PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: **S3**

TEPRILAM 5/5; TEPRILAM 5/10; TEPRILAM 10/5; TEPRILAM 10/10, tablets

Perindopril tosilate/Amlodipine besilate

Each TEPRILAM 5/5 and 5/10 tablet contains 86,6 mg of isomalt

Each TEPRILAM 10/5 and 10/10 tablet contains 173,2 mg of isomalt

Read all of this leaflet carefully before you start taking TEPRILAM.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- TEPRILAM 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 TEPRILAM IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TEPRILAM

3. HOW TO TAKE TEPRILAM

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE TEPRILAM

6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT TEPRILAM IS AND WHAT IT IS USED FOR:

TEPRILAM is an anti-hypertensive medicine containing two active ingredients, perindopril and amlodipine.

Perindopril is an ACE (angiotensin converting enzyme) inhibitor. Amlodipine is a calcium antagonist (which belongs to a class of medicines called dihydropyridines). Together they work to widen and relax the blood vessels so that blood passes through them more easily and makes it easier for your heart to maintain a good blood flow.

It is used in the treatment of high blood pressure (hypertension) in adults. Patients already taking perindopril and amlodipine from separate tablets may instead receive one tablet of TEPRILAM which contains both ingredients.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TEPRILAM:

Do not take TEPRILAM:

- if you are allergic (hypersensitive) to perindopril or any other ACE inhibitor, or to amlodipine or any other calcium antagonists or any of the other ingredients (listed in **section 6**)
- if you have experienced symptoms such as wheezing, swelling of the face or tongue, intense itching or severe skin rashes with previous ACE inhibitor treatment or if you or a member of your family have had these symptoms in any other circumstances (a condition called angioedema)
- if you have recurrent episodes of swelling (angioedema)
- if you have a condition in which the heart muscle becomes abnormally thick (hypertrophic cardiomyopathy)
- if you are pregnant or breastfeeding your baby
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- if you have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased

- if you have an obstruction in blood outflow of the left ventricle of the heart or narrowing of the aortic heart valve (aortic stenosis)
- if you take lithium or potassium-sparing diuretics (spironolactone, triamterene) as their use with TEPRILAM should be avoided. (see **Other medicines and TEPRILAM**)
- if you have porphyria (a rare blood disorder that results from a build-up of natural chemicals called porphyrins in the body)
- if you have kidney problems with decreased blood supply to the kidneys (stenosis renal arterial)
- if you are taking fluoroquinolones (antibiotics) and have impaired or severe kidney problems
- if you have severe low blood pressure (hypotension)
- if you have cardiogenic shock (a condition where your heart is unable to supply enough blood to the body)
- suffer from heart failure after a heart attack
- if you are taking aliskiren-containing medicines.

Warnings and precautions:

Before treatment with TEPRILAM, tell your doctor:

- if you are taking any of the following medicines, the risk of serious allergic reaction (angioedema) may be increased: racecadotril, mTOR inhibitors, vildagliptin, sacubitril. (see **Other medicines and TEPRILAM**)
- have abnormally high levels of a hormone called aldosterone in your blood (primary aldosteronism)
- if you are on a salt restricted diet or use salt substitutes which contain potassium (a well-balanced potassium blood level is essential)
- heart failure
- severe increase in blood pressure (hypertensive crisis)
- any other heart problems
- kidney problems or if you are receiving dialysis

- liver problems
- if you are a black patient, this medicine may increase the risk of serious allergic reaction (angioedema) and may be less effective on lowering your blood pressure compared to other patients
- collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma
- diabetes
- if you are elderly and your dose needs to be increased.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

When you are taking TEPRILAM, you should also inform your doctor or the medical staff:

- if you are to undergo anaesthesia and/or surgery
- if you are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings
- if you have recently suffered from diarrhoea or vomiting, or are dehydrated
- if you are to undergo dialysis or LDL apheresis (which is removal of cholesterol from your blood by a machine).

Children and adolescents:

TEPRILAM is not for use in children and adolescents.

Other medicines and TEPRILAM:

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

You should not take TEPRILAM with:

- lithium (used to treat mania or depression)
- aliskiren (medicine used to treat hypertension)
- other medicines for treating high blood pressure including angiotensin II receptor blocker (ARB)
- potassium-sparing diuretics (e.g. triamterene, amiloride), potassium salts, other medicines which can increase potassium in your body (such as heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole)
- sacubitril/valsartan (used to treat long-term heart failure)
- extracorporeal circulation treatments which are used to promote the removal of toxins from the body and support vital organs
- fluoroquinolones (an antibiotic).

