Approved 28/04/2021

SCHEDULING STATUS S3

1 NAME OF THE MEDICINE
TELEASE 40 tablets
TELEASE 80 tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
TELEASE 40: Each tablet contains 40 mg telmisartan. Contains mannitol: 166,64 mg per tablet.
TELEASE 80: Each tablet contains 80 mg telmisartan. Contains mannitol: 333,28 mg per tablet. For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
TELEASE 40: White or off-white to yellowish oblong biconvex uncoated tablets with break-line on one side and plain on the other side.
TELEASE 80: White or off-white to yellowish oval biconvex uncoated tablets with break-line 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
The recommended dose is 40 mg once daily. In cases where the target blood pressure is not achieved, the TELEASE dose can be increased to a maximum of 80 mg once daily. Alternatively, TELEASE 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 TELEASE. 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 TELEASE are effective in preventing cardiovascular morbidity and mortality. When initiating TELEASE therapy for the prevention 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.
Renal impairment: No dosage adjustment is required for patients with renal impairment, including those on haemodialysis. TELEASE is not removed from blood by hemofiltration.
Hepatic impairment: In patients with mild to moderate hepatic impairment the dosage should not exceed 40 mg once daily.
Elderly: No dosage adjustment is necessary.
Children and adolescents up to 18 years: The safety and efficacy of TELEASE for use in children below 18 years have not been established.
Method of administration
TELEASE tablets are for once-daily oral administration and should be taken with liquid, with or without food.
4.3 Contraindications
- Hypersensitivity to telmisartan or to any of the ingredients of TELEASE (see section 2 and 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.
- Concomitant therapy with potassium sparing diuretics such as spironolactone, triamterene, amiloride (see section 4.4).
- Porphyria.
- Lithium therapy: Concomitant administration with TELEASE may lead to toxic blood concentrations of lithium (see section 4.5).
- Pregnancy and lactation (see section 4.6).
- Severe hepatic impairment.
- Obstructive biliary disorders.
- The concomitant use of TELEASE with aliskiren-containing products is contraindicated (see section 4.4 and 4.5).
- Concomitant use of fluoroquinolones with Angiotensin-converting enzyme (ACE) inhibitors/Angiotensin receptor blockers (ARBs) 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 TELEASE, the treatment should be stopped promptly and switched to a different class of antihypertensive medicine (see sections 4.3 and 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 TELEASE (see section 4.3).
Renal impairment and kidney transplant: When TELEASE is used in patients with impaired renal function, a periodic monitoring of potassium and creatinine serum levels is recommended. There is no experience regarding the administration of TELEASE 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 vigorous diuretic therapy, dietary salt restriction, diarrhoea or vomiting. Such conditions, especially volume and/or sodium depletion, should be corrected before the administration of TELEASE.
Dual blockade of the renin-angiotensin-aldosterone system (RAAS): There is evidence that the concomitant use of angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers or aliskiren may increase the risk of hypotension, hyperkalaemia and decreases renal function (including acute renal failure). Dual blockade of RAAS through the combined use of TELEASE and aliskiren is therefore contraindicated (see section 4.3). TELEASE 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 medicines that affect this system, such as TELEASE, has been associated with acute hypotension, uraemia, oliguria, or acute renal failure.
Concomitant use of fluoroquinolones: Concomitant use of fluoroquinolones and Angiotensin-converting enzyme (ACE) inhibitors/Angiotensin receptor blockers (ARBs) 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 Angiotensin-converting enzyme (ACE) inhibitors/Angiotensin receptor blockers (ARBs) whether used separately and/or concomitantly.
Primary aldosteronism: Patients with primary aldosteronism generally will not respond to TELEASE. Therefore, the use of TELEASE is not recommended.
Aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy: TELEASE is contraindicated in patients suffering from aortic or mitral stenosis, or obstructive hypertrophic cardiomyopathy (see section 4.3.). Excessive reduction in blood pressure in patients with ischaemic cardiopathy or ischaemic cardiovascular disease could result in a myocardial infarction or stroke.
Diabetic patients treated with insulin or antidiabetics: In these patients hypoglycaemia may occur with TELEASE treatment. Therefore, in these patients, appropriate blood glucose monitoring should be considered; a dose adjustment of insulin or antidiabetics may be required, when indicated.
Hyperkalaemia: During treatment with TELEASE, 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 patients with renal insufficiency, in diabetic patients, in patients concomitantly treated with other medicines that may increase potassium levels, and/or in patients with intercurrent events, hyperkalaemia may be fatal.
The main risk factors for hyperkalaemia are:
- Diabetes mellitus, renal impairment, age (>70 years)
- Combination with one or more other medicines that affect the renin-angiotensin-aldosterone system and/or potassium supplements. Medicines or therapeutic classes of medicines that may provoke hyperkalaemia are salt substitutes containing potassium, potassium-sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, non-steroidal anti-inflammatory medicines (NSAIDs, including selective COX-2 inhibitors), heparin, immunosuppressives (ciclosporin or tacrolimus), and trimethoprim.
- Intercurrent events, in particular 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).

Hepatic impairment: TELEASE is mostly eliminated in the bile. Patients with biliary obstructive disorders, cholestasis, or hepatic insufficiency can be expected to have reduced clearance (see section 4.3) and should not take TELEASE. TELEASE should be used only with caution in patients with mild to moderate hepatic impairment.
Other: Angiotensin receptor blockers, including TELEASE, 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.

4.5 Interaction with other medicines and other forms of interaction
TELEASE may increase the hypotensive effect of other antihypertensive medicines. Co-administration of telmisartan did not result in a clinically significant interaction with warfarin, hydrochlorothiazide, glibenclamide, paracetamol, ibuprofen, simvastatin and amlodipine.
Digoxin: Co-administration of telmisartan did not result in a clinically significant interaction with digoxin, warfarin, hydrochlorothiazide, glibenclamide, paracetamol, ibuprofen, simvastatin and amlodipine. When telmisartan was co-administered with digoxin, median increases in digoxin peak plasma concentration (49 %) and in trough concentration (20 %) were observed (in a single case a 39 %). When initiating, adjusting, and discontinuing telmisartan, monitor digoxin levels in order to maintain levels within the therapeutic range.
Potassium sparing diuretics or potassium supplements: As with other medicines 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 medicines that may also provoke hyperkalaemia (salt substitutes containing potassium, potassium-sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, non-steroidal anti-inflammatory medicines [NSAIDs, including selective COX-2 inhibitors], heparin, immunosuppressives [ciclosporin or tacrolimus], and trimethoprim).Angiotensin II receptor antagonists such as telmisartan, 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.
Lithium: 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.
Non-steroidal anti-inflammatory drugs: Concomitant treatment with NSAIDs (including acetylsalicylic acid at anti- inflammatory dosage regimens, COX-2 inhibitors and non-selective NSAIDs) may reduce the antihypertensive effect of angiotensin II receptor antagonists. 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. Compounds acting on the Renin-Angiotensin-System like TELEASE may have synergistic effects. Patients receiving NSAIDs and TELEASE should be adequately hydrated and be monitored for renal function at the beginning of combined treatment. A reduced effect of antihypertensive medicines like TELEASE by inhibition of vasodilating prostaglandins has been reported during combined treatment with NSAIDs.
Ramipril: In one study the co-administration of telmisartan and ramipril led to an increase of up to 2, 5 fold in the AUC0-24 and Cmax of ramipril and ramiprilat. The clinical relevance of this observation is not known.
Dual blockade of the RAAS with ARBs, ACE inhibitors or aliskiren: Clinical trial data has shown that dual blockade of the renin-angiotensin-aldosterone-system (RAAS) through the combined use of angiotensin-converting enzyme (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 sections 4.3 and 4.4). Based on their pharmacological properties it can be expected that the following medicines may potentiate the hypotensive effects of all antihypertensives including telmisartan: Baclofen, amifostine. Furthermore, orthostatic hypotension may be aggravated by alcohol, barbiturates, narcotics, or antidepressants.
Concomitant use of fluoroquinolones: Concomitant use of fluoroquinolones and Angiotensin-converting enzyme (ACE) inhibitors/Angiotensin receptor blockers (ARBs) 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).
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. To be taken into account with concomitant use.
Corticosteroids (systemic route): Reduction of the antihypertensive effect.
4.6 Fertility, pregnancy and lactation
Women of childbearing potential: Women of childbearing age should ensure effective contraception.
Pregnancy: Safety in pregnancy has not been established (see section 4.3). When pregnancy is planned or confirmed TELEASE should be discontinued. Medicines affecting the renin-angiotensin system, such as TELEASE, can cause embryonal toxicity, foetal and neonatal morbidity and mortality when administered to pregnant women.
Breastfeeding: TELEASE is contraindicated during lactation (see section 4.3).
Fertility: In preclinical studies, no effects of TELEASE on male and female fertility were observed
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 should be taken into account that dizziness or drowsiness may occasionally occur when taking antihypertensive therapy including TELEASE.
4.8 Undesirable effects
Tabulated list of adverse reactions

