

TESTOGEL[®]

16.2mg/g Testosterone

Transdermal gel

Consumer Medicine Information (CMI)

What is in this leaflet

Please read this leaflet carefully before you start using TESTOGEL.

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

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

This medicine is used in adult men for testosterone replacement to treat various health problems caused by a lack of testosterone (male hypogonadism). This should be confirmed by two separate blood testosterone measurements and also include clinical symptoms such as:

- impotence
- infertility
- low sex drive
- tiredness
- depressive moods
- bone loss caused by low hormone levels

Your doctor may have prescribed TESTOGEL for another reason.

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

This medicine is available only with a doctor's prescription.

Before you use TESTOGEL

When you must not use it

Do not use TESTOGEL if:

- you have or are suspected of having prostate cancer
- you have or are suspected of having breast cancer
- you are allergic to testosterone or any of the other ingredients of this medicine
- Children and young men under the age of 18 years should not use this medicine.
- This medicine should not be used by females of any age.
- Do not allow women (especially women that are pregnant or breast-feeding) or children to come into contact with TESTOGEL gel or the areas of skin where TESTOGEL has been applied.

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

Before you start to use it

Talk to your doctor or pharmacist before using this medicine, if you have or ever had any of the following:

- you have difficulty in passing urine (urinating) due to an enlarged prostate gland
- you have high blood calcium levels associated with tumours (hypercalcaemia)
- you have high blood pressure, or if you are treated for high blood pressure, as this medicine may cause a rise in blood pressure
- you have severe heart, liver or kidney disease, as treatment with this medicine may cause complications such as fluid retention, sometimes accompanied by (congestive) heart failure (fluid overload in the heart)
- you have ischaemic heart disease (which affects the supply of blood to the heart)
- blood clotting problems
 - such as Thrombophilia or other risk factors for developing blood clots
- you have epilepsy
- you have migraines

If you have not told your doctor about any of the above, tell them before you start using TESTOGEL, as using this medicine may make these conditions worse.

Your doctor will do the necessary tests before you can use this medicine and do follow-up checks by carrying out periodic blood tests.

TESTOGEL may increase the risk of an enlarged prostate gland or cause the growth of an existing prostate cancer. Regular examinations of the prostate gland before and during therapy should be performed, following your doctor's recommendations.

Worsening of breathing problems during sleep have been reported during treatment with testosterone in some people, particularly those who are very overweight or are already suffering from breathing difficulties.

If you have diabetes and you use antidiabetic medication to control your blood sugar levels, testosterone treatment may affect your response to your antidiabetic medication and may require a dose adjustment.

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

This medicine should not be used by women due to possible virilising effects (such as growth of facial or body hair, deepening of the voice or changes in the menstrual cycle).

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are using TESTOGEL.

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

- oral anticoagulants (medicines used to thin the blood)
- corticosteroids (medicines used to reduce inflammation)
- insulin (medicines used to control your blood sugar levels in diabetes). You may need to reduce your dose of insulin when using this medicine.

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

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking TESTOGEL.

How to use TESTOGEL

This medicine is for use by adult men only.

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Using the pump for the first time

Before using your new pump for the first time, you need to prepare it for use as follows:

- Remove the cap from the canister to reveal the plunger
- Press the plunger down three times
- **Do not use** the gel from the initial three actuations of the plunger. This dose should be safely discarded by wiping the excess with a tissue. Safely discard the used tissues to avoid transfer to women, children or pets.
- Your pump is now ready to use. You will not need to prime it again
- Each time the plunger is depressed it delivers 1.25g of gel

How much to use

The recommended dose is 2 pumps applied once daily at approximately the same time each day, preferably in the morning. The dose may be

adjusted by your doctor, and the maximum dose is 4 pumps actuations per day.

Your doctor will tell you how many depressions of the plunger to make to get the correct dose of gel for you.

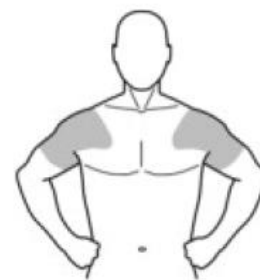
Please carefully follow your doctors instructions on how much and when to use the medicine.

After priming the pump as described above, the gel is now ready to be used.

How to apply the gel:

1. Press the plunger down once to dispense the gel into the palm of the hand.
2. Select a clean, dry and healthy area of skin on the shoulder and upper arm (see marked areas on the picture below).
3. Using your fingers, gently spread the gel evenly across one shoulder and upper arm. Do not rub it into the skin.
4. Repeat steps 2 and 3 on the other shoulder and upper arm.
5. If you are using 3 or more pumps, apply up to 2 pumps to the first shoulder and upper arm and up to 2 pumps to the other shoulder and upper arm.
6. After having applied the gel, wash your hands with soap and water.
7. You should allow the gel to dry completely for at least 3-5 minutes before dressing. Do not apply to the genital areas (penis and testes) as the

high alcohol content may cause local irritation.



