Each tablet contains either 40 or 80 mg Telmisartan

Professional Information

SCHEDULING STATUS

S3

1 NAME OF THE MEDICINE

TELGEN® 40 (Tablets)

TELGEN® 80 (Tablets)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

TELGEN® 40

Each tablet contains telmisartan 40 mg.

Contains sugar: sorbitol 174,64 mg per tablet.

Contain sodium hydroxide 3,36 mg per tablet.

TELGEN® 80

Each tablet contains telmisartan 80 mg.

Contains sugar: sorbitol 349,28 mg per tablet.

Contains sodium hydroxide 6,72 mg per tablet.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

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.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of mild to moderate hypertension, either alone or in combination with hydrochlorothiazide.

Reduction of cardiovascular morbidity and mortality in patients 55 years or older at high risk of cardiovascular disease; the benefit of treatment is evident after at least 6 months of continued treatment.

4.2 Posology and method of administration

Posology

Adults

Treatment of essential hypertension in adults:

The recommended dose is 40 mg once daily. In cases where the target blood pressure is not achieved, the TELGEN® dose can be increased to a maximum of 80 mg once daily. Alternatively, TELGEN® may be used in combination with a low dose thiazide diuretic such as hydrochlorothiazide 12,5 mg, which has been shown to have an additive blood pressure lowering effect with TELGEN®. When considering raising the dose, it must be borne in mind that the maximum antihypertensive effect is generally attained four to eight weeks after the start of treatment.

Reduction of cardiovascular morbidity and mortality:

The recommended dose is 80 mg once daily. It is not known whether doses lower than 80 mg of TELGEN® are effective in reducing cardiovascular morbidity and mortality.

When initiating TELGEN® therapy for the reduction of cardiovascular morbidity and mortality, monitoring of blood pressure is recommended and, if appropriate, adjustment of medications that lower blood pressure may be necessary.

The benefit of treatment is evident only after 6 months of continued treatment.

Special populations

Renal impairment:

No dosage adjustment is required for patients with mild to moderate renal impairment. TELGEN® is not removed from blood by haemofiltration.

Hepatic impairment:

In patients with mild to moderate hepatic impairment the dosage should not exceed 40 mg once daily.

Elderly:

No dosing adjustment is necessary.

Paediatric population

Children and adolescents up to 18 years:

There are no data on the safety and efficacy of TELGEN® in children and adolescents up to 18 years.

4.3 Contraindications

- Hypersensitivity to any of the components of TELGEN® listed in section 6.1.
- A history of angioedema related to previous therapy with ACE inhibitors or angiotensin receptor blockers (ARBs): Such patients must never again be given these medicines.

- Hereditary or idiopathic angioedema.
- Hypertrophic obstructive cardiomyopathy (HOCM).
- Severe renal function impairment (creatinine clearance less than 30 mL/min).
- Bilateral renal artery stenosis.
- Renal artery stenosis in patients with a single kidney.
- Aortic stenosis.
- Concomitant therapy with potassium sparing diuretics such as spironalactone, triamterene, amiloride (See section 4.4).
- Porphyria.
- Lithium therapy: Concomitant administration with TELGEN® may lead to toxic blood concentrations of lithium (see section 4.5).
- Pregnancy and lactation (see Section 4.4 and 4.6)
- Severe hepatic impairment
- Obstructive biliary disorders
- In case of rare hereditary conditions that may be incompatible with sorbitol, an excipient of the product, the use of TELGEN® is contra-indicated (see Section 4.4).
- The concomitant use of TELGEN® with aliskiren-containing products is contraindicated (see Section 4.4 and 4.5).
- Concomitant use of fluoroquinolones with ACE inhibitors/renin-angiotensin blockers is contraindicated in patients with moderate to severe renal impairment (Creatinine Clearance ≤30 mL/min) and in elderly patients.

4.4 Special warnings and precautions for use

Pregnancy:

TELGEN® should not be initiated during pregnancy.