MedDRA system organ class	Frequency	Adverse reactions
Infections and infestations	Less frequent	Urinary tract infection (including cystitis), upper respiratory tract infection including pharyngitis and sinusitis
	Frequency unknown	Sepsis including fatal outcome
Blood and lymphatic system disorders	Less frequent	Anaemia, thrombocytopenia
	Frequency unknown	Eosinophilia
Immune system disorders	Less frequent	Hypersensitivity, angio-oedema (with fatal outcome)
	Frequency unknown	Anaphylactic reaction
Metabolism and nutrition disorders	Less frequent	Hyperkalaemia
	Frequency unknown	Hypoglycaemia (in diabetic patients)
Psychiatric disorders	Less frequent	Insomnia, depression, anxiety
Nervous system disorders	Less frequent	Syncope/fainting, somnolence
Eye disorders	Less frequent	Visual disturbance
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	Cough
	Less frequent	Dyspnoea, interstitial lung disease
Gastrointestinal disorders	Less frequent	Abdominal pain, diarrhoea, dyspepsia, flatulence, vomiting, dry mouth, stomach discomfort, dysgeusia
Hepato-biliary disorders	Frequency unknown	Hepatic function abnormal/liver disorder
Skin and subcutaneous tissue disorders	Less frequent	Increased sweating (hyperhidrosis), pruritis, rash, eczema, erythema, drug eruption, toxic skin eruption
	Frequency unknown	Urticaria
Musculoskeletal and connective tissue disorders	Less frequent	Back pain (e.g. sciatica), muscle spasms (cramps in legs), myalgia, arthralgia, pain in extremity (leg pain)
	Frequency unknown	Tendon pain (tendinitis like symptoms)
Renal and urinary disorders	Less frequent	Renal impairment including acute renal failure
General disorders and administration site conditions	Less frequent	Chest pain, asthenia (weakness), influenza-like symptoms
Investigations	Less frequent	Blood creatinine increased, haemoglobin decreased, blood uric acid increased, hepatic enzymes increased, blood creatine phosphokinase increased

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 & Quality Problem Reporting Form**", found online under SAHPRA's publications: https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf
4.9 Overdose
Symptoms: Limited information is available with regard to overdose in humans. 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.
Management: If symptomatic hypotension should occur, supportive treatment should be instituted. Telmisartan, as in TELEASE is not removed by haemodialysis. Management depends on the time since ingestion and the severity of the symptoms. 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
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 human, an 80 mg dose of telmisartan almost completely inhibits the angiotensin II evoked blood pressure increase. The inhibitory effect is maintained over 24 hours and is still measurable up to 48 hours. After administration of the first dose of telmisartan in hypertensive patients, 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. Telmisartan treatment has been shown in clinical trials 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 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 TELEASE is taken with food, the reduction in the area under the plasma concentration-time curve ($AUC_{0-\infty}$) of telmisartan 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 biexponential 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. There is no evidence of clinically relevant accumulation of telmisartan. 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 dose. Total plasma clearance (CL_{tot}) is high (approximately 900 mL/min) when compared with hepatic blood flow (about 1 500 mL/min).
Special populations
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 PARTICULARS
6.1 List of excipients
Mannitol (E421), Meglumine, Povidone, Sodium hydroxide (E524), Sodium stearyl fumarate.
6.2 Incompatibilities
Not applicable.
6.3 Shelf life
36 months.
6.4 Special precautions for storage
Store at or below 25 °C. Keep the blisters in the original container until required for use.
6.5 Nature and contents of container
TELEASE tablets are packed in the following pack: Blister pack using aluminium foil with heat seal lacquer coating sealed with cold forming blister aluminium foil (Alu/Alu blister). The blister strips will be packed in cartons with 14, 28, 30 or 56 tablets. Not all pack sizes may be marketed.
6.6 Special precautions for disposal and other handling
Not applicable

7 HOLDER OF CERTIFICATE OF REGISTRATION
Trinity Pharma (Pty) Ltd. 106 16th Road, Midrand, 1686.

8 REGISTRATION NUMBERS
TELEASE 40: 47/7.1.3/0334
TELEASE 80: 47/7.1.3/0335

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
16 February 2021

10 DATE OF REVISION OF THE TEXT

SKEDULERINGSTATUS S3

1 HANDELSNAAM VAN DIE MEDISYNE
TELEASE 40 tablette
TELEASE 80 tablette

2 KWALITATIEWE EN KWANTITATIEWE SAMESTELLING
TELEASE 40: Elke tablet bevat 40 mg telmisartan. Bevat mannitol: 166,64 mg per tablet.
TELEASE 80: Elke tablet bevat 80 mg telmisartan. Bevat mannitol: 333,28 mg per tablet. Vir 'n volledige lys van hulpstowwe, sien afdeling 6.1.

3 DOSEERVORM
TELEASE 40: Wit of effewit tot geel, langwerpige, bikonvekse onbedekte tablet met `n breuklyn gebosseleer aan die een kant en aan die ander kant `n plein afwerking.
TELEASE 80: Wit of effewit tot geel, ovaalvormige, bikonvekse onbedekte tablet met `n breuklyn gebosseleer aan die een kant en aan die ander kant `n plein afwerking.

4 KLINIESE INLIGTING
4.1 Terapeutiese indikasies
Behandeling van ligte tot matige hipertensie, as enkelmiddel of in kombinasie met hidrochloortiasied. Verlaging van kardiovaskulêre morbiditeit en mortaliteit in pasiënte 55 jaar en ouer met `n hoë risiko vir kardiovaskulêre siektes; die voordeel van die behandeling is duidelik na 6 maande van ononderbroke behandeling.

4.2 Posologie en metode van toediening
Posologie
Volwassenes
Behandeling van essensiële hipertensie: Die aanbevole dosis is 40 mg daagliks. In gevalle waar die gewenste bloeddruk nie verkry word nie, kan die TELEASE dosis verhoog word tot 80 mg daagliks. Alternatiwelik, kan TELEASE in kombinasie met `n lae dosis tiasied-tipe diuretikum soos hidrochloortiasied 12,5 mg, wat 'n aanvullende bloeddrukverlagende effek met TELEASE getoon het, toegedien word. Wanneer daar oorweeg word om die dosis te verhoog, moet daar in gedagte gehou word dat die maksimum antihipertensiewe effek oor die algemeen vier tot agt weke, na aanvang van behandeling, verkry word.
Vermindering van kardiovaskulêre morbiditeit en mortaliteit: Die aanbevole dosis is 80 mg daagliks. Dit is nie bekend of dosisse laer as 80 mg TELEASE doeltreffend is om kardiovaskulêre morbiditeit en mortaliteit te voorkom nie. Tydens die aanvang van behandeling met TELEASE vir die voorkoming van kardiovaskulêre morbiditeit en mortaliteit, word dit aanbeveel dat die bloeddruk van die pasiënt gemonitor word, en indien van toepassing, kan die medisyne wat die bloeddruk verlaag sodoende aangepas word. Die voordeel van die behandeling is eers duidelik na 6 maande van ononderbroke behandeling.
Ingekorte nierfunksie: Geen aanpassing in die dosis is nodig by pasiënte met ingekorte nierfunksie nie, insluitend diegene wat op hemodialise is. TELEASE word nie deur hemofiltrasie uit die bloed verwyder nie.
Ingekorte lewerfunksie: Pasiënte met ligte tot matige lewerontoereikendheid moet nie die dosis van 40 mg daagliks oorskry nie.
Bejaardes: Geen aanpassing in die dosis is nodig nie.
Kinders en adolessente tot en met 18 jaar: Die veiligheid en doeltreffendheid van TELEASE vir gebruik by kinders onder 18 jaar is nie nog nie vasgestel nie.
Metode van toediening: TELEASE tablette is vir een keer per dag orale toediening bestem en moet saam met vloeistof, met of sonder voedsel geneem word.
4.3 Kontraïndikasies
- Hipersensitiwiteit vir telmisartan of enige van die ander bestandele in TELEASE (sien afdeling 2 en 6.1).
- `n Geskiedenis van angioëdeem vanweë vorige behandeling met angiotensien-omskakelingsensiem (AOE) inhibeerders of angiotensien-reseptor blokkeerders (ARBs): Daar moet nooit weer van die medisyne vir hierdie pasiënte gegee word nie.
- Oorerflike of idiopatiese angioëdeem.
- Hipertrofiese obstruktiewe kardiomiopatie (HOKM).
- Ernstige belemmerde nierfunksie (kreatinienopruiming minder as 30 mL/min).
- Bilaterale nieraarstenose.
- Nieraarstenose by pasiënte met 'n enkele nier.
- Stenose van die aorta.
- Gelyktydige behandeling met kaliumsparende diuretika soos spironolaktoon, triamtereen, amiloried (verwys na afdeling 4.4).
- Porfirie.
- Litiumbehandeling: Gelyktydige toediening van TELEASE kan lei tot 'n toksiese bloedkonsentrasie van litium (verwys na afdeling 4.5).
- Swangerskap en laktasie (verwys na afdeling 4.4 en 4.6).
- Ernstige ingekorte lewerfunksie.
- Obstruksie galbuisafwykings.
- Die gelyktydige gebruik van TELEASE met aliskiren-bevattende produkte word teenaangedui (verwys na afdeling 4.4 en 4.5).
- Gelyktydige gebruik van fluorokinolone met Angiotensien-omskakelingsensiem (AOE) inhibeerders/Angiotensien reseptor blokkeerders (ARBs) is teenaangedui in pasiënte met matige tot ernstige nierversaking (kreatinienopklaring van ≤ 30 mL/min) en in bejaarde pasiënte.

