Approved Patient Information Leaflet for ANDROGEL

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 5

ANDROGEL

50 mg transdermal gel per 5 g sachet

Testosterone

Read all of this leaflet carefully before you start using ANDROGEL.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ANDROGEL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ANDROGEL is and what it is used for
2. What you need to know before you use ANDROGEL
3. How to use ANDROGEL
4. Possible side effects
5. How to store ANDROGEL
6. Contents of the pack and other information

1. What ANDROGEL is and what it is used for

ANDROGEL contains testosterone, which is a male hormone.

ANDROGEL is used to replace testosterone when the body is unable to produce enough on its own.

2. What you need to know before you use ANDROGEL

Do not use ANDROGEL:

- If you are hypersensitive (allergic) to testosterone or any of the other ingredients of ANDROGEL (listed in section 6).
- If you have or suspect you have prostate cancer.
- If you have or suspect you have breast cancer.

Warnings and precautions

Take special care with ANDROGEL:

- **ANDROGEL is only approved for men who have low levels of testosterone related to certain medical conditions. Examples of these conditions include genetic problems, and chemotherapy or infections that have damaged the testicles.**
- **ANDROGEL is not indicated for use in men who have low testosterone levels due to their age. Testosterone levels can decrease naturally as men age, and sometimes these levels can become lower than the normal range seen in young, healthy men. Ageing men can also experience signs and symptoms such as decreases in energy level and problems with sexual function, but it is uncertain whether these are caused by the lowered testosterone levels or due to normal ageing. Therefore, the need to replace testosterone in these ageing men is unclear.**
- **Heart attacks and strokes have been reported with testosterone treatment. Seek medical attention immediately if you have symptoms of a heart attack or stroke, such as:**
  - **chest pain**
  - **shortness of breath or trouble breathing**
  - **weakness in one part or one side of the body**
  - **slurred speech.**

Talk to your doctor if you have questions or concerns about ANDROGEL treatment.

Before starting any treatment with ANDROGEL, 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 2 separate laboratory tests carried out in the same laboratory.

ANDROGEL is not recommended for:

- The treatment of male sterility or impotence.
- Children, as no clinical information is available for boys under 18 years.
- Women, due to the possibility of developing male characteristics.

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 according to your doctor's recommendations.

If you are suffering from a severe heart, liver or kidney disease or ischaemic heart disease (a condition that affects the supply of blood to the heart), treatment with ANDROGEL may cause severe complications in the form of water retention in your body, sometimes accompanied by (congestive) heart failure. In this case, ANDROGEL treatment must be stopped immediately and diuretic therapy (water pills) may be required.

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

Tell your doctor if you have high blood pressure or if you are treated for high blood pressure, as testosterone may cause a rise in blood pressure.

ANDROGEL should be used with caution if you have or ever had a blood clotting problem called thrombophilia (when blood clots form too easily) or have the following 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, 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.

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 cancer that affects your bones, you may develop increased levels of calcium in your blood or urine. ANDROGEL may further affect these calcium levels. Your doctor may wish to check these calcium levels using blood tests during your treatment with ANDROGEL.

If you receive ANDROGEL 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.
ANDROGEL may also affect your blood fat profile and your liver function.

There is limited experience on the use of ANDROGEL if you are over 65 years of age. Currently, there is no consensus about age-specific testosterone reference values. However, it should be considered that physiologically testosterone serum levels are lower with increasing age.

ANDROGEL must be used with caution if you are suffering from epilepsy and/or from migraine, as these conditions may be made worse.

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

The following may indicate you are using too much ANDROGEL: irritability, nervousness, weight gain, frequent or prolonged erections. Report any of these to your doctor, who will adjust the daily dose of ANDROGEL.

Before starting treatment, your doctor will perform a full examination. He/she will need to take blood samples on 2 visits to measure your levels of testosterone before you are given ANDROGEL. You will have regular check-ups (at least once a year and twice a year if you are elderly or an at-risk patient) during treatment.

For diabetic patients:

ANDROGEL may affect blood sugar levels and may require a decrease in the dose of antidiabetic medicine. Your doctor may monitor your glucose and haemoglobin levels if you are being treated with ANDROGEL. If you notice a change in the results of your blood or urine sugar tests or if you have any questions, consult your doctor.

For sportsmen and women:

The attention of sportsmen and women is drawn to the fact that ANDROGEL contains an active substance (testosterone) which may produce a positive reaction in anti-doping tests.

Possible transfer of testosterone:

During periods of close skin contact testosterone may be transferred to another person, including children, unless you cover the treated area. This could cause your partner to show the signs of

increased testosterone, such as more hair on the face and body and a deepened voice. It may cause changes in the menstrual cycle of women. Wearing clothes covering the application area or showering before contact protects against such transfer.

The following precautions are recommended:

- wash your hands with soap and water after applying the gel,
- cover the application area with clothing once the gel has dried,
- wash the application area before intimate contact.

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

- wash the area of skin which may have been affected due to contact immediately with soap and water,
- report any signs such as acne or changes in the growth or pattern of hair on the other person's body or face to your doctor.

To make sure no one else is accidentally put at risk you should leave a long period of time between applying ANDROGEL and making contact. You should also either wear a T-shirt during times of close contact to cover the area where ANDROGEL has been applied or take a bath or shower before making contact.

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

Children and adolescents

ANDROGEL is not intended to be used in children and adolescents under the age of 18 years.

Other medicines and ANDROGEL

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Please consult with your doctor, pharmacist or health care provider for advice if you need to take any other medicines.

When you are using ANDROGEL, it is especially important that your doctor and pharmacist know if you are taking any of the following:

- oral anticoagulants (blood thinners)
- corticosteroids (used to treat inflammation, allergic reactions or asthma)
- antidiabetic medicines (used to treat diabetes (high blood sugar)).

