Package Leaflet: Information for the Patient

TESTOGEL® 16.2 mg/g Gel

Testosterone

Read all of this 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.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Testogel 16.2mg/g Gel will be referred to as "this medicine" throughout this leaflet.

What is in this leaflet:

1. What TESTOGEL® 16.2 mg/g Gel is and what it is used for
2. What do you need to know before you use TESTOGEL® 16.2 mg/g Gel
3. How to use TESTOGEL® 16.2 mg/g Gel
4. Possible side effects
5. How to store TESTOGEL® 16.2 mg/g Gel
6. Contents of the pack and other information

1. What TESTOGEL® 16.2 mg/g is and what it 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
- regression of masculine characteristics,
- reduced lean body mass,
- inability to have/maintain an erection.

2. What you need to know before you use TESTOGEL® 16.2 mg/g

Who can use TESTOGEL® 16.2 mg/g
- Only men can use this medicine.
- 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 this medicine or the areas of skin where this medicine has been applied.

Do not use this medicine
- if you have or are suspected of having prostate cancer
- if you have or are suspected of having breast cancer

- if you are allergic to testosterone or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor or pharmacist before using this medicine.

Before starting any treatment with this medicine, your testosterone deficiency must be clearly demonstrated by clinical signs (regression of masculine characteristics, reduced lean body mass, weakness or fatigue, reduced sexual desire/drive, inability to have/maintain an erection, etc.) and confirmed by laboratory tests. Your doctor will do the necessary tests before you can use this medicine and do follow-up checks by carrying out periodic blood tests.

If any of the below apply to you (or you are not sure), talk to your doctor before using this medicine as using this medicine may make these conditions worse.

- you have difficulty in passing water (urinating) due to an enlarged prostate gland
- you have bone cancer – your doctor will check your calcium levels
- 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 severe complications in the form of water retention in your body 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
    - (thrombophilia an abnormality of blood coagulation that increases the risk of thrombosis, blood clots in blood vessels)
    - factors that increase your risk for blood clots in a vein: previous blood clots in a vein; smoking; obesity; cancer; immobility; if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50); or as you get older.
    - how to recognise 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.
- you have epilepsy
- you have migraines
- you have breathing difficulties when you sleep - these are more likely to happen if you are overweight or have long term lung problems

Androgens may increase the risk of an enlarged prostate gland (benign prostatic hypertrophy) or prostate cancer. Regular examinations of the prostate gland before the beginning and during therapy should be performed to follow your doctor's recommendations.

If have diabetes and use insulin to control your blood sugar levels, testosterone treatment may affect your response to insulin and your antidiabetics' medication might need 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).

Information on additional monitoring
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.

Children and adolescents
This medicine is not recommended for children, as no clinical information is available for boys under 18 years

Possible transfer of testosterone
During repeated or prolonged periods of physical contact, this medicine may be transferred to another person. This may cause side-effects such as growth of facial or body hair, deepening of the voice or changes in the menstrual cycle of women, or accelerated height, genital enlargement, and early puberty (including development of pubic hair) in children.

The following precautions are recommended to protect against transfer:
- wash your hands thoroughly with soap and water after applying the gel
- once the gel has dried, cover the application area with clothing (such as a T-shirt), after applying this medicine patients should wait at least 1 hour before showering or bathing
- shower and wash the application area(s) thoroughly with soap and water to remove any testosterone residue before any situation in which close contact is foreseen or if not possible wear clothing such as a shirt or a T-shirt covering the application site during the contact period

Additional care should be taken by patients using this product who may be in close physical contact with children as testosterone may pass through clothing. Please make sure you follow the application technique (see section 3 of this leaflet) when in physical contact with children, including covering the application site with clean clothing once the gel has dried. Additionally, please wash the application site with soap once the recommended time period (at least 1 hours) has passed and cover again with clean clothing before physical contact with children.

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

- immediately wash the area of skin onto which may have been affected 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.

Other medicines and this medicine
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, particularly the following:
- oral anticoagulants (used to thin the blood)
- corticosteroids

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

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using this medicine.

These particular medicines may lead to your dose of this medicine being adjusted.

Pregnancy, breast-feeding and fertility
This medicine is not to be used by women.
Sperm production may be reversibly suppressed with this medicine.
If your partner becomes pregnant you **must** follow the advice regarding avoiding transfer of the testosterone gel.

Pregnant women must avoid **any** contact with this medicine's application sites because this product may have adverse virilising effects on the foetus. In the event of accidental skin-to-skin contact, as recommended above, thoroughly wash the area of contact as soon as possible with soap and water.

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

Sportsmen and women
The attention of sportsmen and women is drawn to the fact that this proprietary medicine contains an active substance (testosterone) that may produce a positive result in doping control 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.
Care should be taken to avoid sources of heat / naked flames when first administering the product, as ethanol is flammable until the gel has dried on the skin.