4.4 Spesiale waarskuwings en voorsorgmaatreëls vir gebruik
Indien 'n vrou swanger raak terwyl sy TELEASE neem, moet die behandeling onmiddelik gestaak word en na 'n ander klas van anti-hipertensiewe middel oorgeskakel word (verwys na afdeling 4.3 en 4.6).
Renovaskulêre hipertensie: Daar is 'n hoër risiko van ernstige hipotensie en nierontoereikendheid wanneer pasiënte met bilaterale nierarteriestenose of stenose van die slagaar na 'n enkele funksionerende nier met TELEASE behandel word (verwys na afdeling 4.3).
Belemmerde nierfunksie en nieroorplanting: Wanneer TELEASE gebruik word by pasiënte met belemmerde nierfunksie, word periodieke monitering van die kalium- en kreatinienserumvlakke aanbeveel. Daar is geen ervaring met die toediening van TELEASE in pasiënte met 'n onlangse nieroorplanting nie (verwys na afdeling 4.3).
Intravaskulêre hipovolemie: Simptomatiese hipotensie, veral na die eerste dosis, kan voorkom by pasiënte met volume- en/of natriumuitputting weens drastiese diuretiese terapie, soutbeperkende dieet, diaree of braking. Sulke toestande, veral volume- en/of natriumuitputting, moet voor die toediening van TELEASE reggestel word.
Dubbele blokkade van die renien-angiotensien-aldosteroonstelsel (RAAS): Daar is bewyse dat die gelyktydige gebruik van angiotensien omskakelingsensiem (AOE) inhibeerders angiotensien-II reseptorblokkeerders of aliskiren die risiko mag verhoog van hipotensie, hiperkalemie en verswakking van die nierfunksie (insluitend akute nierversaking). Dubbele blokkade van RAAS deur die gelyktydige gebruik van TELEASE en aliskiren word dus teenaangedui (verwys na afdeling 4.3).
TELEASE moet nie gelyktydig met aliskiren geneem word nie (verwys na afdeling 4.3). AOE-inhibeerders en angiotensien-II reseptorblokkeerders moet nie gelyktydig gebruik word in pasiënte met diabetiese nefropatie nie.
Ander siektetoestande met stimulasie van die renien-angiotensien-aldosteroonstelsel: By pasiënte wie se vaskulêre tonus en nierfunksie hoofsaaklik afhanklik is van die aktiwiteit van die renien-angiotensien-aldosteroonstelsel (bv. pasiënte met ernstige kongestiewe hartversaking of onderliggende niersiekte, insluitend nieraarstenose), word die behandeling met geneesmiddels wat hierdie stelsel affekteer, soos TELEASE, geassosieer met akute hipotensie, uremie, oligurie of akute nierversaking.
Gelyktydige gebruik van fluorokinolone: Gelyktydige gebruik van fluorokinolone en Angiotensien-omskakelingsensiem (AOE) inhibeerders/ Angiotensien reseptor blokkeerders (ARBs) kan akute nierbesering in pasiënte bespoedig, veral die met matige tot ernstige nierversaking en bejaarde pasiënte (verwys na afdeling 4.3.) Nierfunksie moet bepaal word voor die inisiëring van behandling en moet gemonitor word tydens behandeling met fluorokinolone of AOE inhibeerders/
Angiotensien reseptor blokkeerders; wanneer dit afsonderlik of gesamentlik geneem word.
Primêre aldosteronisme: Pasiënte met primêre aldosteronisme sal oor die algemeen nie op TELEASE reageer nie. Gevolglik word die gebruik van TELEASE nie aanbeveel nie.
Aorta- en mitraalklep stenose, obstruktiewe hipertrofiese kardiomiopatie: TELEASE is teenaangedui in pasiënte wat ly aan aortiese- of mitralestenose of hipertrofiese obstruktiewe kardiomiopatie (verwys na afdeling 4.3). Oormatige verlaging in bloeddruk in pasiënte met iskemiese kardiopatie of iskemiese kardiovaskulêre siekte mag ontaard in 'n miokardiale infarksie of beroerte.
Diabetiese pasiënte wat behandel word met insulien of antidiabetiese medisyne: Hipoglisemie mag voorkom by hierdie pasiënte tydens behandeling met TELEASE. Daarom moet daar gepaste bloedglukose monitering oorweeg word by hierdie pasiënte; 'n dosisaanpassing van insulin of antidiabetiese medisyne mag nodig wees, soos aangedui.
Hiperkalemie: Tydens die behandeling met TELEASE mag hiperkalemie voorkom, veral in die teenwoordigheid van belemmerde nierfunksie en/ of hartversaking. Monitering van serumkalium
by risikopasiënte word aanbeveel.
By bejaardes, by pasiënte met nierontoereikendheid, by diabete, by pasiënte wat gelyktydige behandeling ontvang wat kaliumvlakke mag verhoog, en/of by pasiënte met tussentydse gebeurtenisse, mag hiperkalemie fataal wees.
Die hoof risikofaktore vir hiperkalemie is:
- Diabetes mellitus, nierontoereikendheid, ouderdom (>70 jaar)
- Kombinasie van een of meer medisyne wat die renienangiotensien-aldosteroon sisteem en/of kaliumaanvullers. Medisyne of terapeutiese klasse van medisyne wat hiperkalemie mag bevorder, sluit in kaliumbevattende soutvervangers, kaliumsparende diuretika, AOE inhibeerhders, angiotensien II reseptor antagoniste, nie-steroïed anti-inflammatoriese middels (NSAIMs, insluitend selektiewe COX-2 inhibeerders), heparien, immuun-onderdrukkers (siklosporien of takrolimus), en trimetoprim.
- Tussentydse gebeurtenisse, veral dehidrasie, akute hartdekompensasie, metaboliese asidose, verergering van nierfunksie, skielike verergering van die niertoestand (bv. aansteeklike siektes), sellulêr-lise (bv. akute ledemaat iskemie, rabdomiolise, verlening van trauma).

