Approved Patient Information Leaflet for Medicines for Human Use:

TELMISARTAN 40 mg SHANUR

TELMISARTAN 80 mg SHANUR

SCHEDULING STATUS: S3

TELMISARTAN 40 mg SHANUR tablets

Telmisartan

Sugar free.

Each tablet contains 175,240 mg mannitol.

TELMISARTAN 80 mg SHANUR tablets

Telmisartan

Sugar free.

Each tablet contains 350,480 mg mannitol.

Read all of this leaflet carefully before you start taking/using/are given TELMISARTAN SHANUR

- 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.
- TELMISARTAN SHANUR 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 TELMISARTAN SHANUR is and what it is used for

TELMISARTAN SHANUR belongs to a class of medicines known as angiotensin II receptor antagonists. Angiotensin II is a hormone produced in your body which causes your blood vessels to narrow, thus increasing your blood pressure. TELMISARTAN SHANUR blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

TELMISARTAN SHANUR is used to treat essential hypertension (high blood pressure).

TELMISARTAN SHANUR can also be used to reduce cardiovascular events like heart attack or stroke and death in patients who are 55 years or older who are at high risk of cardiovascular disease. The benefit of treatment for these patients is evident after at least 6 months of continued treatment.

2. What you need to know before you take TELMISARTAN SHANUR

Do not take TELMISARTAN SHANUR

- If you are hypersensitive (allergic) to telmisartan or any of the other ingredients of TELMISARTAN SHANUR (listed in section 6)
- If you are pregnant or breastfeeding your baby (see section “Pregnancy, breastfeeding and fertility”)
- If you have had angioedema (swelling of your face, lips, mouth, tongue or throat, with or without difficulty in swallowing or breathing) while taking an angiotensin-converting enzyme inhibitor (ACE-inhibitor) or an angiotensin receptor blocker, such as TELMISARTAN SHANUR
- If you have a disorder that results in regular outbreaks of severe swelling (hereditary angioedema) or swelling that occurs for no reason at all (idiopathic angioedema)
- If you have aortic stenosis, a narrowing of the aortic valve opening between the left ventricle (large pumping chamber of your heart) and the aorta (the main artery leading away from your heart)
- If you have hypertrophic obstructive cardiomyopathy, a serious heart disorder where the muscles of the heart are thickened, interfering with normal blood flow
- If you have narrowing of the blood vessels to both kidneys or to a single functioning kidney
- If you are taking diuretics (water tablets) such as spironolactone, triamterene or amiloride, that cause your body to retain potassium.

- If you have severe kidney disease
- If you have severe liver problems such as problems with the drainage of the bile from the liver and gall bladder, or any other severe liver disease
- If you have a condition called porphyria (a metabolic disorder)
- If you are taking lithium (used as treatment for mood disorders)
- If you are using medicines containing aliskiren (used to treat high blood pressure)
- Contact your doctor to re-evaluate your treatment if you are treated with ACE-inhibitors/Angiotensin receptor blockers together with a fluoroquinolone antibiotic.

Warnings and precautions

Take special care with TELMISARTAN SHANUR:

- If you are pregnant or trying to fall pregnant. You should stop treatment immediately and use a different medicine to control your high blood pressure
- If you are also taking any of the following medicines to treat your high blood pressure:
  - an ACE-inhibitor (for example lisinopril) or aliskiren. When these medicines are used together, it may increase the risk for you to have very low blood pressure and can increase the amount of potassium in your blood. It can also decrease your kidney function
- If you are also taking a type of antibiotic known as fluoroquinolones (ciprofloxacin, moxifloxacin, levofloxacin). Your doctor should assess your kidney function before you use these antibiotics with TELMISARTAN SHANUR.

Before taking TELMISARTAN SHANUR tell your doctor, pharmacist or other health care professional if you are suffering or have ever suffered from any of the following conditions or illnesses:

- Kidney disease or kidney transplant
- Renal artery stenosis (narrowing of the blood vessels to one or both of your kidneys)
- Liver disease
- Heart problems
- Raised aldosterone levels (water and salt retention in the body along with imbalance of various

Austell Pharmaceuticals (Pty) Ltd, 590949-50, TELMISARTAN 40 mg and 80 mg SHANUR tablets

blood minerals)

- Low blood pressure (hypotension), likely to occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy ('water tablets'), low-salt diet, diarrhoea, or vomiting
- Elevated potassium levels in your blood, or if you are taking medicines that may increase the potassium levels in your blood such as potassium-sparing diuretics (water tablets), potassium supplements, salt substitutes containing potassium or other medicines that may increase the potassium level (for instance heparin)

  Your doctor will monitor your potassium levels while you are taking TELMISARTAN SHANUR
- Diabetes
- TELMISARTAN SHANUR may be less effective in lowering the blood pressure in black patients.