Make sure to tell your doctor if you are taking any of the following medicines as special care may be required:

- estramustine (used in cancer therapy)
- medicines, which are most often used to treat diarrhoea (racecadotril) or avoid rejection of transplanted organs (sirolimus, everolimus, temsirolimus and other medicines belonging to the class of so-called mTor inhibitors). (See **section Warnings and precautions**)
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) or high dose salicylates (e.g. aspirin)
- medicines to treat diabetes such as insulin, metformin or gliptins
- potassium-sparing medicines used in the treatment of heart failure: eplerenone and spironolactone at doses between 12,5 mg to 50 mg per day
- corticosteroids used to treat various conditions including severe asthma and rheumatoid arthritis
- immunosuppressants used for the treatment of auto-immune disorders or following transplant surgery to prevent rejection (e.g. ciclosporin)

- simvastatin (used to lower cholesterol)
- verapamil, diltiazem (for the treatment of an irregular heartbeat)
- injectable gold (used to treat rheumatoid polyarthritis)
- vasodilators including nitrates (products that make the blood vessels become wider)
- baclofen (to treat muscle stiffness occurring in diseases such as multiple sclerosis)
- itraconazole, ketoconazole (medicines used for treatment of fungal infections)
- erythromycin, rifampicin, clarithromycin (antibiotic treatment)
- alpha-blockers used for the treatment of enlarged prostate such as prazosin, alfuzosin, doxazosin, tamsulosin, terazosin
- tetracosactide (to treat Crohn's disease)
- medicines to treat mental disorders such as depression, anxiety, schizophrenia (e.g. tricyclic antidepressants, neuroleptics (such as amisulpride, sulpiride, sultopride, tiapride, haloperidol, droperidol))
- amifostine (used to prevent or reduce side effects caused by other medicines or radiation therapy that are used to treat cancer)
- anaesthetics.

TEPRILAM with food and drink:

It is advisable to take TEPRILAM before a meal.

Grapefruit juice and grapefruit should not be consumed by people who are taking TEPRILAM. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of TEPRILAM.

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 healthcare provider for advice before taking TEPRILAM.

Do not take TEPRILAM if you are pregnant or breastfeeding your baby.

Driving and using machines:

TEPRILAM may affect your ability to drive and use machines. TEPRILAM tablets may make you feel sick, dizzy, weak or tired, or give you a headache.

It is not always possible to predict to what extent TEPRILAM may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or the use of machines until you are aware of the measure to which TEPRILAM affects you.

TEPRILAM tablets contain sodium:

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

TEPRILAM tablets contain isomalt:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking TEPRILAM tablets.

3. HOW TO TAKE TEPRILAM:

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

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

Swallow your tablet with a glass of water, preferably at the same time each day, in the morning before a meal.

Your doctor will decide on the appropriate dosage for you. This will normally be one tablet per day.

Your doctor will tell you how long your treatment with TEPRILAM will last. If you have the impression that the effect of TEPRILAM is too strong or too weak, tell your doctor or pharmacist.

If you take more TEPRILAM than you should:

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

The most likely effect in case of overdose is low blood pressure which can make you feel dizzy or faint. If this happens, lying down with the legs raised can help.

If you forget to take TEPRILAM:

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

If you stop taking TEPRILAM:

As the treatment for high blood pressure is usually life-long, you should discuss with your doctor before stopping TEPRILAM.

4. POSSIBLE SIDE EFFECTS:

TEPRILAM can have side effects.

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

If any of the following happens, stop taking TEPRILAM 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 all very serious side effects. If you have them, you may have had a serious reaction to TEPRILAM. 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:

- weakness of arms or legs, or problems speaking which could be a sign of a possible stroke
- cardiovascular disorders (irregular heartbeat, angina pectoris (pains to the chest, jaw and back, brought on by physical effort), heart attack)
- life-threatening irregular heartbeat
- severe dizziness or fainting due to low blood pressure
- bronchospasm (tightening of the chest, wheezing and shortness of breath)
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell
- yellowing of the skin or eyes (jaundice) which could be a sign of hepatitis
- severe skin reactions including erythema multiforme (a skin rash which often starts with red itchy patches on your face, arms or legs) or intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome) or other allergic reactions.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- drowsiness
- dizziness
- headache
- taste disturbances
- visual impairment
- vertigo (spinning of head)
- tinnitus (sensation of noises in the ears)
- redness in face
- cough
- shortness of breath
- abdominal pain
- nausea, vomiting
- indigestion
- dry mouth
- altered bowel habits
- diarrhoea
- constipation
- allergic reactions (skin rashes, itching)
- joint swelling
- muscle spasms
- swelling
- tiredness

- lack of energy.