Should a woman become pregnant while receiving TELGEN®, the treatment should be stopped promptly and an alternate antihypertensive medicine used (see Section 4.3 and Section 4.6).

Renovascular hypertension:

There is an increased risk of severe hypotension and renal insufficiency when patients with bilateral renal artery stenosis or stenosis of the artery to a single functioning kidney are treated with medicinal products that affect the renin-angiotensin-aldosterone system (see Section 4.3).

Renal impairment and kidney transplant:

When TELGEN® is used in patients with moderate impaired renal function, a periodic monitoring of potassium and creatinine serum levels is recommended. There is no experience regarding the administration of TELGEN® in patients with a recent kidney transplant (see Section 4.3).

Intravascular volume depletion:

Symptomatic hypotension, especially after the first dose, may occur in patients who are volume and/or sodium depleted by diuretic therapy, dietary salt restriction, diarrhoea or vomiting. Such conditions should be corrected before the administration of TELGEN®. Volume and/or sodium depletion should be corrected prior to administration of TELGEN®.

Dual blockade of the renin-angiotensin-aldosterone system (RAAS):

There is evidence that the concomitant use of ace-inhibitors, angiotensin II receptor blockers (ARBS) or aliskiren may increase the risk of hypotension and hyperkalaemia, and decrease renal function (including acute renal failure). Dual blockade of RAAS through the combined use of TELGEN® and aliskiren is therefore contra-indicated (see Section 4.3).

TELGEN® should not be used concomitantly with aliskiren (see Section 4.3).

ACE-inhibitors and angiotensin II receptor blockers should not be used concomitantly in patients with diabetic nephropathy.

Other conditions with stimulation of the renin-angiotensin-aldosterone System:

In patients whose vascular tone and renal function depend predominantly on the activity of the renin-angiotensin-aldosterone system (e.g. patients with severe congestive heart failure or underlying renal disease, including renal artery stenosis), treatment with other medicinal products that affect this system, such as TELGEN®, has been associated with acute hypotension, hyperureamia, hyperazotaemia, oliguria, or rarely acute renal failure (see Section 4.3).

Concomitant use of fluoroquinolones:

Concomitant use of fluoroquinolones and ACE inhibitors/Angiotensin receptor blockers may precipitate acute kidney injury in patients, especially those with moderate to severe renal impairment and elderly patients. (See Section 4.3). Renal function should be assessed before initiating treatment and monitored during treatment with fluoroquinolones or ACE inhibitors/Angiotensin receptor blockers whether used separately and/or concomitantly.

Primary aldosteronism:

Patients with primary aldosteronism generally will not respond to antihypertensive medicinal products acting through inhibition of the renin-angiotensin system. Therefore, the use of TELGEN® is not recommended.

Aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy:

See section 4.3.

Diabetic patients treated with insulin or antidiabetics:

In these patients hypoglycaemia may occur under telmisartan treatment. Therefore, in these patients an appropriate blood glucose monitoring should be considered; a dose adjustment of insulin or antidiabetics may be required, when indicated.

In diabetic patients with an additional cardiovascular risk, i.e. patients with diabetes mellitus and co-existent coronary artery disease (CAD), the risk of fatal myocardial infarction and unexpected cardiovascular death may be increased when treated with blood pressure lowering agents such as ARBs or ACE-inhibitors. In patients with diabetes mellitus, CAD may be asymptomatic and therefore undiagnosed. Patients with diabetes mellitus should undergo appropriate diagnostic evaluation, e.g. exercise stress testing, to detect and to treat CAD accordingly before initiating treatment with TELGEN®.

Hyperkalaemia:

During treatment with products that affect the renin-angiotensin-aldosterone system such as TELGEN®, hyperkalaemia may occur, especially in the presence of renal impairment and/or heart failure. Monitoring of serum potassium in patients at risk is recommended.

In the elderly, in diabetic patients, in patients concomitantly treated with other medicinal products that may increase potassium levels, and/or in patients with intercurrent events, hyperkalaemia may be fatal.