Children and adolescents

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

Other medicines and TELMISARTAN SHANUR

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

Tell your doctor or pharmacist if you are currently using:

- Angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs) or renin inhibitors, such as aliskiren (used to treat high blood pressure). The combined use of these medicines may lead to a higher frequency of side effects such as low blood pressure, high levels of potassium in your blood and decreased kidney function
- Any other medicines that lower blood pressure
- Medicine containing lithium, used to treat some types of mood disorders. The amount of lithium in your blood may increase to toxic levels when taken with TELMISARTAN SHANUR
- Digoxin, used to treat heart problems

- Nonsteroidal anti-inflammatory medicines (NSAIDs), such as aspirin, diclofenac and ibuprofen. You have an increased risk to develop kidney damage especially if you are dehydrated when taking with TELMISARTAN SHANUR
- Spironolactone, eplerenone, triamterene, amiloride. The amount of potassium in your blood may increase when taken with TELMISARTAN SHANUR

  Combination treatment with potassium-sparing diuretics is contraindicated (see section “Do not take TELMISARTAN SHANUR”)
- Potassium supplements, salt substitutes containing potassium and other medicines that may increase potassium levels. The amount of potassium in your blood may increase when taken with TELMISARTAN SHANUR
- Other medicines that may lead to increased potassium levels in your blood when taken with TELMISARTAN SHANUR are ACE-inhibitors, other angiotensin II receptor antagonists, NSAIDs, heparin, immunosuppressives (such as cyclosporin and tacrolimus) and trimethoprim
- Baclofen (used to treat muscle stiffness). This medicine may increase the blood pressure lowering effect of TELMISARTAN SHANUR
- Amifostine (used after initial treatment for cancer, to suppress secondary tumour formation). This medicine may increase the blood pressure lowering effect of TELMISARTAN SHANUR
- Barbiturates (used to treat sleeping disorders)
- Narcotics (used to treat mood and behaviour disorders)
- Antidepressant medicine (used to treat depression)
- Alcohol
- Corticosteroids (cortisone-like medicines used to treat inflammation). Treatment with corticosteroids and TELMISARTAN SHANUR may lead to a decrease of the blood pressure lowering effect of TELMISARTAN SHANUR
- Fluoroquinolone antibiotics (antibiotics to treat your infection). When taken with TELMISARTAN SHANUR, it may trigger kidney injury
- When taking TELMISARTAN SHANUR just after you have taken high doses of furosemide and/or hydrochlorothiazide may lead to volume depletion and lower than usual blood pressure.

TELMISARTAN SHANUR may increase the blood pressure lowering effect of other medicines used to treat high blood pressure.

Pregnancy, breastfeeding and fertility

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 use TELMISARTAN SHANUR if you are pregnant or breastfeeding.
When pregnancy is planned or confirmed, TELMISARTAN SHANUR should be stopped immediately.
When you take TELMISARTAN SHANUR while you are pregnant, it can cause harm to your unborn baby.
Women who can become pregnant should use reliable birth control.
Studies have shown that telmisartan, as in TELMISARTAN SHANUR does not affect the ability of men or women to have children.

Driving and using machines

TELMISARTAN SHANUR may cause dizziness or drowsiness, thereby impairing your ability to drive a vehicle or use machines. Take special care before performing tasks requiring your attention, until you know how TELMISARTAN SHANUR will affect you.

It is not always possible to predict to what extent TELMISARTAN SHANUR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TELMISARTAN SHANUR affects them.

TELMISARTAN SHANUR contains sodium

TELMISARTAN SHANUR contains less than 1 mmol sodium (23 mg) per dosage unit (5 mL), that is to say essentially 'sodium-free'.

3. How to take TELMISARTAN SHANUR

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

Always take TELMISARTAN SHANUR exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Treatment for high blood pressure

The usual dose of TELMISARTAN SHANUR for most patients is one 40 mg tablet once a day to control blood pressure over the 24-hour period. Your doctor may recommend a lower dose of one 20 mg tablet daily. Your doctor may also increase your dose to one 80 mg tablet per day if your target blood pressure is not achieved. Try to take the tablet at the same time each day. The tablets should be swallowed with some water.

TELMISARTAN SHANUR may also be used in combination with diuretics ('water tablets') such as hydrochlorothiazide (12,5 mg), which has been shown to have an additive blood pressure lowering effect with TELMISARTAN SHANUR.

If your doctor increases your dose, you must bear in mind that the maximum blood pressure lowering effect is generally achieved four to eight weeks after the start of treatment.

If you have mild to moderate liver disease, you should not take more than one 40 mg tablet per day.

To reduce cardiovascular events and death in patients who are 55 years or older who are at high risk of cardiovascular disease

The usual dose is one 80 mg tablet daily.

When TELMISARTAN SHANUR therapy is started for the reduction of cardiovascular events and death, your doctor should monitor your blood pressure and if appropriate, adjust your blood pressure lowering medicines.

