

TESTOGEL™

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 and how it works

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

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

Testosterone is essential for the development and maintenance of the male reproductive organs as well as other male characteristics, such as deep voice, increased muscle strength, hair growth etc.

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.

The testosterone in Testogel is identical to the naturally occurring testosterone present in the body.

Your doctor may prescribe Testogel for other reasons. Ask your doctor if you have any questions about why Testogel has been prescribed for you.

A doctor's prescription is required to obtain this medicine.

This medicine is not addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery.

For further information please talk to your doctor or pharmacist.

Before you use Testogel

When you must not use Testogel

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

- prostate cancer
- breast cancer

Do not use Testogel if you have an allergy to:

- testosterone
- any of the ingredients listed at the end of this leaflet

Testogel must not be used by children.

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

Pregnancy: Testogel must not be used by women.

Do not use it after the expiry date printed on the pack.

If you use it after the expiry date has passed, it may not work as well.

Do not use if it or the packaging does not look quite right, or if the packaging is torn or shows signs of tampering.

Before you start to use Testogel

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

- high blood pressure or heart problems
- a tendency to retain fluid (signs may include swollen feet or ankles)
- liver or kidney disease
- epilepsy
- migraines
- diabetes
- any form of cancer
- high levels of calcium in the blood (hypercalcaemia)
- high levels of calcium in the urine (hypercalciuria)
- enlargement of the prostate (signs may include difficulty passing urine or frequent passing of urine)

Testogel may increase the risk of benign prostatic hypertrophy (enlargement of the prostate gland) and/or prostate cancer. It may also increase the risk of breast cancer. During treatment, your doctor may monitor the effects of this medicine on the prostate gland and the breast.

Worsening of breathing problems during sleep has been reported during treatment with testosterone replacement in predisposed people. This is especially true in overweight people or people with lung problems.

People using testosterone replacement over long periods of time may develop polycythaemia (an abnormal increase in the number of red blood cells in the blood). Your doctor may organise regular blood tests to check this is not happening.

Sportsmen and women

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

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.

Also tell any doctor or dentist who prescribes another medicine for you that you are using Testogel.

Some medicines may be affected by Testogel or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

In particular:

- oral anticoagulants ('blood thinning' medications to treat or prevent blood clots)
- insulin (a medicine used to control blood sugar in diabetes)
- corticosteroids

How to use Testogel

How much to use

The usual starting dose is one 5 g sachet of gel per day. Your doctor or pharmacist will tell you exactly how much to use. You should not use more than 10 g of gel per day.

How to use it

Testogel is for use by adult men only.

Do not apply Testogel to the testes, scrotum or penis.
The high alcohol content may cause local irritation.

Follow these steps when applying Testogel:

1. Open the sachet(s)
2. Spread a thin layer of Testogel onto clean dry healthy skin over the upper arms, shoulders or stomach.
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. Cover the application area with clothing once the gel has dried.
6. Do not shower for at least six (6) hours after applying Testogel.

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 (telephone 131 126) if you think you or anyone else may have used too much Testogel.

While you are using Testogel

Things you must not do

Do not give Testogel to anyone else, even if they have the same condition as you.

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

Things to be careful of

Testosterone may be transferred to another person during close and relatively prolonged skin contact with the gel application area.

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.

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 make sure that your partner is 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.

You should also follow these precautions before coming into close contact with children.

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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Testogel. Ask your doctor or pharmacist to answer any questions you may have.

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 this list of possible side effects. You may not experience any of them.

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

- Skin reactions such as: irritation, redness, acne, dry or stinging skin
- Headaches, dizziness, 'pins and needles'
- Nausea
- Diarrhoea
- Retention of salt and water
- Swelling
- Increased blood pressure
- Painful, tender or enlarged breasts
- Hair loss
- Changes in your mood

These are the most common side effects of Testogel. Mostly these are mild and short-lived.

The following side effects have been observed during treatment with oral or injectable testosterone. These may also occur with Testogel. You may need urgent medical attention. Serious side effects are rare.

- Difficulty passing urine (this may be due to an enlarged prostate gland or prostate cancer)
- Jaundice (yellowing of the skin)
- Itchy skin
- Unwanted increased sex drive

- Depression/nervousness/irritability
- Weight gain
- Muscular pain
- Electrolyte changes (changes in the salts of the blood)
- Changes in the results of tests that check how your liver is working
- Oligospermia (reduction in the number of sperm)
- Unwanted priapism (frequent or prolonged and painful erections)

Other side effects not listed above may also occur in some patients.
Tell your doctor if you notice anything else that is making you feel unwell.

After using it

Storage

Please note the expiry date on the pack. Do not use after this date.

Store all medicines out of the reach of children.

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

Product description

What it looks like

Testogel comes in sachets of two sizes:

- 5 g

Packs contain 30 sachets.

Ingredients

Testogel is the brand name for a 1% testosterone gel presented in 5 g sachets.

Each sachet contains 50 mg (in 5 g gel) testosterone as active ingredient.

Testogel also contains as inactive ingredients:

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

Supplier

Bayer Australia Limited
ABN 22 000 138 714
875 Pacific Highway
Pymble
NSW 2073

Date of information

This leaflet was prepared in July 2007.

Testogel 5 g
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