Before considering the concomitant use of medicinal products that affect the renin-angiotensin-aldosterone system, the benefit risk ratio should be evaluated.

The main risk factors for hyperkalaemia

- Diabetes mellitus, age (>70 years).

Based on experience with the use of medicinal products that affect the renin-angiotensin system, concomitant use with potassium-sparing diuretics, potassium supplements, salt substitutes

containing potassium or other medicinal products that may increase the potassium level (heparin, etc.) ACE inhibitors, angiotensin II receptor antagonists, non-steroidal anti-inflammatory medicinal products (NSAIDs, including selective COX-2 inhibitors), immunosuppressives (cyclosporin or tacrolimus), and trimethoprim may lead to an increase in serum potassium and should therefore not be co-administered with TELGEN®.

to be considered are:

- Intercurrent events, in particular dehydratation, acute cardiac decompensation, metabolic acidosis, worsening of renal function, sudden worsening of the renal condition (e.g. infectious diseases), cellular lysis (e.g. acute limb ischemia, rhabdomyolysis, extend trauma).

Close monitoring of serum potassium in at risk patients is recommended.

Hepatic impairment:

TELGEN® is mostly eliminated in the bile. Patients with biliary obstructive disorders or hepatic insufficiency can be expected to have reduced clearance. TELGEN® should be used with caution in these patients (see Section 4.3). TELGE^{N}® should be used only with caution in patients with mild to moderate hepatic impairment.

Active gastric or duodenal ulcer or gastro-intestinal pathologies:

In clinical trials with telmisartan as in TELGEN®, gastro-intestinal adverse events apparently occurred more frequently than with placebo and gastro-intestinal bleedings have been reported infrequently and this has occurred mainly in patients with baseline gastro-intestinal disease. Therefore, caution should be exercised when administering TELGEN® to this group of patients.

Other:

As observed for angiotensin converting enzyme inhibitors, TELGEN® and the other angiotensin antagonists are apparently less effective in lowering blood pressure in black people than in non-

blacks, possibly because of higher prevalence of low-renin states the black hypertensive population.

Excessive reduction in blood pressure in patients with ischaemic cardiopathy or ischaemic cardiovascular disease could result in a myocardial infarction or stroke.

Concomitant use of fluoroquinolones and ACE inhibitors/renin-angiotensin receptor blockers may precipitate acute kidney injury in patients, especially those with moderate to severe renal impairment and elderly patients (see Section 4.3). Renal function should be assessed before initiating treatment, and monitored during treatment, with fluoroquinolones or ACE inhibitors/renin-angiotensin receptor blockers.

Sorbitol:

TELGEN® 40 and TELGEN® 80 tablets contain 176,64 mg and 349,28 mg sorbitol, respectively. Patients with the rare hereditary condition of sorbitol intolerance should not take TELGEN®.

4.5 Interaction with other medicines and other forms of interaction

TELGEN® may increase the hypotensive effect of other antihypertensive agents.

Co-administration of telmisartan did not result in a clinically significant interaction with digoxin, warfarin, hydrochlorothiazide, glibenclamide, paracetamol, ibuprofen, simvastatin and amlodipine. For digoxin a 20 % increase in median plasma digoxin trough concentration has been reported (in a single case a 39 %). Monitoring of plasma digoxin levels should be considered.

As with other medicinal products acting on the renin-angiotensin-aldosterone system, telmisartan may provoke hyperkalaemia (see Section 4.4). The risk may increase in case of treatment combination with other medicinal products that may also provoke hyperkalaemia [salt substitutes containing potassium, potassium-sparing diuretics, ACE inhibitors, angiotensin II receptor

antagonists, non-steroidal anti-inflammatory medicinal products (NSAIDs, including selective COX-2 inhibitors), heparin immunosuppressives (cyclosporin or tacrolimus), and trimethoprim].

In one reported study the co-administration of telmisartan and ramipril led to an increase of up to 2,5 fold in the AUC_{0-24} and C_{max} of ramipril and ramiprilat. The clinical relevance of this observation is not known.

Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with angiotensin converting enzyme inhibitors. Increased serum levels have also been reported with telmisartan. Careful monitoring of serum lithium levels is recommended during concomitant use.

Concomitant treatment with NSAIDs (including aspirin at anti-inflammatory dosage regimens, COX-2 inhibitors and non-selective NSAIDs) is associated with the potential for acute renal insufficiency in patients who are dehydrated. Compounds acting on the Renin-Angiotensin-System like telmisartan may have synergistic effects. Patients receiving NSAIDs and telmisartan should be adequately hydrated and be monitored for renal function at the beginning of combined treatment.

A reduced effect of antihypertensive medicines like telmisartan by inhibition of vasodilating prostaglandins has been reported during combined treatment with NSAIDs.

Dual blockade of the RAAS with ARBs, ACE inhibitors or aliskiren

Reported clinical trial data has shown that dual blockade of the renin-angiotensin-aldosterone-system (RAAS) through the combined use of ACE inhibitors, angiotensin II receptor blockers or aliskiren is associated with a higher frequency of adverse events such as hypotension, hyperkalaemia and decreased renal function (see Section 4.3 and 4.4).

Diuretics (loop diuretics)

Prior treatment with high dose diuretics such as furosemide (loop diuretic) may result in volume depletion, and in a risk of hypotension when initiating therapy with telmisartan.

Other antihypertensive agents

Based on their pharmacological properties it can be expected that the following medicinal products may potentiate the hypotensive effects of all antihypertensives including telmisartan: Baclofen, amifostine. Furthermore, orthostatic hypotension may be aggravated by alcohol, barbiturates, narcotics, or antidepressants.

Corticosteroids (systemic route)

Reduction of the antihypertensive effect.

Concomitant use of fluoroquinolones and ACE inhibitors/renin-angiotensin receptor blockers may precipitate acute kidney injury. The mechanism of the possible interaction between the different classes of medicines, over and above different mechanisms of kidney damage, is unknown (see Section 4.3).

TELGEN® may increase the hypotensive effect of other antihypertensive agents.
Compounds which have been studied in pharmacokinetic trials include digoxin, warfarin, hydrochlorothiazide, glibenclamide, paracetamol, ibuprofen, simvastatin and amlodipine.
For digoxin a 20 % increase in median plasma digoxin trough concentration has been observed (in a single case a 39 %), monitoring of plasma digoxin levels should be considered.
Increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with angiotensin converting enzyme inhibitors. Increased serum levels have also been reported with telmisartan as in TELGEN® (see Section 4.4).

Potassium sparing diuretics or potassium supplements

Angiostenin II receptor antagonists such as TELGEN®, attenuate diuretic induced potassium loss. Potassium sparing diuretics e.g. spirinolactone, eplerenone, triamterene, or amiloride, potassium supplements, or potassium-containing salt substitutes may lead to a significant increase in serum potassium. If concomitant use is indicated because of documented hypokalaemia, they should be used with caution and with frequent monitoring of serum potassium.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established (see Section 4.3). When pregnancy is planned or confirmed, TELGEN® should be discontinued.

Medicines affecting the rennin-angiotensin system, such as TELGEN®, can cause embryonal toxicity, foetal and neonatal morbidity and mortality when administered to pregnant women.

Women of childbearing age should ensure effective contraception.

Exposure to angiotensin II receptor antagonist therapy during the second and third trimesters is known to induce human fetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia). (See section 5.3). Should exposure to angiotensin II receptor antagonists have occurred from the second trimester of pregnancy, ultrasound check of renal function and skull is recommended.

Infants whose mothers have taken angiotensin II receptor antagonists should be closely observed for hypotension (see sections 4.3 and 4.4).

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed. However, when driving vehicles or operating machinery it must be borne in mind that dizziness or drowsiness may occasionally occur when taking antihypertensive therapy, such as TELGEN®.