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

Your doctor will tell you how long your treatment with TELMISARTAN SHANUR will last. It is important

Austell Pharmaceuticals (Pty) Ltd, 590949-50, TELMISARTAN 40 mg and 80 mg SHANUR tablets that you take TELMISARTAN SHANUR every day until your doctor tells you otherwise. Do not stop treatment without consulting your health care provider.
If you have the impression that the effect of TELMISARTAN SHANUR is too strong or too weak, tell your doctor or pharmacist.

Duration of administration

Your doctor will tell you how long your treatment with TELMISARTAN SHANUR will last. Do not stop treatment early unless instructed by your doctor. If you have the impression that the effect of TELMISARTAN SHANUR is too strong or too weak, tell your doctor or pharmacist.

Method of administration

TELMISARTAN SHANUR is taken orally.

If you take more TELMISARTAN SHANUR than you should

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

Take this leaflet and the rest of the remaining TELMISARTAN SHANUR with you so the doctor will know what you have taken.
If you take more TELMISARTAN SHANUR than you should, you may experience very low blood pressure (you may feel dizzy or you may faint) and an increased heartbeat. In some instances, you may also experience a very slow heartbeat.
Treatment of overdose is symptomatic and supportive. Serum electrolytes and creatinine concentrations should be monitored frequently. Activated charcoal may be useful in the treatment of overdosage. If you get very low blood pressure, you should be placed on your back and salt and volume replacement given as quick as possible.

If you forget to take TELMISARTAN SHANUR

If you forget to take a dose, leave that dose out completely.

Take your next dose at the right time and continue as before.

Do not take a double dose to make up for the forgotten individual dose.

If you stop taking TELMISARTAN SHANUR

Do not stop taking TELMISARTAN SHANUR unless instructed by your doctor. If you do your symptoms could return or 'flare-up'.

4. Possible side effects

TELMISARTAN SHANUR can have side effects.

Not all side effects reported for TELMISARTAN SHANUR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TELMISARTAN SHANUR, please consult your health care provider for advice.

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

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

These are very serious side effects. If you have them, you may have had a serious reaction to TELMISARTAN SHANUR. 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:

- Fast heartbeat (tachycardia), slow heartbeat (bradycardia)
- Shortness of breath, cough, interstitial lung disease (a group of disorders that cause progressive scarring of lung tissue)
- Chest pain, symptoms of weakness, flu-like illness
- Abnormal liver function (causing yellowing of the skin and whites of the eyes), discomfort in the abdomen
- Kidney impairment, including kidney failure (producing less urine than is normal for you)
- Sepsis (often called blood poisoning, a severe infection with whole body inflammatory response which can lead to death).

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

Tell your doctor if you notice any of the following:

Less Frequent side effects:

- Upper respiratory tract infection (e.g. sore throat, inflamed sinuses, common cold)
- Urinary tract infections
- Deficiency in red blood cells (anaemia), low platelet count (thrombocytopenia), increase in certain white blood cells (eosinophilia)
- High potassium levels in the blood, low blood sugar levels (in diabetic patients)
- Abdominal pain, diarrhoea, vomiting (being sick), dry mouth, upset stomach, passing gas, change in sense of taste, indigestion
- Increased levels of uric acid, creatinine, hepatic enzymes or creatine phosphokinase in the blood, decreased haemoglobin
- Muscle pain (myalgia) or cramps, joint pain (arthralgia), back pain, pain in extremity, tendon pain (symptoms like inflammation of the tendons)
- Weakness, lack of energy
- Sudden drop in heart rate and blood pressure, causing fainting, paleness and a rapid heartbeat
- Dizziness when standing up (orthostatic hypotension), feeling of spinning (vertigo), low blood pressure

- Feeling anxious, feeling sad (depression), difficulty falling asleep.
- Sleepiness, feeling drowsy
- Increased sweating, redness of skin, medicine rash, eczema (a skin disorder), itching, hives (urticaria)
- Impaired vision.

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 or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA's website. By reporting side effects, you can help provide more information on the safety of TELMISARTAN SHANUR**.**

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za

5. How to store TELMISARTAN SHANUR

Store all medicines out of reach of children.

Store at or below 25 °C.

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

Do not use after the expiry date printed on the carton.

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 TELMISARTAN SHANUR contains

- The active substance is telmisartan.

Austell Pharmaceuticals (Pty) Ltd, 590949-50, TELMISARTAN 40 mg and 80 mg SHANUR tablets

- The other ingredients are Magnesium stearate, Mannitol (Pearlitol SD 200), Meglumine, Povidone (Polyvinylpyrolidone-PVPK-30), Sodium hydroxide.

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.

What TELMISARTAN SHANUR looks like and contents of the pack

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.

TELMISARTAN 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.

Holder of Certificate of Registration

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TELMISARTAN 80 mg SHANUR tablets: 59/7.1.3/0950

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

https://austell.co.za/product-info/

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