3. How to use TESTOGEL® 16.2 mg/g

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 these three depressions of the plunger. This dose should be safely discarded.
- Your pump is now ready to use. You will not need to prime it again
- Each time the plunger is depressed it delivers 1.25 g of gel

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. The table below gives you more information on this.

Number of Depressions	Amount of Gel (g)	Quantity 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

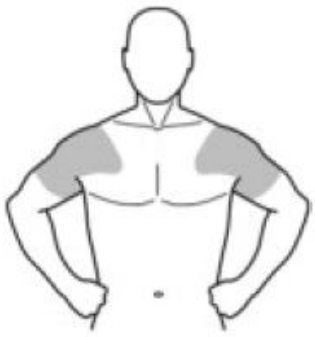
The gel must be gently spread onto clean, dry, healthy skin as a thin layer on both shoulders and upper arms. Do not rub it into the skin. Allow the gel to dry for at least 3-5 minutes before dressing. Wash your hands with soap and water after applying. Do not apply to the genital areas (penis and testes) as the high alcohol content may cause local irritation.

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

How to apply the gel:
The gel should be applied by the patient himself.

1. Press the plunger down once to dispense the gel into the palm of the hand.
2. Select a clean, dry and healthy skin area 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. If you are using 2 pumps, repeat steps 1, 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 before dressing.

Do not apply to the genital areas (penis and testes) as the high alcohol content may cause local irritation.



Patients should be informed that other persons (adult or child) should not come in contact with the area of the body where the gel has been applied.
Once the gel has dried, cover the application site with clean clothing (such as a t-shirt)
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 again with clean clothing.

The gel should be administered by the patient himself, onto clean, dry, healthy skin over both shoulders, or both arms.

If you use more of this medicine than you should

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 (see Warnings and Precautions, section 2).

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.

If you stop using this medicine
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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them:

Common side effects (may affect up to 1 in 10 people)

- mood disorders
- emotional symptoms (mood swings, affective disorder, anger, aggression, impatience, insomnia, abnormal dreams, increased libido)
- dizziness
- paraesthesia
- amnesia
- hyperaesthesia
- headache
- hypertension
- diarrhoea
- alopecia
- urticaria
- gynaecomastia
- application site reaction
- changes in laboratory tests (polycythaemia, lipids)
- haematocrit increased
- haemoglobin increased
- red blood cell count increased

Uncommon side effects (may affect up to 1 in 100 people)
This medicine may cause:

- malignant hypertension
- hot flushes/flushing
- phlebitis
- oral pain
- abdominal distension
- acne
- hirsutism
- rash
- dry skin

- seborrhoea
- skin lesions
- contact dermatitis
- hair colour changes
- application site hypersensitivity
- application site pruritus
- nipple disorder
- prostate-abnormalities
- testicular pain
- increased frequency of erections
- pitting oedema
- PSA increased

Rare (may affect up to 1 in 1000 people)
This medicine may cause:
- priapism
- hepatic neoplasm

Very rare (may affect up to 1 in 10'000 people)
This medicine may cause:
- jaundice
- urinary tract obstruction

Frequency not known (cannot be estimated from the available data)
This medicine may cause:
- prostate cancer
- asthenia
- nervousness
- depression
- hostility
- sleep apnoea
- urinary tract obstruction
- muscle cramps
- libido changes
- therapy with high dose of testosterone preparations commonly reversibly interrupts or reduces spermatogeneisis, thereby reducing the size of the testicles
- malaise
- oedema
- hypersensitivity reactions
- weight gain
- electrolyte changes (retention of sodium, chloride, potassium, calcium, inorganic phosphate and water) during high dose and/or prolonged treatment
- skin reactions (because of the alcohol contained in the product, frequent applications to the skin may cause irritation and dry skin)
- increases the occurrences of water retention and oedema

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

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance,
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store TESTOGEL® 16.2 mg/g

This medicinal product does not require any special storage conditions.

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

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What this medicine contains

- The active substance is testosterone.
- The other ingredients are Carbomer 980, isopropyl myristate, ethanol 96%, sodium hydroxide, purified water.

What this medicine looks like and contents of the pack

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

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

This medicine is available in packs containing one, two, three or six containers. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
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75003 Paris
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This medicinal product is authorised in the Member States of the EEA under the following names:
Austria, Belgium, France, Iceland, Luxembourg, Romania, The Netherlands, Czech Republic, Hungary: **Androgel 16,2 mg/g**
Germany, Ireland, United Kingdom, Spain: **Testogel 16.2 mg/g Gel**
Poland: **Androtop**
Slovenia: **Androtop 20,25 mg/sprožitev gel**

For Further information on this medicine, please contact Medical Information: 01-4004466

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