4.8 Undesirable effects

System Organ Class	**Frequency**	**Side effect**
Infections and infestations:	Frequent:	Urinary tract infections (including cystitis), upper respiratory tract infections including pharyngitis and sinusitis
Blood and the lymphatic systemic disorders:	Less frequent:	Eosinophilia, thrombocytopenia, anaemia
Immune system disorders:	Less frequent:	Hypersensitivity, Angioedema (with fatal outcome)
Psychiatric disorders:	Less frequent:	Anxiety, depression, insomnia.
Nervous system disorders:	Less frequent:	Faintness/ syncope, somnolence
Eye disorders:	Less frequent:	Abnormal vision
Ear and labyrinth disorders:	Less frequent:	Vertigo
Cardiac disorders:	Less frequent:	Bradycardia, tachycardia
Vascular disorders:	Less frequent:	Hypotension, orthostatic hypotension
Respiratory, thoracic and mediastinal disorders:	Frequent: Less frequent:	Cough, dyspnoea, interstitial lung disease

Gastro-intestinal disorders:	Less frequent:	Abdominal pain, diarrhoea, dyspepsia, stomach upset, nausea, vomiting, dry mouth, flatulence, dysgeusia
Skin and subcutaneous tissue disorders:	Less frequent:	Eczema, increased sweating (hyperhidrosis), rash, erythema, pruritus, urticaria, drug eruption, toxic skin eruption, angioedema (also with fatal outcome)
Musculoskeletal, connective tissue and bone disorders:	Frequent: Less frequent:	Arthralgia, myalgia, back pain, muscle spasms (cramps in legs or leg pain), Tendinitis like symptoms, weakness
Renal and urinary disorders:	Less frequent:	Renal impairment including acute renal failure
General disorders and administration site conditions:	Less frequent:	Chest pain, influenza-like symptoms, asthenia (weakness), lack of efficacy
Investigations:	Less frequent:	Blood creatinine increased, haemoglobin decreased, blood uric acid increased, hepatic enzymes increased, blood creatine phosphokinase increased.

Post-marketing:

System Organ Class	**Frequency**	**Side effect**
Infections and infestations:	Frequency unknown:	Sepsis including fatal outcome
Blood and the lymphatic systemic disorders:	Frequency unknown:	Eosinophilia
Immune system disorders:	Frequency unknown:	Anaphylactic reaction
Skin and subcutaneous tissue disorders:	Frequency unknown:	Urticaria
Musculoskeletal, connective tissue and bone disorders:	Frequency unknown:	Tendon pain (tendinitis like symptoms)
Metabolism and nutrition disorders:	Frequency unknown:	Hypoglycaemia (in diabetic patients)
Hepato-biliary disorders:	Frequency unknown:	Hepatic function abnormal/liver disorder

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

See **Section 4.8 Undesirable effects.**

No data are available with regard to overdose in humans. The most prominent manifestations of TELGEN® overdose were hypotension and tachycardia; bradycardia also occurred. If symptomatic hypotension should occur, supportive treatment should be instituted. TELGEN® is not removed by haemodialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 7.1.3 Vascular medicines - other hypotensives.

Pharmacotherapeutic group: Angiotensin II Antagonists , plain, ATC Code: C09CA07.

Telmisartan is a specific angiotensin II receptor (type AT_1) antagonist. It displaces angiotensin II from its binding site at the AT_1, receptor subtype, which is responsible for the known actions of angiotensin II. Telmisartan does not exhibit any partial agonist activity at the AT_1 receptor. Telmisartan selectively binds at the AT_1 receptor. The binding is long-lasting. Telmisartan does not inhibit human plasma renin or block ion channels.

In man, an 80 mg dose of telmisartan almost completely inhibits the angiotensin II evoked blood pressure increase. The inhibitory effect is 50 % at 24 hours and still measurable up to 48 hours.

After administration of the first dose of telmisartan, onset of antihypertensive activity occurs within 3 hours. The maximum reduction in blood pressure is generally attained 4-weeks after the start of treatment and is sustained during long-term therapy.

The antihypertensive effect persists over 24 hours after dosing.

