PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

TELGEN® 40 Tablets

TELGEN® 80 Tablets

Read all of this leaflet carefully before you start taking TELGEN®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other health care provider.
- TELGEN® 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 TELGEN® is and what it is used for

TELGEN® contains telmisartan.

Telmisartan in TELGEN® belongs to a group of medicines called Vascular medicines (other hypotensives), which is used for the treatment of high blood pressure. This is also known as essential hypertension.

TELGEN® is used to reduce cardiovascular events (i.e. heart attack or stroke) death in patients 55 years or older who are at high risk of cardiovascular disease; the benefit of treatment is evident after at least 6 months of continued treatment.

2. What you need to know before you take TELGEN®

Do not take TELGEN® (telmisartan) if you are pregnant, are considering becoming pregnant or are breastfeeding. A switch to a suitable alternative treatment should be carried out in advance of planned pregnancy.

Do not take TELGEN®:

- If you are allergic to telmisartan, or any of the other ingredients of TELGEN® (listed in section 6).
- If you have previously been treated with a medication in the same group of medicines as TELGEN® (angiotensin receptor antagonists) or with a medication in the group of medicines known as ACE inhibitors and have had allergic reactions with swelling of the face, lips, tongue, and or throat with difficulty in swallowing or breathing.
- If you suffer from inherited or of unknown cause or spontaneous angioedema (swelling of the face, lips, tongue, and or throat with difficulty in swallowing or breathing).
- If you have obstruction of the heart's blood vessels (left ventricle outflow).

- If you have severe kidney function impairment.
- If you have narrowing of the blood vessel of the kidney on both sides.
- If you have narrowing of the blood vessels in the kidney if you only have one kidney.
- If you have narrowing of the heart's aortic blood vessel.
- If you are taking TELGEN® together with potassium sparing diuretics (water tablets) such as spironolactone, triamterene, amiloride.
- If you have a rare blood pigment disorder called porphyria.
- If you are taking TELGEN® together with lithium, as this may lead to toxic blood concentrations of lithium.
- Pregnancy and breastfeeding (see **Pregnancy and Breastfeeding**).
- If you have severe liver disease or biliary obstruction (a problem with the drainage of the bile from the gall bladder).
- If you have rare hereditary condition called sorbitol intolerance.
- If you are currently taking aliskiren-containing products.
- If you are taking fluoroquinolones (class of medicines used to treat infections).

Warnings and precautions

Take special care with TELGEN®:

- if you suffer from kidney disease or have had a kidney transplant.
- if you suffer from liver problems.
- if you have heart problems.
- if your body could be lacking salt due to a low salt diet, or if you have recently lost a lot of body fluids due to taking strong diuretic medicines (water tablets), vomiting or diarrhea (loose stools).

- if you have high potassium levels in your blood or use salt substitutes containing potassium.
- if you have been told previously that you have raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals).
- if you have diabetes (too much sugar in the blood) symptoms include excessive thirst, increased appetite with weight loss and passing large amounts of urine and/or elderly (>70 years)

TELGEN® may be less effective in lowering the blood pressure in black patients.

If you are taking medicines used to treat high blood pressure (an ACE-inhibitor such as enalapril, lisinopril, ramipril); or fluoroquinolones (class of medicines used to treat infections such as ciprofloxacin, levofloxacin).

Your doctor may check your kidney function at regular intervals.

Other medicines and TELGEN®:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Your doctor may need to change the dose of these other medicines or take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below taken at the same time with TELGEN®:

- Lithium containing medicines to treat some types of depression.
- Medicines that may increase blood potassium levels such as
  - salt substitutes containing potassium,
  - potassium-sparing diuretics (certain ‘water tablets’),
  - ACE inhibitors (used to treat high blood pressure e.g. enalapril, lisinopril, ramipril),

- angiotensin II receptor antagonists (used to treat high blood pressure e.g. valsartan, losartan),
- NSAIDs (non-steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen),
- heparin (used to thin blood),
- immunosuppressives (used to prevent organ rejection e.g. cyclosporin or tacrolimus), and
- antibiotic trimethoprim (used to treat infection)
- fluoroquinolones (class of medicines used to treat infections e.g. ciprofloxacin, levofloxacin, moxifloxacin).

- Diuretics ('water tablets'), especially if taken in high doses together with TELGEN, may lead to excessive loss of body water and low blood pressure (hypotension).
- Alskiren (used to treat high blood pressure)
- Medicines for heart problems, high blood pressure that your doctor does not know about (e.g. digoxin)

The effect of TELGEN® may be reduced when you take NSAIDs (non-steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen) or corticosteroids (used to provide relief for inflammation).

TELGEN® may increase the blood pressure lowering effect of other medicines used to treat high blood pressure or of medicines with blood pressure lowering potential (e.g. baclofen, amifostine). Furthermore, low blood pressure may be aggravated by alcohol, barbiturates, narcotics or antidepressants. You may notice this as dizziness when standing up. You should consult with your doctor if you need to adjust the dose of your other medicine while taking TELGEN®.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Do not take TELGEN® if you are pregnant or breastfeeding. If you become pregnant while taking TELGEN®, stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking TELGEN® by using suitable contraception.
TELGEN® can cause toxicity in the embryo, foetal and neonatal deaths when given to pregnant women. Women of childbearing age should use effective contraception.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:

When driving vehicles or operating machinery, it should be borne in mind that dizziness or drowsiness may occasionally occur when taking blood pressure lowering medication, including TELGEN®.