Lewerontoereikendheid: TELEASE word hoofsaaklik in die gal uitgeskei. Daar kan verwag word dat pasiënte met obstruktiewe biliêre afwykings of lewerontoereikendheid 'n afname in opruiming sal hê (verwys na afdeling 4.3) en moet dus nie TELEASE neem nie. TELEASE moet dus slegs met sorg gebruik word by pasiënte met ligte tot matige lewerontoereikendheid.
Ander: Angiotensien-reseptorblokkeerders, waaronder TELEASE, is skynbaar minder doeltreffend in die verlaging van bloeddruk by swartmense as by nie-swartmense, waarskynlik as gevolg van 'n hoër voorkoms van lae-renien toestande in die swart hipertensiewe populasie.
4.5 Interaksies met ander medisyne en ander vorme van interaksies
TELEASE mag die hipotensiewe effek van ander antihipertensiewe geneesmiddels verhoog. Gelyktydige toediening van TELEASE het nie gelei tot 'n klinies beduidende interaksie met warfarien, hidrochloorthiasied, glibenklamied, parasetamol, ibuprofen, simvastatien en amlodipien nie.
Digoksien: Gelyktydige toediening van TELEASE het nie gelei tot 'n klinies beduidende interaksie met digoksien, warfarien, hidrochloorthiasied, glibenklamied, parasetamol, ibuprofen, simvastatien en amlodipien nie. Tydens gelyktydige toegediening van telmisartan met digoksien, was daar 'n gemiddelde toename in die digoksien piekplasmakonsentrasie (49 %) en in die trogkonsentrasie (20 %) waargeneem (in 'n enkele geval was dit 39 %). Wanneer behandeling met telmisartan begin, aangepas en gestaak word, moet die monitering van digoksienvlakke oorweeg word om sodoende vlakke binne die terapeutiese omvang te handhaaf.
Kaliumsparende diuretika of kaliumaanullings: Soos met ander medisyne wat ook op die renien-angioternsien-aldosterone sisteem inwerk, mag telmisartan ook hiperkalemie vererger (sien seksie 4.4). Die risiko mag verhoog waar daar 'n kombinasie behandeling met ander medisyne is, waar hiperkalemie ook kan ontstaan (kaliumbevattende soutvervangers, kaliumbesparende diuretika, AOE inhibeerders, angiotensien II reseptor antagoniste, nie-steroïed anti-inflammatories medisyne [NSAIMs, insluitende selektiewe COX-2 inhibibeerders], heparien, immuunonderdrukkers [siklosporien of takrolimus], en trimetoprim). Angiotensien II reseptor antagoniste soos telmisartan, verminder diuretika geïnduseerde kaliumverlies. Kaliumsparende diuretika bv. spironolaktoon, eplerenoon, triamtereen, of amiloried, kaliumaanvullings, of kaliumbevattende soutvervangers mag tot 'n aansienbare verhoging in serumkalium lei.
Litium: Omkeerbare toenames in serum-litiumkonsentrasie en toksisiteit is gerapporteer tydens gelyktydige toediening van litium met angiotensie-omskakelingsensiem remmers. Verhoogde serumvlakke is ook met telmisartan gerapporteer. Noukeurige monitering van serum litiumvlakke word aanbeveel tydens gelyktydige gebruik.
Nie-steroïed anti-inflammatoriese medisyne: Gelyktydige behandeling met NSAIMs (insluitend asetielsalisielsuur by anti-inflammatoriese behandelings, COX-2 inhibeerders en nie-selektiewe NSAIMs) mag die antihipertensiewe effek van angiotensien II reseptor antagoniste verlaag. By sommige pasiënte met ingekorte nierfunksie (bv. gedehidreerde pasiënte of bejaardes met ingekorte nierfunksie), mag die gelyktydige toediening van angiotensien II reseptor antagoniste en medisyne wat siklo-oksigenase inhibeer lei tot verdere verswakking van nierfunksie, insluitend moontlike akute nierversaking, wat omkeerbaar is. Dus, die kombinasie moet met sorg toegedien word, veral by bejaardes. Medisyne wat op die Renien-Angiotensien-Sisteem inwerk, soos TELEASE, kan sinergistiese effekte hê. Pasiënte wat NSAIMs en TELEASE neem moet voldoende hidreer and moet gemonitor word vir nierfunksie aan die begin van die kombinasie behandeling.
'n Verminderde effek van anti-hipertensiewe medisyne soos TELEASE is aangemeld met gekombineerde behandeling met NSAIMs omdat dit vasodilatoriese prostaglandiene inhibeer.
Ramipriel: In een studie het die gelyktydige toediening van TELEASE en ramipriel 'n toename van tot en met 2,5-voudig die AOK_{0-24} en K_{maks} van ramipriel en ramiprilaat veroorsaak. Die kliniese betekenis van hierdie waarneming is onbekend.
Dubbele blokkade van die RAAS met ARBs, AOE-inhibeerders of aliskiren: Data uit kliniese studies het aangetoon dat dubbele blokkade van die renien-angiotensien-aldosteroonstelsel (RAAS) deur die gekombineerde gebruik van angiotensien-omskakelingsensiem (AOE) in hibeerders, angiotensien-II reseptorblokkeerders of aliskiren geassosieer kan word met 'n verhoogde voorkoms van nadelige effekte soos hipotensie, hiperkalemie en verminderde nierfunksie (sien afdelings 4.3 en 4.4). Op grond van die farmakologiese eienskappe kan dit verwag word dat die volgende medisyne die hipotensiewe effek van alle antihipertensiewe medisyne kan verhoog insluitend telmisartan: Baklofen, amifostien. Verder kan ortostatiese hipotensie vererger word deur alkohol, barbiturate, verdowingsmiddels of antidepressante.
Bygaande gebruik van fluorokinolone: Bygaande gebruik van fluorokinolone en angiotensien-omskakelingsensiem (AOE) inhibeerders/ Angiotensien reseptor blokkeerders (ARBs) kan akute nierbesering bespoedig. Die meganisme van die moontlike interaksie tussen die verskillende klasse medisynes, bowenal verskillende meganismes van nierskade, is onbekend (sien seksie 4.3).
Diuretika (tiasied of lusdiuretikum): Voorafbehandeling met hoë dosis diuretika soos furosemied (lusdiuretikum) en hidrochloortiasied (tiasiediuretikum) kan lei tot volume-uitputting, en die risiko van hipotensie wanneer die behandeling met telmisartan begin. Moet in ag geneem word met gepaardgaande gebruik.
Kortikosteroïede (sistemiese roete): Vermindering van die antihipertensiewe effek.
4.6 Fertiliteit, swangerskap en laktasie
Vroue wat vrugbaar is: Vroue in vrugbare ouderdom moet doeltreffende voorbehoedmiddels gebruik.
Swangerskap: Veiligheid tydens swangerskap is nog nie vasgestel nie (sien afdeling 4.3). Wanneer swangerskap beplan of bevestig word, moet TELEASE gestaak word. Medisyne wat die renien-angiotensienstelsel beïnvloed, soos TELEASE, kan embrionaletoksisiteit, fetale en neonatale morbiditeit en mortaliteit veroorsaak wanneer dit aan swanger vroue toegedien word.
Borsvoeding: TELEASE is teenaangedui tydens laktasie (sien afdeling 4.3).
Vrugbaarheid: In pre-kliniese studies is geen effekte van TELEASE op manlike en vroulike vrugbaarheid waargeneem nie.
4.7 Effekte op die vermoë om te bestuur en masjiene te gebruik
Geen studies is uitgevoer oor die uitwerking op die vermoë om te bestuur en masjiene te gebruik nie. Wanneer voertuie bestuur of masjinerie gebruik word, moet dit egter in ag geneem word dat daar soms, af en toe, duiseligheid of lomerigheid kan voorkom tydens die gebruik van bloeddrukverlagende behandeling, insluitend TELEASE.
4.8 Newe-effekte
Getabuleerde lys van newe-effekte

MedDRA Sisteem Orgaan Klas	Dikwels/ nie dikwels, onbekend	Newe-effekte
Infeksies en infestasies	Minder algemeen	Urienweginfeksies (waaronder sistitis), boonste lugweginfeksies (waaronder faringitis en sinusitis)
	Onbekend	Sepsis insluitend noodlottige gevolg
Bloed- en limfstelselafwykings	Minder algemeen	Anemie, trombositopenie
	Onbekend	Eosinofilie
Immuunstelselafwykings	Minder algemeen	Hypersensitiwiteit, angioëdeem (met noodlottige gevolg)
	Onbekend	Anafilaktiese reaksie
Metabolisme- en voedingsafwykings	Minder algemeen	Hiperkalemie
	Onbekend	Hipoglisemie (in diabetiese pasiënte)
Psigiatriese afwykings	Minder algemeen	Slapeloosheid, depressie, angs
Senuweestelselafwykings	Minder algemeen	Sinkopee, floute, slaaperigheid
Oogafwykings	Minder algemeen	Visuele steurnisse
Oor- en labirintafwykings	Minder algemeen	Vertigo
Hartafwykings	Minder algemeen	Bradikardie, tagikardie
Vaskulêre afwykings	Minder algemeen	Hipotensie, ortostatiese hipotensie
Respiratoriese-, torakale- en mediastinale afwykings	Algemeen	Hoes
	Minder algemeen	Dispnee, interstitiële longsiekte.
Gastroïntestinale afwykings	Minder algemeen	Buikpyn, diaree, dispepsie, winderigheid, braking, droë mond, maag ongemak, disgeusie
Hepatobiliêre afwykings	Onbekend	Abnormale lewer funksie/ ingekorte lewer
Vel- en onderhuidse weefselafwykings	Minder algemeen	Verhoogde sweetafskeiding (hiperhidrose), pruritis, veluitslag, ekseem, eriteem, geneesmiddel-uitslag, toksiese veluitbraak
	Onbekend	Urtikarie
Muskuloskeletale-, bindweefsel- en beenafwykings	Minder algemeen	Rugpyn, spierspasmas (krampe in bene), mialgie, artralgie, pyn in ledemate (beenpyn)
	Onbekend	Tendonpyn (simptome vergelykbaar met die van tendonitis)
Nier- en urienwegafwykings	Minder algemeen	Ingekorte nierfunksie waaronder akute nierversaking
Algemene afwykings en toestande van die toedieningsplek	Minder algemeen	Borspyn, astenie (swakheid), griepagtige simptome
Ondersoeke	Minder algemeen	Verhoogde kreatinien in bloed, verlaagde hemoglobien, verhoogde uriensuur in bloed, verhoogde lewerensieme, verhoogde kreatienfosfokinase in bloed.