There is an apparent trend to a dose relationship with regard to a time to recovery of baseline systolic blood pressure. In this respect data concerning diastolic blood pressure are inconsistent.

In patients with hypertension, telmisartan reduces both systolic and diastolic blood pressure without affecting pulse rate.

Upon abrupt cessation of treatment with telmisartan, blood pressure gradually returns to pre-treatment values over a period of several days without evidence of rebound hypertension.

In reported clinical trials, telmisartan treatment has been shown to be associated with statistically significant reductions in proteinuria (including microalbuminuria and macroalbuminuria) in patients with hypertension and diabetic nephropathy.

Telmisartan treatment has been shown in clinical trials to be associated with statistically significant reductions in Left Ventricular Mass and Left Ventricular Mass Index in patients with hypertension and Left Ventricular Hypertrophy.

5.2 Pharmacokinetic properties

Absorption of telmisartan is rapid although the amount absorbed varies. The mean absolute bioavailability for telmisartan is about 50 %.

When telmisartan is taken with food, the reduction in the area under the plasma concentration-time curve ($AUC_{0-\infty}$) varies from approximately 6 % (40 mg dose) to approximately 19 % (160 mg dose). After 3 hours post administration, plasma concentrations are similar whether telmisartan is taken fasting or with food.

The small reduction in AUC is not expected to cause a reduction in the therapeutic efficacy.

Gender differences in plasma concentrations were observed, C_{max} and AUC being approximately 3-and 2-fold higher, respectively, in females compared to males without relevant influence on efficacy.

Telmisartan is highly bound to plasma protein (>99,5 %), mainly albumin and alpha-1 acid glycoprotein. The mean steady state apparent volume of distribution (V_{dss}) is approximately 500 L. Telmisartan is metabolised by conjugation to the glucuronide.

No pharmacological activity has been shown for the conjugate. Telmisartan, is characterised by bi-exponential decay pharmacokinetics with a terminal elimination half-life of >20 hours. The maximum plasma concentration (C_{max}) and, to a smaller extent, area under the plasma

concentration-time curve (AUC) increase disproportionately with dose. Plasma concentrations were higher in females than in males, without relevant influence on efficacy.

After oral administration telmisartan is nearly exclusively excreted with the faeces, mainly as unchanged compound. Cumulative urinary excretion is <2 % of the dose.

Total plasma clearance (CL_{tot}) is high (approximately 900 mL/min) when compared with hepatic blood flow (about 1 500 mL/mm).

Elderly patients:

The pharmacokinetics of telmisartan do not differ between younger and elderly patients.

Patients with renal impairment:

Lower plasma concentrations were observed in patients with renal insufficiency undergoing dialysis. Telmisartan is highly bound to plasma protein in renal-insufficient subjects and cannot be removed by dialysis. The elimination half-life is not changed in patients with renal impairment.

Patients with hepatic impairment:

Pharmacokinetic studies in patients with hepatic impairment showed an increase in absolute bioavailability up to nearly 100 %. The elimination half-life is not changed in patients with hepatic impairment.

6 PHARMACEUTICAL PARTICULAR

6.1 List of excipients

TELGEN® also contains the following excipients:

- magnesium stearate
- meglumine
- povidone

- sodium hydroxide
- sorbitol

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 Months

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.

KEEP OUT OF REACH OF CHILDREN.

6.4 Special precautions for storage

This medicine does not require any special storage conditions

6.5 Nature and contents of container

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

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

RANBAXY (SA) (PTY) LTD

a Sun Pharma company

Ground Floor, Tugela House

Riverside Office Park

1303 Heuwel Avenue

Centurion

8 REGISTRATION NUMBERS

TELGEN® 40: 45/7.1.3/0610

TELGEN® 80: 45/7.1.3/0611

DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of registration: 10 October 2013

Date of last approval: 20 March 2024

Namibia: NS2 TELGEN® 40: Reg No.: 14/7.1.3/0002 TELGEN® 80: Reg No.: 14/7.1.3/0001