

## PATIENT INFORMATION LEAFLET FOR ANDROGEL

### SCHEDULING STATUS

Schedule 5

### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

**ANDROGEL** gel in sachet

### 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 or your pharmacist.
- **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.

### 1. WHAT **ANDROGEL** CONTAINS

The active ingredient of **ANDROGEL** is testosterone.

One sachet of 5 g contains 50 mg of testosterone.

#### Inactive ingredients:

Carbopol 980, ethanol 96 % v/v, isopropyl myristate, sodium hydroxide and purified water.

### 2. WHAT **ANDROGEL** IS USED FOR

Testosterone is a male hormone.

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

**ANDROGEL** is available only with your doctor's prescription and is only recommended for the use as indicated.

### 3. BEFORE YOU USE ANDROGEL

#### Do not use ANDROGEL:

- If you are hypersensitive (allergic) to testosterone or any of the other ingredients of **ANDROGEL** (see **WHAT ANDROGEL CONTAINS**).
- If you are suffering from prostate cancer.
- If you are suffering from breast cancer.

#### 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 for no reason other than 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 any 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.

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.

**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.

Response to Clinical recommendation dated: 20 September 2017

*For diabetic patients:*

**ANDROGEL** may affect blood sugar levels. If you notice a change in the results of your blood or urine sugar tests or if you have any questions, check with 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 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,
- take a shower 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 bathe or shower before making contact.

You should preferably wait at least 6 hours between applying the gel and taking a bath or shower.

### **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 machinery**

You should not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how **ANDROGEL** affects you.

### **Using other medicines with ANDROGEL**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. 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).

#### 4. 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. You should check with your doctor or pharmacist if you are unsure.

**ANDROGEL** must be applied to the skin.

##### ***For adult and elderly men:***

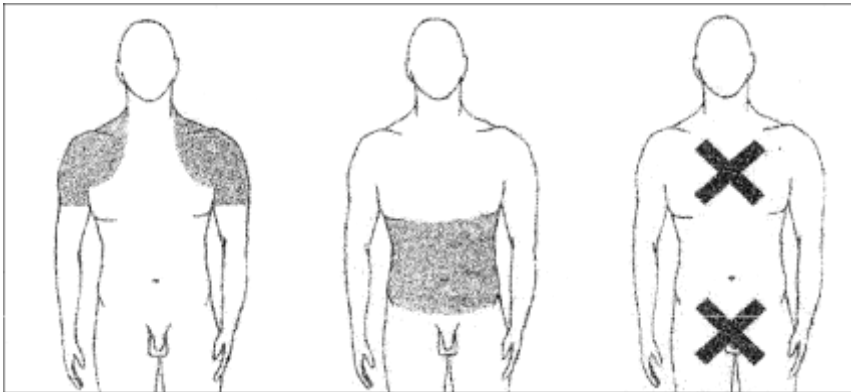
The recommended dose is 5 g of gel (i.e. 50 mg of testosterone) applied once daily at about the same time, preferably in the morning.

The 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, or 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 simply has to 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 testes) as the high alcohol content may cause local irritation.

**If you use more ANDROGEL than you should:**

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

**If you forget to use ANDROGEL:**

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

**5. 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 using ANDROGEL, please consult your doctor, pharmacist or other healthcare professional 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, 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:

*The following side effects occur frequently:*

- Mood disorders.
- Loss of memory.
- Weakness.
- Headache.
- Dizziness.
- Tingling in hands and feet.
- Excessive physical skin sensitivity (hyperaesthesia).
- High blood pressure.
- Diarrhoea (watery stools).
- 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.
- Increase in haematocrit (ratio of the volume of red blood cells to the total volume of blood), red blood cell count and haemoglobin (the component of red blood cells that carries oxygen).

*The following side effects may occur less frequently:*

- Weight gain.
- Electrolyte changes during high dose and/or prolonged treatment.
- Feeling nervous, depressed, angry, anxious or irritable.
- Stomach cramps or upset.
- Inflammation, pain or tenderness of your gums.
- Nausea.
- Yellowing of skin and eyes (also called jaundice).
- Changes in taste.
- Toothache.
- Oily skin, balding.
- 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.
- Tiredness.

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.

## 6. STORING AND DISPOSING OF ANDROGEL

Store at or below 25 °C.

Do not keep outdated or medicines no longer needed. Be sure that any discarded medicine is out of reach of children.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

## 7. PRESENTATION OF ANDROGEL

5 g in sachet (PET/aluminium/PE).

Boxes of 1, 2, 7, 10, 14, 28, 30, 50, 60, 90 or 100 sachets.

Not all the pack sizes may be marketed.

## 8. IDENTIFICATION OF ANDROGEL

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

## 9. REGISTRATION NUMBER

A40/21.7/0260

## 10. NAME AND ADDRESS OF REGISTRATION HOLDER

Medi Challenge (Pty) Ltd

Fancourt Office Park

Block 13, Loft

Felstead Road

North Riding

Johannesburg

## 11. DATE OF PUBLICATION

Date of registration: 1 October 2010.