Rapportering van vermoedelik nadelige reaksies: Dit is belangrik om verslag te doen oor vermoedelik newe-reaksies na goedkeuring van die medisyne. Dit laat voortgesette monitering van die voordeel / risikobalans van die medisyne toe. Verskaffers van gesondheidsorg word versoek om enige vermoedelik nadelige reaksies aan te meld by SAHPRA met gebruik van die volgende vorm "**6.04 Adverse Drug Reactions Reporting Form**", wat aanlyn aangetref kan word by SAHPRA se publikasies: https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf
4.9 Oordosering
Simptome: Daar is slegs beperkte inligting beskikbaar aangaande oordosering by mense. Die mees opvallende tekens van TELEASE oordosering was hipotensie en tagikardie; bradikardie duiseligheid, verhoogde serum kreatinien, en akute nierversaking het ook voorgekom.
Behandeling: Indien simptome van hipotensie voorkom, moet ondersteunende terapie / behandeling voortgesit word. Telmisartan, die aktiewe bestandeel van die produk TELEASE, word nie deur hemodialise verwyder nie. Die hantering van `n oordosering word bepaal volgens die aanvang van inname en die erns van die simptome. Serumelektroliete en kreatinien moet dikwels gemonitor word. Indien hipotensie voorkom, moet die pasiënt op die rug neergelê word, en sout en volume vervanging so spoeding moontlik gegee word.

5 FARMAKOLOGIESE EIENSKAPPE
5.1 Farmakodinamiese eienskappe
A 7.1.3 Vaskulêre medisyne – ander hipotensiewes. Farmakoterapeutiese groep: Angiotensien-II Antagoniste, gewoon, ATC Kode: C09CA07.
Telmisartan is 'n spesifieke angiotensien-II reseptor (tipe AT_1) antagonis. Dit verplaas angiotensien-II van sy plek van binding op die AT_1 reseptor-subtipe, wat verantwoordelik is vir die bekende uitwerking van angiotensien-II. Telmisartan vertoon nie enige gedeeltelike agonisme op die AT_1 reseptor nie. Telmisartan bind selektief aan die AT_1 reseptor. Die binding is langdurig. Telmisartan inhibeer nie menslike plasmarenien nie en blokkeer ook nie die ioonkanale nie. By die mens inhibeer 'n dosis van 80 mg telmisartan die toename in bloeddruk wat deur angiotensien-II veroorsaak word, byna volledig. Die inhiberende effek word vir 24 ure volgehou en is steeds na 48 ure bepaalbaar. Na toediening van die eerste dosis van telmisartan aan hipertensiewe pasiënte begin die anti-hipertensiewe werking binne 3 ure. Die maksimum verlaging in bloeddruk word gewoonlik 4 weke na aanvang van behandeling bereik en word volgehou met langdurige behandeling.
Die anti-hipertensiewe effek duur voort vir meer as 24 uur na dosering. Daar is 'n klaarblyklike tendens van 'n verhouding tussen die dosis en die hersteltyd tot basislynwaarde van die sistoliese bloeddruk. In hierdie opsig is data rakende die diastoliese bloeddruk teenstrydig. By pasiënte met hipertensie verlaag telmisartan sowel die sistoliese as die diastoliese bloeddruk sonder om die polsspoed te beïnvloed. Na skielike staking van behandeling met telmisartan keer die bloeddruk geleidelik, oor 'n tydperk van 'n paar dae, terug na die waardes van voor die behandeling sonder dat daar aanduidings is van terugslag-hipertensie. Daar is in kliniese studies aangetoon dat behandeling met telmisartan geassosieer kan word met 'n statisties-beduidende vermindering in proteïenurie (waaronder mikro-albuminurie en makro-albuminurie) by pasiënte met hipertensie en diabetiese nefropatie. Behandeling met telmisartan geassosieer met statisties-beduidende verminderings in linker-ventrikulêre massa (LVM) en linker-ventrikulêre massa-indeks (LVMI) by pasiënte met hoë bloeddruk en linker-ventrikulêre hipertrofie (LVH).
5.2 Farmakokinetiese eienskappe
Die absorpsie van telmisartan is vinnig, alhoewel die hoeveelheid wat geabsorbeer word wissel. Die gemiddelde absolute biobeskikbaarheid is ongeveer 50 % vir telmisartan. Wanneer TELEASE met voedsel geneem word, wissel die vermindering in oppervlakte onder die plasmakonsentrasie-tydkromme ($AUC_{0-\infty}$) van telmisartan vanaf ongeveer 6 % (40 mg dosis) tot ongeveer 19 % (160 mg dosis). Drie (3) ure na toediening is die plasmakonsentrasies vergelykbaar, ongeag daarvan of telmisartan vastend of met voedsel geneem is. Daar word nie verwag dat die klein vermindering in AOK verminderde terapeutiese doeltreffendheid sal veroorsaak nie. Verskille in plasmakonsentrasies tussen geslagte word waargeneem; die K_{maks} en AOK is onderskeidelik ongeveer 3- en 2- keer hoër by vroue in vergelyking met mans, sonder 'n relevante invloed op doeltreffendheid. Telmisartan word sterk (> 99,5 %) aan plasmaproteïen gebind, hoofsaaklik albumien en alfa 1-suur-glikoproteïen. Die gemiddelde skynbare verspreidingsvolume (Vdss) by stabiele staat is ongeveer 500 L. Telmisartan word deur middel van konjugasie na die glukuroniед gemetaboliseer. Die konjugaat toon geen farmakologiese aktiwiteit nie. Telmisartan word gekenmerk deur bi-eksponensiële afbraak farmakokinetika met 'n terminale eliminasiehalfleeftyd van > 20 uur. Die maksimum plasmakonsentrasie (K_{maks}) en tot 'n mindere mate die area onder die plasmakonsentrasietydkromme (AOK), styg disproporsioneel met die dosis. Daar is geen bewys van klinies relevante akkumulasie van telmisartan nie. Plasmakonsentrasies was hoër by vroue as by mans, sonder enige relevante invloed op die doeltreffendheid. Na mondelikse toediening word telmisartan feitlik net deur die feses uitgeskei, hoofsaaklik as die onveranderde produk. Die kumulatiewe hoeveelheid wat via die uriene uitgeskei word is < 2 % van die dosis. Algehele opruiming uit die plasma (CL_{tot}) is hoog (ongeveer 900 mL/min) indien dit met die hepatiese bloedvloei (ongeveer 1 500mL/min) vergelyk word.
Spesiale pasiëntgroepe
Bejaarde pasiënte: Die farmakokinetika van telmisartan verskil nie tussen jonger en ouer pasiënte nie.
Pasiënte met ingekorte nierfunksie: Laer plasmakonsentrasies is by pasiënte met nierontoereikendheid wat dialise ondergaan waargeneem. By pasiënte met nierontoereikendheid is telmisartan baie sterk aan plasmaproteïene gebind en kan dit nie deur dialise verwyder word nie. Die eliminasiehalfleeftyd verander nie by pasiënte met belemmerde nierfunksie nie.
Pasiënte met belemmerde lewerfunksie: By pasiënte met lewerontoereikendheid is daar met farmakokinetiese studies 'n toename van bykans 100 % in die absolute biobeskikbaarheid waargeneem. Die eliminasiehalfleeftyd verander nie by pasiënte met lewerontoereikendheid nie.

6 FARMASEUTIESE BESONDERHEDE/INLIGTING
6.1 Lys van bymiddels
Mannitol (E421), Meglumien, Povidoon, Natriumhidroksied (E524) , Natriumstearielfumaraat.
6.2 Onverenigbaarheid
Nie van toepassing.
6.3 Rakleeftyd
36 maande.
6.4 Spesiale voorsorgmaatreëls tydens berging
Stoor teen of benede 25 °C. Hou die stulpstrook in die oorspronklike verpakking, tot voor gebruik.
6.5 Aard en inhoud van die houer
TELEASE tablette word verpak in die volgende verpakking: Stulpstroke van gewone silwer aluminiumfolie met `n hitte verseëlde laag bedek met `n koue vormende aluminiumfolie stulpstrook. Die stulpstroke word verpak in kartonhouers van 14, 28, 30 of 56 tablette. Nie alle verpakkingsgroottes word bemark nie
6.6 Spesiale voorsorgmaatreëls vir die vegdoening en ander hantering
Nie van toepassing nie.

