Approved Professional Information for Medicines for Human Use:

TELMISARTAN 40 mg SHANUR

TELMISARTAN 80 mg SHANUR

SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

TELMISARTAN 40 mg SHANUR tablets

TELMISARTAN 80 mg SHANUR tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

TELMISARTAN 40 mg SHANUR tablets

Each tablet contains 40 mg telmisartan.

Sugar free.

Contains mannitol: 175,240 mg.

TELMISARTAN 80 mg SHANUR tablets

Each tablet contains 80 mg telmisartan.

Sugar free.

Contains mannitol: 350,480 mg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets

TELMISARTAN 40 mg SHANUR tablets

White to off-white, oblong, uncoated tablets debossed with 'P12' on one side and plain on the other side.

TELMISARTAN 80 mg SHANUR tablets

White to off-white, oblong, uncoated tablets debossed with 'P11' on one side and plain on the 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

The usually effective dose is 40 mg once daily. Some patients may already benefit at a daily dose of telmisartan 20 mg. In cases where the target blood pressure is not achieved, the dose of TELMISRATAN SHANUR can be increased to a maximum of 80 mg once daily. Alternatively, TELMISRATAN SHANUR may be used in combination with thiazide-type diuretics such as hydrochlorothiazide 12,5 mg which has been shown to have an additive blood pressure lowering effect with TELMISRATAN SHANUR. 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 TELMISRATAN SHANUR are effective in reducing cardiovascular morbidity and mortality.

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

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

Special populations

Elderly population

No dosing adjustment is necessary for elderly patients.

Renal impairment

No dosage adjustment is required for patients with mild to moderate renal impairment. Limited experience is available in patients with severe renal impairment or haemodialysis (see section 4.3).

Hepatic impairment

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

Paediatric population

Children and adolescents up to 18 years of age

TELMISRATAN SHANUR is not recommended for use in children below 18 years due to a lack of data on safety and efficacy.

Method of administration

TELMISRATAN SHANUR is for oral use.

4.3 Contraindications

- Hypersensitivity to telmisartan or to any of the excipients listed in section 6.1
- A history of angioedema related to previous therapy with angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs): These 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
- Biliary obstructive disorders
- Severe hepatic impairment
- Concomitant therapy with potassium sparing diuretics such as spironolactone, triamterene, amiloride (see section 4.5)
- Porphyria
- Lithium therapy: Concomitant administration with TELMISRATAN SHANUR may lead to toxic blood concentrations of lithium (see section 4.5)
- Pregnancy and lactation (see section 4.6)
- The concomitant use of TELMISRATAN SHANUR with renin inhibitors, such as aliskiren-containing products is contraindicated (see section 4.4 and 4.5)
- Concomitant use of fluoroquinolones with ACE-inhibitors/Angiotensin receptor 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

Should a woman become pregnant while receiving TELMISRATAN SHANUR, the treatment should be stopped promptly and switched to a different class of

antihypertensive medicine. (see section 4.3 and 4.6).

Pregnancy

Angiotensin II receptor antagonists should not be initiated during pregnancy. Unless continued angiotensin II receptor antagonist therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started (see sections 4.3 and 4.6).

Hepatic impairment

Telmisartan as in TELMISRATAN SHANUR is not to be given to patients with cholestasis, biliary obstructive disorders or severe hepatic impairment (see section 4.3) since telmisartan is mostly eliminated with the bile. These patients can be expected to have reduced hepatic clearance for telmisartan. Telmisartan as in TELMISRATAN SHANUR should be used only with caution in patients with mild to moderate hepatic impairment.

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 medicine that affect the renin-angiotensin-aldosterone system such as telmisartan as in TELMISRATAN SHANUR.

Renal impairment and kidney transplantation

When telmisartan as in TELMISRATAN SHANUR is used in patients with impaired renal function, periodic monitoring of potassium and creatinine serum levels is recommended. There is no experience regarding the administration of telmisartan in patients with recent kidney transplantation.

Intravascular hypovolaemia

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

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

There is evidence that the concomitant use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren increases the risk of hypotension, hyperkalaemia and decreased renal function (including acute renal failure). Dual blockade of RAAS through the combined use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren is therefore contraindicated (see sections 4.3).