Pregnancy and breastfeeding

ANDROGEL is intended for use by men only.

ANDROGEL is not to be used by pregnant or breastfeeding women.

Pregnant women must avoid any contact with the ANDROGEL application sites. ANDROGEL may cause the development of unwanted male characteristics in the developing baby. In the event of contact, as recommended above, wash the area of contact as soon as possible with soap and water.

If your partner becomes pregnant, you must follow the advice regarding avoiding transfer of ANDROGEL.

Driving and using machines

ANDROGEL does not directly affect your ability to drive or use machines. However, you may experience side effects during the treatment course which could make driving or using machines unsafe, such as dizziness. If you are affected, stop these activities immediately.

ANDROGEL contains alcohol (ethanol)

ANDROGEL contains 96 % *v/v* ethanol (alcohol).

It may cause burning sensation on damaged skin.

ANDROGEL is flammable until dry.

3. How to use ANDROGEL

Do not share medicines prescribed for you with any other person.

Always use ANDROGEL exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are not sure.

ANDROGEL must be applied to the skin.

For adult and elderly men

The recommended dose is 5 g of gel (i.e. 50 mg of testosterone) applied once daily at about the same time, preferably in the morning.

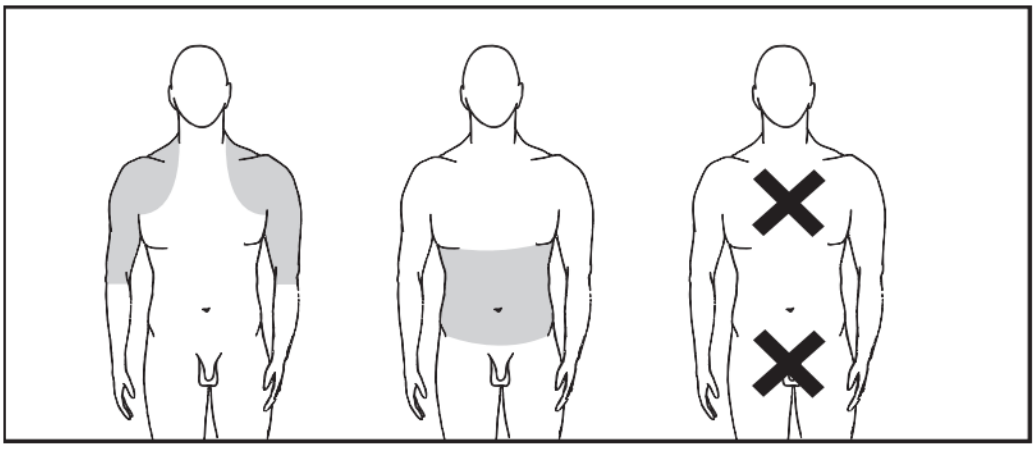
The adjustment of posology should be achieved in steps of 2,5 g of gel.

The daily dose may be adjusted by your doctor, on an individual patient basis, not exceeding 10 g of gel per day.

Apply ANDROGEL yourself, onto clean, dry, healthy skin over both shoulders, both arms or abdomen. After opening a sachet, the total contents must be removed from the sachet and applied immediately onto the skin. The gel should be gently spread on the skin as a thin layer. It is not necessary to rub it on the skin.

Allow drying for at least 3 – 5 minutes before dressing. Wash hands with soap and water after applications.

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



If you apply more ANDROGEL than you should

In the event of overdosage or unintentional oral ingestion, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to apply ANDROGEL

If you have missed your dose by only a few hours, apply the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and apply ANDROGEL at the next regularly scheduled time. Do not apply a double dose to make up for forgotten individual doses.

4. Possible side effects

ANDROGEL can have side effects.

Not all side effects reported for ANDROGEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while you are using ANDROGEL, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop using ANDROGEL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ANDROGEL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- breathing problems during sleep

- asthma
- difficulty or painful urination, less urine than what is normal for you.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

Frequent side effects

- mood disorders
- loss of memory
- headache
- dizziness
- tingling in hands and feet
- excessive physical skin sensitivity (hyperaesthesia)
- high blood pressure
- diarrhoea
- redness of your skin, acne, dry skin
- hair loss (temporary)
- prostatic disorders
- enlargement of male breasts or pain in the breasts
- reaction at the application site
- changes in laboratory tests results.

Less frequent side effects

- weight gain
- electrolyte changes during high dose and/or prolonged treatment
- feeling nervous, depressed, angry, anxious or irritable
- nausea (feeling sick)
- yellowing of skin and eyes (also called jaundice)
- oily skin, acne, balding

- itching skin
- muscle pain and cramps
- sex drive changes, frequent or prolonged erections
- persistent or painful erection
- reduction in the number of sperm, reduced size of testicles
- prostate cancer
- swelling due to water retention.

Because of the alcohol contained in ANDROGEL, frequent applications to the skin may cause irritation and dry skin.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of ANDROGEL.

5. How to store ANDROGEL

Store at or below 25 °C.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What ANDROGEL contains:

The active substance is testosterone.

The other ingredients are carbopol 980, ethanol 96 % *v/v*, isopropyl myristate, purified water and

sodium hydroxide (pH adjuster).

What ANDROGEL looks like and contents of the pack:

ANDROGEL is a transparent or slightly opalescent, colourless gel in a sachet.

5 g PET/aluminium/PE sachets.

Pack sizes: 1, 2, 7, 10, 14, 28, 30, 50, 60, 90 or 100 sachets.

Not all pack sizes may be marketed.

Holder of the certificate of registration:

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