7 HOUER VAN DIE REGISTRASIESERTIFIKAAT
Trinity Pharma (Pty) Ltd. 16e Straat 106, Midrand, 1686

8 REGISTRASIENOMMERS
TELEASE 40: 47/7.1.3/0334
TELEASE 80: 47/7.1.3/0335

9 DATUM VAN DIE EERSTE GOEDKEURING/HERSIENING VAN DIE GOEDKEURING
16 Februarie 2021

10 DATUM VAN DIE HERSIENING VAN DIE TEKS

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

TELEASE 40 tablets
TELEASE 80 tablets
Telmisartan
Contains sugar: mannitol 166,64 mg per 40 mg tablet
Contains sugar: mannitol 333,28 mg per 80 mg tablet

Read all of this leaflet carefully before you take TELEASE
· 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.
· TELEASE 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 is in this leaflet
1. What TELEASE is and what it is used for
2. What you need to know before you take TELEASE
3. How to take TELEASE
4. Possible side effects
5. How to store TELEASE
6. Contents of the pack and other information

2. What TELEASE is and what it is used for
TELEASE belongs to a class of medicines known as angiotensin II receptor antagonists. Angiotensin II is a substance produced in your body which causes your blood vessels to narrow, thus increasing your blood pressure. TELEASE blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

TELEASE tablets are used for the treatment of high blood pressure. TELEASE tablets can also be used to reduce cardiovascular events (i.e. heart attack or stroke) and death in patients 55 years or older who are at high risk of cardiovascular disease.

3. What you need to know before you take TELEASE
Do not take TELEASE:
- If you are allergic to telmisartan or any of the other ingredients of TELEASE (see section 6).
- If you have developed swelling of the face, lips, mouth, tongue or throat and giant wheals on your skin when previously taking medicines called angiotensin- converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) – you should never take these medicines again.
- If your doctor has told you that the thickness of your heart muscle is abnormally increased (hypertrophic obstructive cardiomyopathy (HOCM).
- If you suffer from obstruction of blood vessels to your heart or kidneys.
- If you suffer from severe kidney function problems.
- If you are currently taking potassium sparing diuretics ('water tablets') containing spironolactone, triamterene or amiloride.
- If you have porphyria (a rare hereditary disease).
- If you are currently taking lithium (used to treat some types of depression).
- Do not take TELEASE 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.
- If you suffer from severe liver disease or biliary obstruction (a problem with the drainage of the bile from the gall bladder).
- If you are currently taking aliskiren-containing products.
- If you are taking a fluoroquinolone antibiotic (used to treat a variety of illnesses such as respiratory and urinary tract infections) if you have kidney problems or are elderly.

Warnings and precautions
Take special care with TELEASE and tell your doctor:
- If you become pregnant while taking TELEASE. You should stop treatment immediately and contact your doctor to change your medicine.
- If you suffer from kidney disease or have had a kidney transplant.
- If your body could be lacking in salt due to a low salt diet, or if you have recently lost a lot of body fluids due to taking diuretic medicines (water tablets), vomiting or diarrhoea.
- If you are already taking a medicine called an angiotensin-converting enzyme (ACE) inhibitor
- Contact your doctor to re-evaluate your treatment if you are treated with Angiotensin-converting enzyme (ACE) inhibitors/Angiotensin receptor blockers (ARBs) together with a fluoroquinolone antibiotic.
- If you have been told previously that you have raised aldosterone levels.
- If you have heart problems.
- If you have diabetes.
- If you have high potassium levels in your blood or use salt substitutes containing potassium.
- If you have liver problems.

Children and adolescents
The safety and efficacy of TELEASE for use in children below 18 years have not been established.

Other medicines and TELEASE
Always tell your health care provider if you are taking any other medicine. (This includes all 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 TELEASE:
- Digoxin (used to treat various heart conditions).
- Medicines that may increase blood potassium levels such as salt substitutes containing potassium, potassium-sparing diuretics (certain "water tablets"), ACE inhibitors, angiotensin II receptor antagonists, NSAIDs (non-steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen), heparin, immunosuppressives (e.g. ciclosporin or tacrolimus), and the antibiotic trimethoprim.
- Lithium containing medicines (used to treat some types of depression).
- If you are taking an ACE-inhibitor or aliskiren (see also information under the heading "Do not take TELEASE" and "Warnings and precautions").
- Diuretics ("water tablets"), especially if taken in high doses together with TELEASE, may lead to excessive loss of body water and low blood pressure (hypotension).

The effect of TELEASE may be reduced when you take NSAIDs (non-steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen) or corticosteroids. TELEASE 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). Concomitant use of fluoroquinolones and TELEASE may precipitate acute kidney injury. Furthermore, alcohol, barbiturates, narcotics or antidepressants may aggravate low blood pressure. 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 TELEASE.

TELEASE with food, drink and alcohol
TELEASE can be taken with or without food.

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 TELEASE. Do not take TELEASE if you are pregnant, are considering becoming pregnant or are breastfeeding. If you are a woman of childbearing age, you must use effective contraception.

Driving and using machines
When driving vehicles or operating machinery, it should be taken into account that dizziness or drowsiness may occur when taking blood pressure lowering medication including TELEASE. You should not engage in the above activities until you are aware of the extent to which TELEASE affects you.

4. How to take TELEASE
Do not share medicines prescribed for you with any other person. Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

Adults
The usual dose is 40 mg tablet once daily (preferably at about the same time each day) and swallowed with a drink of water. The dose may be increased to 80 mg in cases where the target blood pressure is not achieved. Your doctor may prescribe TELEASE in combination with other blood pressure lowering medicines.

If you have the impression that TELEASE is too strong or too weak, tell your doctor or pharmacist.

If you take more TELEASE than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take TELEASE
Always take TELEASE as prescribed. If you have missed a dose, take it as soon as you remember. Do not take a double dose of TELEASE to make up for forgotten individual doses.

If you stop taking TELEASE
Do not stop taking TELEASE unless your doctor tells you to.

5. Possible side effects
TELEASE can have side effects.

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

If any of the following happens, stop taking TELEASE and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips, 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 reaction to TELEASE. 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:
- Severe, life-threatening infection (sepsis, also known as 'blood infection') with possible fatal outcome.
- Changes in the way your heart beats, for example, if you notice it is beating faster, slower or irregular.
- Yellowing of the skin and eyes, dark coloured urine, feeling tired or weak which may be symptoms of liver problems or liver failure.
- Passing less urine than is normal for you which may be a sign of serious kidney problems or kidney failure.

These are all serious side effects. You may need urgent medical attention.
Tell your doctor if you notice any of the following:
Frequent
- Coughing

Less frequent
- Urinary tract infections, upper respiratory tract infections (e.g. sore throat, inflamed sinuses, common cold)
- Deficiency in red blood cells (anaemia), low platelet count (thrombocytopenia)
- High levels of potassium in your blood
- Difficulty falling asleep, feeling sad (depression), feeling anxious
- Fainting (syncope), feeling sleepy (somnolence)
- Problems with your vision
- Feeling of spinning (vertigo)
- Low blood pressure (hypotension) in users treated for high blood pressure, dizziness on standing up (orthostatic hypotension)
- Shortness of breath, progressive scarring of lung tissue (interstitial lung disease)
- Abdominal pain, diarrhoea, discomfort in the abdomen, bloating, vomiting, dry mouth, upset stomach, taste disturbance (dysgeusia)
- Increased sweating, itching, drug rash, eczema (a skin disorder), redness of skin
- Back pain, muscle cramps, muscle pain (myalgia), join t pain (arthralgia), pain in extremity
- Chest pain, feeling of weakness (asthenia), flulike-illness
- Increased level of creatinine in the blood, decreased haemoglobin (a blood protein), increased levels of uric acid, increased hepatic enzymes or creatine phosphokinase in the blood.

Frequency unknown
- Increase in certain white blood cells (eosinophilia)
- Low blood sugar levels (in diabetic patients)
- Hives (urticarial)
- Tendon pain.

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. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions & Quality Problem Reporting Form", found online under SAHPRA's publications: https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf
By reporting side effects, you can help provide more information on the safety of TELEASE.