ACE-inhibitors and angiotensin II receptor blockers such as telmisartan as in TELMISRATAN SHANUR 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 medicine that affect this system such as telmisartan as in TELMISRATAN SHANUR has been associated with acute hypotension, hyperazotemia, oliguria, or rarely acute renal failure (see section 4.8).

Fluoroquinolones and ACE inhibitors/Angiotensin receptor blockers

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 medicine acting through inhibition of the renin-angiotensin system. Therefore, the use of telmisartan as in TELMISRATAN SHANUR is not recommended.

Aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy

TELMISRATAN SHANUR is contraindicated in patients suffering from aortic or mitral stenosis, or 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.

Hyperkalaemia

The use of medicine that affect the renin-angiotensin aldosterone system such as telmisartan as in TELMISRATAN SHANUR may cause hyperkalaemia.

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

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

The main risk factors for hyperkalaemia to be considered are:

- Diabetes mellitus, renal impairment, age (> 70 years)
- Combination with one or more other medicine that affect the renin-angiotensin-aldosterone

system and/or potassium supplements. Medicine or therapeutic classes of medicine that may provoke hyperkalaemia are salt substitutes containing potassium, potassium-sparing diuretics, ACE-inhibitors, angiotensin II receptor antagonists, non-steroidal anti-inflammatory medicine (NSAIDs, including selective COX-2 inhibitors), heparin, immunosuppressives (cyclosporin or tacrolimus), and trimethoprim

- Intercurrent events, particularly dehydration, 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 patients at risk is recommended (see section 4.5).

Ethnic differences

As observed for angiotensin converting enzyme inhibitors, telmisartan and the other angiotensin II receptor 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 in the black hypertensive population.

Other

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

Sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicines and other forms of interaction

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

Clinical trial data has shown that dual blockade of the renin-angiotensinaldosterone-system (RAAS) through the combined use of ACE inhibitors, angiotensin II receptor blockers (as contained in

TELMISRATAN SHANUR) or renin inhibitors, such as 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).

Digoxin

When telmisartan as in TELMISRATAN SHANUR was co-administered with digoxin, median increases in digoxin peak plasma concentration (49 %) and in trough concentration (20 %) were observed. When initiating, adjusting, and discontinuing TELMISRATAN SHANUR, monitor digoxin levels in order to maintain levels within the therapeutic range.

Hyperkalaemia

Telmisartan as in TELMISRATAN SHANUR may provoke hyperkalaemia (see section 4.4). The risk may increase in case of treatment combination with other medicines that may also provoke hyperkalaemia (salt substitutes containing potassium, potassium-sparing diuretics, ACE-inhibitors, angiotensin II receptor antagonists, non-steroidal anti-inflammatory medicine (NSAIDs, including selective COX-2 inhibitors), heparin, immunosuppressives (cyclosporin or tacrolimus), and trimethoprim).

The occurrence of hyperkalaemia depends on associated risk factors. The risk is increased in case of the above-mentioned treatment combinations. The risk is particularly high in combination with potassium sparing-diuretics, and when combined with salt substitutes containing potassium. A combination with ACE-inhibitors or NSAIDs, for example, presents a lesser risk provided that precautions for use are strictly followed.

Concomitant use not recommended.

Potassium-sparing diuretics or potassium supplements

Angiotensin II receptor antagonists such as telmisartan as in TELMISRATAN SHANUR, attenuate diuretic induced potassium loss. Potassium sparing diuretics e.g. spironolactone, 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.

Lithium

Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with angiotensin converting enzyme inhibitors, and with angiotensin II receptor antagonists, including telmisartan as in TELMISRATAN SHANUR.

Non-steroidal anti-inflammatory medicine

NSAIDs (i.e. acetylsalicylic acid at anti-inflammatory dosage regimens, COX-2 inhibitors and non-selective NSAIDs) may reduce the antihypertensive effect of angiotensin II receptor antagonists such as telmisartan as in TELMISRATAN SHANUR.

In some patients with compromised renal function (e.g. dehydrated patients or elderly patients with compromised renal function), the co-administration of angiotensin II receptor antagonists and medicines that inhibit cyclo-oxygenase may result in further deterioration of renal function, including possible acute renal failure, which is usually reversible. Therefore, the combination should be administered with caution, especially in the elderly. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy and periodically thereafter.

In one study the co-administration of telmisartan as in TELMISRATAN SHANUR 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.