When to use this medicine

The medicine should be applied once daily at approximately the same time each day, preferably in the morning.

How long to use this medicine

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. You should not stop therapy with this medicine unless told to do so by your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If 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.

While you are using TESTOGEL

Things you must do

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking TESTOGEL

The following blood checks should be carried out by your doctor before and during the treatment: testosterone blood level, full blood count.

You will have regular check-ups (at least once a year and twice a year if you are elderly or if your doctor considers you as a risk patient) during treatment.

If you receive testosterone replacement treatment over long periods of time you may develop an abnormal increase in the number of red blood cells in your blood (polycythaemia). You will need regular blood tests to check that this is not happening.

Things you must not do

Do not give TESTOGEL to anyone else, even if they

have the same condition as you.

This medicine is not to be used by women.

If your partner is or becomes pregnant or is planning to have a baby, you **must** follow the advice regarding avoiding transfer of the testosterone gel (see “**Possible transfer of testosterone**” in “Things to be careful of” section). Pregnant women must avoid **any** contact with this medicine, including application sites. This medicine may cause harm to the unborn baby.

In the event of contact your partner must wash the area of contact as soon as possible with soap and water.

Things to be careful of

Possible transfer of testosterone

During close skin-to-skin contact testosterone may be transferred to another person and could result in the other person showing 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).

The following precautions are recommended to protect against transfer:

- wash your hands with soap and water after applying the gel
- cover the application area with clothing once the gel has dried
- before close physical contact with another person (adult or child), wash the application site with soap and water once the recommended time period (at least 1 hour) has passed and cover the site again with clean clothing
- wear clothing (such as a sleeved shirt) covering the application site during contact periods with children

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

- wash the affected area of skin immediately with soap and water
- contact a doctor if they get signs such as acne, changes in the growth or pattern of hair on their body or face, deepening of the voice, changes in their menstrual cycle.
- For children signs of early puberty and genital enlargement should also be looked out for.

You should preferably wait at least 1 hour before showering or bathing after applying this medicine.

This medicine has no influence on the ability to drive or use machines.

The attention of athletes is drawn to the fact that this proprietary medicinal product contains an active substance (testosterone) which may produce a positive reaction in anti-doping tests.

This medicine contains alcohol (ethanol)

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

It may cause burning sensation on damaged skin.

This product is flammable until dry.

In case of overdose

If you use too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your 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.

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

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

- Irritability
- 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.

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 adverse effects.

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

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

Side effects (may affect up to 1 in 10 people)

- changes to your mood including:

- mood swings
- anger or aggression
- impatience
- sleeplessness
- abnormal dreams
- increased sex drive
- anxiety
- skin reactions including:
 - acne
 - hair loss
 - dry skin
 - skin irritation
 - hair colour changes
 - rash
 - sensitive skin
- increase in red blood cell count
- changes to the prostate gland (including increased blood levels of a protein called prostate specific antigen that is produced by the prostate).
- application site reaction
- allergic reaction

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible or go to the Accident and Emergency department if you notice any of the following side effects (may affect up to 1 in 100 people):

This medicine may cause:

- an increase in blood pressure
- flushing
- inflammation of the veins
- diarrhoea
- bloated stomach
- pain in the mouth
- development of breasts

- tender nipples
- pain in the testicles
- fluid retention
- increased erections
- yellowing of skin and eyes
- decreased sex drive
- headache
- tingling or numbness of the hands or feet
- abnormal body hair growth
- nausea
- muscle cramps
- blood clots
 - the following can all be signs of a blood clot: 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. Seek urgent medical attention if you experience one of these symptoms.
- Other side effects have been observed during treatment with this medicine: nervousness, tiredness, depression, electrolyte changes, persistent painful erections, excess secretion of oil from skin, dizziness, difficulty breathing, feeling sick, sweating, muscle or bone

pain, difficulty passing urine, reduced number of sperm, muscle weakness, feeling unwell, weight gain, sleep apnoea (temporarily stopping breathing while you sleep).

Because of the alcohol this medicine contains, frequent applications to the skin may cause irritation and skin dryness.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using TESTOGEL

Storage

Store below 30°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on carton and bottle. The expiry date refers to the last day of the month.

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.

Product description

What it looks like

TESTOGEL is a colourless transdermal gel presented in a multi-dose container with metering pump with 88 g gel and delivers a minimum of 60 doses.

This medicine is available in single packs.

Ingredients

Active ingredient:

Testosterone.
One gram of gel contains 16.2mg testosterone. One pump actuation delivers 1.25g of gel containing 20.25mg of testosterone.

Inactive ingredients:

Carbomer, isopropyl myristate, ethanol 96%, sodium hydroxide, purified water

Sponsor

TESTOGEL is supplied in New Zealand by:

Pharmaco (NZ) Ltd
4 Fisher Crescent
Mt Wellington
Auckland 1060
Phone (09) 377 3336

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This leaflet was prepared on
20 December 2024.