clear, colourless gel presented in a non-aerosol, metered-dose pump.

Each 100 mL metered-dose pump contains 880 mg of testosterone in 88 g of gel (delivers 60 actuations).

Each actuation delivers 12.5mg of testosterone in 1.25g of gel.

Ingredients

Testosterone - 12.5 mg per 1.25 g gel

- Testosterone

Inactive ingredients:

- carbomer 980
- isopropyl myristate
- ethanol
- sodium hydroxide
- purified water

Supplier

Made in France or Belgium for

Besins Healthcare
Australia Pty Ltd
Level 16, Tower 2, Darling Park,
201 Sussex Street,
Sydney, NSW 2000

Australian Registration Numbers

AUST R 227563

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