Diuretics (thiazide or loop diuretics)

Prior treatment with high dose diuretics such as furosemide (loop diuretic) and hydrochlorothiazide (thiazide diuretic) may result in volume depletion and in a risk of hypotension when initiating therapy with telmisartan. Patients taking telmisartan as in TELMISRATAN SHANUR and diuretics concomitantly should be monitored.

Other antihypertensive medicines

The blood pressure lowering effect of telmisartan as in TELMISRATAN SHANUR can be increased by concomitant use of other antihypertensive medicines.

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 (including acute renal failure) compared to the use of a single RAAS-acting medicine (see sections 4.3, 4.4 and 5.1).

Based on their pharmacological properties it can be expected that the following medicines may potentiate the hypotensive effects of all antihypertensives including telmisartan as in TELMISRATAN SHANUR: baclofen, amifostine. Furthermore, orthostatic hypotension may be aggravated by alcohol, barbiturates, narcotics or antidepressants.

Corticosteroids (systemic route)

Reduction of the antihypertensive effect.

Fluoroquinolones and ACE inhibitors/Angiotensin receptor blockers

Concomitant use of fluoroquinolones and ACE inhibitors/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).

4.6 Fertility, pregnancy and lactation

Women of childbearing potential

Women of childbearing age should use adequate contraception.

Pregnancy and lactation

TELMISRATAN SHANUR is contraindicated during pregnancy. (See section 4.3 and 4.4).

There are no adequate data from the use of ~~T~~telmisartan in pregnant women. Studies in animals have shown reproductive toxicity.

Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE-inhibitors during the first trimester of pregnancy has not been conclusive; however, a small increase in risk cannot be excluded. Whilst there is no controlled epidemiological data on the risk with angiotensin II receptor antagonists, similar risks may exist for this class of medicines. Unless continued angiotensin II receptor antagonist therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started.

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).

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).

When pregnancy is planned or confirmed TELMISRATAN SHANUR should be discontinued. Medicines affecting the renin-angiotensin system, such as TELMISRATAN SHANUR, can cause embryonal toxicity, foetal and neonatal morbidity and mortality when administered to pregnant women.

Breastfeeding

Since it is not known whether telmisartan is excreted in human milk, TELMISRATAN SHANUR is contraindicated during breastfeeding (see section 4.3 and 4.4).

Fertility

No effects of telmisartan, as in TELMISRATAN SHANUR, on male and female fertility were observed in reported studies.

4.7 Effects on ability to drive and use machines

When driving vehicles or operating machinery it should be taken into account that dizziness or drowsiness may occasionally occur when taking antihypertensive therapy such as Telmisartan.

4.8 Undesirable effects

Summary of the safety profile

Serious adverse drug reactions include anaphylactic reaction, angioedema which may occur rarely and acute renal failure.

Tabulated list of adverse reactions

The table below shows all adverse drug reactions (ADRs) observed during clinical trials and post-market spontaneous reports with Telmisartan.

System Organ Class	**Frequency** **Less Frequent**
Infections and infestations	Urinary tract infection (including cystitis), upper respiratory tract infection including pharyngitis and sinusitis Sepsis (including fatal outcome)[1]
Blood and lymphatic system disorders	Anaemia Eosinophilia, thrombocytopenia
Immune system disorders	Anaphylactic reaction, hypersensitivity angioedema (with fatal outcome)
Metabolism and nutrition disorders	Hyperkalaemia Hypoglycaemia (in diabetic patients)
Psychiatric disorders	Insomnia, depression Anxiety

Nervous system disorders	Syncope Somnolence
Eye disorders	Visual disturbance
Ear and labyrinth disorders	Vertigo
Cardiac disorders	Bradycardia Tachycardia
Vascular disorders	Hypotension[2], orthostatic hypotension
Respiratory, thoracic and mediastinal disorders	Dyspnoea, cough Interstitial lung disease[4]
Gastrointestinal disorders	Abdominal pain, diarrhoea, dyspepsia, flatulence, vomiting Dry mouth, stomach discomfort, dysgeusia
Hepatobiliary disorders	Hepatic function abnormal/liver disorder[3]
Skin and subcutaneous tissue disorders	Pruritus, hyperhidrosis, rash Angioedema (also with fatal outcome), eczema, erythema, urticaria, medicine eruption, toxic skin eruption
Musculoskeletal and connective tissue disorders	Back pain (e.g. sciatica), muscle spasms, myalgia Arthralgia, pain in extremity, tendon pain (tendinitis-like symptoms)
Renal and urinary disorders	Renal impairment, including acute renal failure
General disorders and administration	Chest pain, asthenia (weakness)

site conditions	Influenza-like illness
Investigations	Blood creatinine increased Haemoglobin decreased, blood uric acid increased, hepatic enzyme increased, blood creatine phosphokinase increased