6. How to store TELEASE
Store all medicines out of reach of children.
- Store at or below 25 °C.
- Keep the blisters in the original package until required for use.
- 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).

7. Contents of the pack and other information
What TELEASE contains
The active substance is telmisartan.
TELEASE 40: Each tablet contains 40 mg telmisartan.
Contains mannitol: 166,64 mg per tablet.
TELEASE 80: Each tablet contains 80 mg telmisartan.
Contains mannitol: 333,28 mg per tablet.
The other ingredients are mannitol (E421), meglumine, povidone, sodium hydroxide (E524) and sodium stearyl fumarate.

What TELEASE looks like and contents of the pack
TELEASE 40: White or off-white to yellowish oblong biconvex uncoated tablets with breakline on one side and plain on the other side.
TELEASE 80: White or off-white to yellowish oval biconvex uncoated tablets with breakline on one side and plain on other side.

TELEASE tablets are packed in the following pack:
Blister pack using aluminium foil with heat seal lacquer coating sealed with cold forming blister aluminium foil (Alu/Alu blister).
The blister strips will be packed in cartons with 14, 28, 30 or 56 tablets.
Not all pack sizes may be marketed.

Holder of Certificate of Registration
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TELEASE 40: 47/7.1.3/0334
TELEASE 80: 47/7.1.3/0335

INLIGTINGSBLAD VIR PASIËNTE

SKEDULERINGSTATUS S3

TELEASE 40 tablette
TELEASE 80 tablette
Telmisartan
Bevat suiker: mannitol 166,64 mg per 40 mg tablet
Bevat suiker: mannitol 333,28 mg per 80 mg tablet

Lees die hele pamflet noukeurig deur, voordat jy TELEASE tablette neem
- Hou hierdie pamflet. Dit is moontlik dat jy dit weer sal wil deurlees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleër of enige ander gesondheidswerker.
- TELEASE is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik wees vir hulle, selfs al is hulle simptome dieselfde as joune.

1. Wat is in hierdie pamflet
1. Wat TELEASE is en waarvoor dit gebruik word
2. Wat jy moet weet voor jy TELEASE begin neem
3. Hoe om TELEASE te neem
4. Moontlike newe effekte
5. Berging en wegdoening van TELEASE
6. Aard en inhoud van die houer

2. Wat TELEASE is en waarvoor dit gebruik word
TELEASE behoort aan 'n klas medisyne bekend as die angiotensien-II reseptor antagoniste. Angiotensien-II is `n substans wat deur jou liggaam geproduseer word en wat vernouing van jou bloedvate veroorsaak, en gevolglik 'n verhoging in bloeddruk. TELEASE blok die effek van angiotensoen-II sodat bloedvate kan ontspan, en sodoende jou bloeddruk verlaag.

TELEASE tablette word gebruik vir die behandeling van hoë bloeddruk.
TELEASE tablette word ook gebruik vir die vermindering van kardiovaskulêre gevalle (bv. hartaanvalle en beroetes) en sterftes in pasiënte van 55 jaar en ouer met `n hoë risiko vir kardiovaskulêre siektes.

3. Wat jy moet weet voor jy TELEASE begin neem
Moet nie TELEASE neem:
- Indien jy allergies vir telmisartan of enige ander bestandeel in TELEASE is (sien afdeling 6).
- Indien jou gesig, lippe, mond, tong of keel vantevore geswel het en reuse galbulte op jou vel ontwikkel het, na jy medisyne soos angiotensien-omskakelikngsensiem (AOE) inhibeerders of angiotensien-reseptorblokkeerders (ARBs) geneem het – jy moet nooit weer hierdie medisyne gebruik nie.
- Indien jou dokter jou al voorheen ingelig het dat die dikte van jou hartspier abnormal vergoot is (hipertrofiese obstruktiewe kardiomiopatie (HOKM)).
- Indien jy sukkel met obstruksie van bloedvate na jou hart of niere.
- Indien jy aan ernstige nierfunksie probleme ly.
- Indien jy tans kaliumsparende diuretikums ('water tablette'), wat spironolaktoon, triamtereen of amiloried bevat, neem.
- Indien jy aan `n toestand genaamd porfirie (`n seldsame oorerflike siekte) ly.
- Indien jy tans litium (medisyne wat sekere tipes depressie behandel) neem .
- Moet nie TELEASE neem as jy swanger is, dit oorweeg om swanger te raak of as jy borsvoed nie. Omskakeling na 'n geskikte alternatiewe behandeling moet gebeur voor 'n swangerskap beplan word.
- Indien jy aan ernstige lewer siekte of galwegobstruksie (`n problem met die dreinering van gal uit die galblaas) ly.
- Indien jy tans aliskiren-bevattende medisyne neem.
- Indien jy tans `n fluorokinoloon antibiotika neem (vir behandeling van infeksies van die lugweg of urinienweg).
- Indien jy nier probleme het of `n bejaarde is.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
Neem spesiale sorg met TELEASE en vertel vir jou dokter:
- Indien jy swanger raak terwyl jy TELEASE neem. Jy moet onmiddelik jou behandeling staak en jou dokter raadpleeg om jou medisyne te verander.
- Indien jy aan niersiektes ly of `n nieroorplanting gehad het.
- Indien jy dalk te min soute in jou liggaam het as gevolg van `n lae-sout dieet, of as jy onlangs baie van jou ligaamsvloeistof verloor het as gevolg van diuretikums ('water tablette'), braking of diaree.
- Indien jy reeds medisyne neem wat bekend staan as `n angiotensien-omskakelings (AOE) inhibeerders.
- Kontak jou dokter om jou behandeling te herevalueer indien jy behandel word met angiotensien-omskakelingsensiem (AOE) inhibeerders/ Angiotensien reseptor blokkeerders (ARBs) tesame met `n fluorokinoloon antibiotika.
- Indien jy al voorheen ingelig is dat jy verhoogde aldosteroon vlakke het.
- Indien jy hartprobleme het.
- Indien jy diabetes het.
- Indien jy hoë kaliumvlakke in jou bloed het, of as jy kaliumbevattende soutvervangers gebruik.
- Indien jy lewer probleme het.

Kinders en adolessente
Die veiligheid en doeltreffendheid van TELEASE vir die gebruik van kinders jonger as 18 jaar is nog nie vasgestel nie.

Ander medisyne en TELEASE
Vertel jou gesondheidswerker indien jy ander medisyne neem. (Die sluit komplementêre of tradisionele medisyne in.)

Jou dokter mag moontlik die dosis van hierdie ander medisyne verander of mag ander voorsorg tref. Jy mag dalk in sommige gevalle die gebruik van een van hierdie mesdiyne moet staak. Dit geld veral vir die onderstaande medisyne wat terselfdetyd saam met TELEASE geneem word:
- Digoksien (word gebruik om verkillende hartsiektes te behandel).
- Medisyne wat kaliumvlakke in jou bloed kan verhoog soos kaliumbevattende sout vervangers, kalium-sparende diuretikums (sommige "waterpille"), AOE inhibeerders, angiotensien II reseptor antagoniste, NSAIMs (non-steroïed anti-inflammatoriese medisyne, bv. aspirien of ibuprofen), heparien, immuunonderdrukkers (bv. siklosporien of takrolimus), en die antibiotika trimetoprim.
- Litium-bevattende medisyne (wat gebruik word om sommige depressie toestande te behandel).
- Wanneer jy 'n AOE-inhibeerder of aliskirien neem (sien ook inligting onder die volgende afdelings "Moet nie TELEASE neem" en "WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS").
- Diuretikums ("waterpille"), veral wanneer dit in hoë dosisse saam met TELEASE geneem word, mag tot 'n oormatige verlies van liggaamsvloeistof en lae bloeddruk (hipotensie) lei.

Die effke van TELEASE mag verminder word wanneer jy dit saam NSAIMs (nie-steroïed anti-inflammatoriese medisyne bv. aspirien of ibuprofen) of kortikosteroïede neem.

TELEASE mag die bloeddruk verlagende effek van ander medisyne verhoog wat gebruik word vir die behandeling van hoë bloeddruk of van medisyne met bloeddruk verlagende potensiaal (bv. baklofen, amifostien).
Die gelyktydige gebruik van fluorokinolone en TELEASE kan akute nierbeserings veroorsaak.
Verder kan alkohol, barbiturate, verdowingsmiddels of antidepressante lae bloeddruk vererger. Jy mag ook lighoofdig voel wanneer jy regop staan. Raadpleeg jou dokter indien jy die dosis van jou ander medisyne moet aanspas terwyl jy TELEASE neem.

TELEASE kos, drankies en alkohol
TELEASE kan met of sonder kos gebruik word.