TELGEN® contains sorbitol:

TELGEN® tablets contain sorbitol. If you have been told that you have an intolerance to some sugars, you should not take TELGEN®.

3. How to take TELGEN®

Do not share medicines prescribed for you with any other person.
Always take TELGEN® tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that TELGEN® is too strong or too weak, talk to your doctor or pharmacist.

TELGEN® tablets are only for adults should not be taken by children and adolescents up to 18 years.

TELGEN® is usually taken in a dose of one 40 mg or 80 mg tablet once daily, preferably at about the same time each day, and swallowed with a drink of water.

Your doctor may prescribe TELGEN® in combination with other blood pressure lowering medicines.

If you take more TELGEN® than you should:

In the event of overdosage or accidental intake, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take TELGEN®:

If you miss a dose of TELGEN®, take it as soon as you remember on the same day. If you do not take your tablet on that same day, take your normal dose on the next day. Do not double the dose to make up for forgotten individual doses.

4. Possible side effects

TELGEN® can have side effects.

Not all side effects reported for TELGEN® are included in this leaflet. Should your general health worsen or you experience any untoward effects while taking TELGEN®, please consult your doctor, pharmacist, or other health care professional for advice.

If any of the following happens, stop taking TELGEN® and tell your doctor immediately

or go to the casualty department at your nearest hospital:

- sudden allergic reaction including signs like rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath or trouble breathing (anaphylactic reaction)
- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing (angioedema),
- sepsis (often called "blood poisoning", is a severe infection with whole-body inflammatory response which can lead to death)
- allergic reaction

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TELGEN®. 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:

- urinary tract infections (including inflammation of the bladder),
- upper respiratory tract infections (e.g. sore throat or feeling of tension or fullness in the nose)
- bleeding or bruising more easily than normal due to low blood platelet count (thrombocytopenia)
- dizziness on standing up, especially when getting up from a sitting or lying position (orthostatic hypotension)
- progressive scarring of lung tissue (interstitial lung disease)
- skin rash with inflammation of the skin, marked by itching and rash and often including blisters that weep and become crusted (eczema)
- flu-like symptoms, such as high temperature, sore throat, runny nose, cough

and chills (influenza-like symptoms)

- low blood sugar levels (in diabetic patients)
- kidney problems including symptoms, little or no urine, drowsiness, nausea, vomiting, breathlessness

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

Tell your doctor if you notice any of the following:

Frequent:

- cough

Less frequent:

- chest pain
- a condition in which the amount of oxygen-carrying pigment (haemoglobin) in the blood is below normal due to decreased number of red blood cells, symptoms includes tiredness, headaches, being short of breath when exercising, dizziness and looking pale (anaemia)
- abdominal pain, diarrhea (loose stools), indigestion, stomach discomfort vomiting; loss of taste, dry mouth, flatulence
- joint pain, muscle tenderness, back pain, cramps in the legs or leg pain;
- anxiety, depression, difficulty sleeping;
- fainting drowsiness, abnormal vision, dizziness;
- changes in the heart-rate, low blood pressure, shortness of breath
- increased sweating, skin rashes and itching, hives, severe drug rash, redness of the skin (erythema)
- sore tendons, weakness.

Effect on laboratory tests

There may be changes in the results of certain laboratory tests.

- high potassium levels in the blood (hyperkalaemia)
- Increase in some white blood cells (eosinophilia)
- abnormal liver function or enzyme levels/liver problem, increased hepatic enzymes or creatine phosphokinase in the blood
- decreased haemoglobin level in blood
- increased level of creatinine in the blood
- increased levels of uric acid

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, pharmacist or nurse. 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 TELGEN®.

5. How to store TELGEN®

Store at or below 25 °C in the original package, protected from light and moisture. Do not remove the blister strips from the carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not store in bathrooms in order to protect from moisture.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems e.g. toilets.

6. Contents of the pack and other information

What TELGEN® contains

TELGEN® 40

The active substance is telmisartan 40 mg

Contains sugar: sorbitol 174,64 mg per tablet.

Contain sodium hydroxide 3,36 mg per tablet.

TELGEN® 80

The active substance is telmisartan 80 mg

Contains sugar: sorbitol 349,28 mg per tablet.

Contains sodium hydroxide 6,72 mg per tablet.

TELGEN® also contains the following inactive ingredients:

Magnesium stearate, meglumine, povidone, sodium hydroxide and sorbitol.

Carton contains 30 tablets packed in desiccant embedded silver cold form blisters or silver cold form blisters of 10 tablets each.

What TELGEN® looks like and contents of the pack

TELGEN® 40

Off white to light yellow coloured, oblong tablets, debossed with **'T12'** on one side and plain on other side.

TELGEN® 80

Off white to light yellow coloured, oblong tablets, debossed with **'T13'** on one side and

plain on other side.

Holder of Certificate of Registration

RANBAXY (SA) (PTY) LTD

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