1, 2, 3, 4: for further descriptions, please see sub-section below *"Description of selected adverse reactions".*

Description of selected adverse reactions

Sepsis

In the PRoFESS trial, an increased incidence of sepsis was observed with telmisartan compared with placebo. The event may be a chance finding or related to a mechanism currently not known (see also section 5.1).

Hypotension

This adverse reaction was reported as common in patients with controlled blood pressure who were treated with telmisartan for the reduction of cardiovascular morbidity on top of standard care.

Hepatic function abnormal/liver disorder

Most cases of hepatic function abnormal/liver disorder from post-marketing experience occurred in Japanese patients. Japanese patients are more likely to experience these adverse reactions.

Interstitial lung disease

Cases of interstitial lung disease have been reported from post-marketing experience in temporal association with the intake of telmisartan. However, a causal relationship has not been established.

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 requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA's website.

Suspected adverse reactions can also be reported directly to the HCR via medsafety@austell.co.za.

4.9 Overdose

There is limited information available with regard to overdose in humans.

Symptoms:

The most prominent manifestations of telmisartan overdose were hypotension and tachycardia; bradycardia, dizziness, increase in serum creatinine, and acute renal failure have also been reported.

Treatment:

Telmisartan is not removed by haemodialysis. The patient should be closely monitored, and the treatment should be symptomatic and supportive. Management depends on the time since ingestion and the severity of the symptoms. Activated charcoal may be useful in the treatment of overdosage. Serum electrolytes and creatinine should be monitored frequently. If hypotension occurs, the patient should be placed in a supine position, with salt and volume replacement given quickly.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: 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. Telmisartan displaces angiotensin II with high affinity 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 show affinity for other receptors, including AT_2 and other less characterised AT receptors. Plasma aldosterone levels are decreased by telmisartan. Telmisartan does not inhibit

human plasma renin or block ion channels.

After the first dose of telmisartan, the antihypertensive activity gradually becomes evident 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 (SBP). In this respect data concerning diastolic blood pressure (DBP) are inconsistent.

5.2 Pharmacokinetic properties

Telmisartan is well absorbed from the gastrointestinal tract. The mean oral bioavailability is about 50 %. Peak plasma concentrations of telmisartan are reached about 0.5 to 1 hour after an oral dose. Telmisartan is highly bound to plasma proteins (> 99.5 %). Telmisartan is metabolised by conjugation to the glucuronide, which is inactive. The terminal elimination half-life is about 24 hours. It is excreted almost entirely in the faeces via bile, mainly as unchanged compound.

Gender differences

C_{max} and area under the curve (AUC) were approximately 3- and 2-fold higher, respectively, in females compared to males.

Elderly patients

No difference in the pharmacokinetics of telmisartan was reported between younger and elderly patients.

Patients with renal impairment

Patients with renal insufficiency undergoing dialysis had lower telmisartan plasma concentrations.

Telmisartan is highly bound to plasma proteins and cannot be removed by dialysis. The elimination half-life is not changed in these patients.

Patients with hepatic impairment

Absolute bioavailability was increased up to nearly 100 % in patients with hepatic impairment.

The elimination half-life is not changed in these patients.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate

Mannitol (Pearlitol SD 200)

Meglumine

Povidone (Polyvinylpyrolidone-PVPK-30)

Sodium hydroxide

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.

Keep the blister strips in the original package to protect from moisture.

6.5 Nature and contents of container

TELMISRATAN SHANUR tablets are packed in aluminium blister packs and into cardboard cartons.

Blister packs of 14, 28, 30, 56, 84, 90, or 98 tablets are available.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Austell Pharmaceuticals (Pty) Ltd

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8. REGISTRATION NUMBERS

TELMISRATAN 40 mg SHANUR tablets: 59/7.1.3/0949

TELMISRATAN 80 mg SHANUR tablets: 59/7.1.3/0950

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28 July 2026.

10. DATE OF REVISION OF THE TEXT