Swangerskap, borsvoeding en vrugbaarheid
Indien jy swanger is of borsvoed, vermoed dat jy dalk swanger kan wees of indien jy daaraan dink om 'n baba binnekort te hê, raadpleeg jou dokter, apteker of ander gesondheidswerker vir advies voor jy TELEASE neem.
Moet nie TELEASE neem as jy swanger is, oorweeg om swanger te raak of as jy borsvoed nie.
Indien jy 'n vrou van vrugbare ouderdom is, moet jy doeltreffende kontrasepsie gebruik.

Bestuur en gebruik van masjinerie
Wanneer voertuie bestuur of masjinerie gebruik word, moet dit egter in ag geneem word dat daar soms, af en toe, duiseligheid of lomerigheid kan voorkom tydens die gebruik van bloeddrukverlagende behandeling, insluitend TELEASE.
Jy moet nie deelneem aan die bogenoemde aktiwiteite tot jy nie bewus is van die uitwerking wat TELEASE op jou het nie.

4. Hoe om TELEASE te neem
Moet nie medisyne wat vir jou voorgeskryf is, met enige ander mense deel nie.
Neem TELEASE presies soos jou dokter gesê het. Indien jy onseker is, kontak jou dokter of apteker.

Volwassenes
Die aanbevole dosis is 'n 40 mg tablet daagliks (verkieslik op dieselfde tyd elke dag) en wat geneem word met `n glas water. Die dosis kan verhoog word tot 80 mg in gevalle waar die gewenste bloeddruk nie verkry word nie.
Jou dokter kan TELEASE in kombinasie met ander bloeddrukverlagende medisyne voorskryf.
Indien jy die indruk kry dat die effek van TELEASE te sterk of te swak is, lig jou dokter of apteker in.

Indien jy meer TELEASE neem as wat jy moet
In die geval van `n oordosering, raadpleeg jou dokter of apteker. Indien niemand beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om `n dosis TELEASE te neem
Neem altyd TELEASE soos voorgeskryf. Indien jy `n dosis van TELEASE oorgeslaan het, neem die dosering so gou as wat jy onthou. Moet nie `n dubbele dosis van TELEASE neem om op te maak vir die vergete individuele dosisse nie.

Indien jy ophou om TELEASE te neem
Moet nie ophou om TELEASE te neem, tensy jou dokter so sê nie.

5. Moontlike newe-effekte
TELEASE kan newe-effekte hê.

Nie alle newe-effekte wat vir TELEASE aangemeld is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak, of indien jy enige ongewenste effekte ervaar terwyl jy TELEASE neem, raadpleeg asseblief jou gesondheidswerker vir advies.

Indien enige van die volgende gebeur, staak die gebruik van TELEASE onmiddelik en vertel jou dokter of gaan na die ongevalle afdeling by jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat dit moeilik maak om asem te haal of te sluk.
- veluitslag of jeukerigheid,
- floute.

Hierdie is alles baie ernstige newe-effekte. Indien jy dit het, mag jy `n ernstige reaksie met TELEASE hê. Jy kort dringende mediese aandag of hospitalisasie.

Vertel jou dokter onmiddelik of gaan na die ongevalle afdeling by jou naaste hospitaal, indien jy enige van die volgende opmerk:
- Ernstige, lewensbedreigende infeksie (sepsis, ook bekend as 'bloedinfeksie') met moontlike noodlottige gevolge.
- Veranderinge van jou hartklop, byvoorbeeld as jy opmerk dat jou hart vinniger of stadiger klop as wat normaal is.
- Wanneer jou vel of oë geel word, uriene donker is, jy moeg of swak voel wat `n teken van lewerprobleme of -versaking is.
- As jy minder as gewoonlik uriene passeer wat tekens aandui van ernstige nierprobleme of -versaking.

Hierdie is alles baie ernstige newe-effekte. Jy kort dringende mediese sorg.

Vertel jou dokter indien jy enige van die volgende opmerk:
Newe-effekte wat dikwels voorkom:
- Hoes

Newe-effekte wat minder dikwels voorkom:
- Urienweginfeksie, boonste lugweginfeksie (bv. seerkeel, inflammasie van die sinusse, verkoue)
- Afname in die aantal rooibloedselle (anemie), `n afname in bloedplaatjietelling (trombositopenie)
- Verhoogde vlakke van kalium in jou bloed
- Sukkel om aan die slaap te raak, hartseer gevoel (depressie), angstig voel
- Duiseligheid (sinkopee), slaperigeheid
- Visiesteurnisse
- Dronkheid (vertigo)
- Lae bloeddruk (hipotensie) in verbruikers wat behandel word vir hoë bloeddruk, duiseligheid nadat jy opstaan (ortostatiese hipotensie)
- Kortasem, letsels op die long weefsel wat met verloop van tyd vererger (interstitiële long siekte)
- Maagpyn, waterige stoelgang, ongemaklikheid van die laer buik, winderigheid, braking, droë mond, omgekrapte maag, smaak versteuring (disgeusie)
- Verhoogde sweetafskeiding, jeukerigheid, medisyne verwante veluitslag, ekseem ('n velsiekte), rooiheid van die vel
- Rugpyn, spierkrampe, spierpyn (mialgie), gewrigspyn (artralgie), pyn van die ekstremiteite (ledemate)
- Borskaspyn, gevoel van swakheid of uitputting (astenie), griepsimptome
- Verhoogde vlakke van kreatinien in die bloed, verlaagde hemoglobien (`n bloed-proteïen), verhoogde vlakke van uriensuur, verhoogde vlakke van lewerensieme of kreatinienfosfokinase in die bloed.

Newe-effekte met 'n onbekende frekwensie
- Verhoging in spesifieke tipes witbloedselle (eosinofilie)
- Lae bloedsuikervlakke (in diabetiese pasiënte)
- Bulte (urtikaria)
- Tendonpyn.

Indien jy enige newe-effekte ervaar wat nie in hierdie inligtingsblad genoem is nie, lig asseblief jou dokter of apteker in.

Rapportering van vermoedelik nadelige reaksies:
Indien daar newe-effekte ervaar word, kommunikeer dit met jou dokter of apteker.
Jy kan ook newe-effekte aanmeld aan SAHPRA met gebruik van die volgende vorm "6.04 Adverse Drug Reactions Reporting Form", wat aanlyn gevind kan word by SAHPRA se publikasies:
https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf
Die rapportering van newe-effekte, bied meer inligting wat 'n bydrae lewer rondom die veiligheid van TELEASE.

6. Berging van TELEASE
Stoor alle medisyne buite die bereik van kinders.
- Stoor teen of benede 25 °C.
- Hou die stulpstrook in die oorspronklike verpakking, tot voor gebruik.
- Moenie die tablette neem na die vervaldatum wat op die etiket aangedui is nie.

Neem alle ongebruikte medisyne terug na jou apteker.
Moenie ongebruikte medisyne in dreine of rioolstelsel (bv. toilette) weggooi nie.

7. Inhoud van die houer en ander inligting
Wat TELEASE bevat
Die aktiewe bestandeel is telmisartan.
TELEASE 40: Elke tablet bevat 40 mg telmisartan.
Bevat mannitol: 166,64 mg per tablet.
TELEASE 80: Elke tablet bevat 80 mg telmisartan.
Bevat mannitol: 333,28 mg per tablet.
Die ander bestandele is mannitol (E421), meglumien, povidoon, natriumhidroksied (E524) en natriumstearielfumaraat.

Hoe TELEASE lyk en die inhoud van die verpakking
TELEASE 40: Wit of effewit tot geel, langwerpige, bikonvekse onbedekte tablet met `n breuklyn gebosseleer aan die een kant en aan die ander kant `n plein afwerking.
TELEASE 80: Wit of effewit tot geel, ovaalvormige, bikonvekse onbedekte tablet met `n breuklyn gebosseleer aan die een kant en aan die ander kant `n plein afwerking.

TELEASE tablette word verpak in die volgende verpakking:
Stulpstroke van gewone silwer aluminiumfolie met `n hitte verseëlde laag bedek met `n koue vormende aluminiumfolie stulpstrook.
Die stulpstroke word verpak in kartonhouers van 14, 28, 30 of 56 tablette.
Nie alle verpakkingsgroottes word bemark nie

Houer van die registrasiesertifikaat
Trinity Pharma (Pty) Ltd.
16de Straat 106
Midrand
1686

Datum van hersiening van die teks
16 Februarie 2021

Registrasienommers
TELEASE 40: 47/7.1.3/0334
TELEASE 80: 47/7.1.3/0335

300 x 670 mm
F/B