Less frequent side effects:

- runny nose
- unusual bruising or easy bleeding, feeling generally tired or lethargic, pale skin, signs of infection such as sore throat, fever and chills (these may indicate changes or damage to your blood cells)
- hypoglycaemia (very low blood sugar level)
- changes in blood composition (levels of potassium, sodium and calcium) that have the following symptoms: tiredness or weakness, nausea and vomiting, irregular heartbeats, confusion, seizures, loss of appetite, abdominal pain, disorientation
- mood swings, sleep disturbances
- sleeplessness, depression
- shakiness, a decreased sense of touch or sensation
- confusion, too much muscle tone so that arms or legs, for example, are stiff and difficult to move, pins and needles
- inflammation of blood vessels that results in a reddish rash, fever, loss of appetite and fatigue
- eosinophilic pneumonia (a rare type of pneumonia), inflamed stomach lining
- dry mouth, overgrowth of gum tissue around the teeth
- abnormal hepatic function (skin and eyes appear yellowish, abdominal pain, dark urine colour); increased liver enzymes
- hives, swelling of the lower legs and arms
- red pinpoints on skin
- excessive sweating
- photosensitivity reactions
- rare autoimmune conditions that causes blistering and rashes on the skin and mucous membranes

- flare-ups of psoriasis
- joint pain
- muscle pain, back pain
- kidney impairment, acute kidney failure, difficulty in passing urine, increased urination
- impotence, breast enlargement in men
- swelling of ankles
- chest pain, fever, general feeling of discomfort
- weight increase or weight decrease
- high level of serum bilirubin
- increase in liver enzymes (AST; ALT)
- high uric acid levels in the blood that cause fever, chills, fatigue, joint inflammation (called 'gout')
- decreased haemoglobin and haematocrit
- fall.

Side effects with unknown frequency:

- a movement disorder
- numbness and pain in fingers or toes (Raynaud's phenomenon)
- severe skin peeling and blistering. The peeling progresses quickly, resulting in large raw areas that may ooze or weep.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of TEPRILAM.

5. HOW TO STORE TEPRILAM:

Store all medicine out of reach of children.

Store at or below 25 °C.

Store in the original container in order to protect from light and moisture.

Do not use the tablets after the expiry date shown on the container.

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 TEPRILAM contains:

The active ingredients are perindopril tosilate and amlodipine besilate.

TEPRILAM 5/5: Each tablet contains 5 mg perindopril tosilate equivalent to 3,6 mg perindopril converted *in situ* to perindopril sodium and 6,935 mg amlodipine besilate equivalent to 5 mg amlodipine.

TEPRILAM 5/10: Each tablet contains 5 mg perindopril tosilate equivalent to 3,6 mg perindopril converted *in situ* to perindopril sodium and 13,87 mg amlodipine besilate equivalent to 10 mg amlodipine.

TEPRILAM 10/5: Each tablet contains 10 mg perindopril tosilate equivalent to 7,2 mg perindopril converted *in situ* to perindopril sodium and 6,935 mg amlodipine besilate equivalent to 5 mg amlodipine.

TEPRILAM 10/10: Each tablet contains 10 mg perindopril tosilate equivalent to 7,2 mg perindopril converted *in situ* to perindopril sodium and 13,87 mg amlodipine besilate equivalent to 10 mg amlodipine.

The other ingredients are cellulose, microcrystalline (type 102), isomalt, magnesium stearate, povidone K30, sodium hydrogen carbonate (as starting material), sodium starch glycolate (type A) and water (purified).

What TEPRILAM looks like and contents of the pack:

TEPRILAM 5/5: White, oval, biconvex tablet, debossed 5/5 on one side and plain on the other side. Dimensions: approx. 9 × 5 mm diameter.

TEPRILAM 5/10: White, round, biconvex tablet, debossed 5/10 on one side and plain on the other side. Dimension: approx. 7 mm diameter.

TEPRILAM 10/5: White, oval, biconvex tablet, debossed 10/5 on one side and plain on the other side.

Dimensions: approx. 13 × 7 mm diameter.

TEPRILAM 10/10: White, round, biconvex tablet, debossed 10/10 on one side and plain on the other side. Dimension: approx. 9 mm diameter.

White opaque polypropylene tablet containers with white opaque polyethylene stopper with desiccant insert equipped with a tamper-evident (TE) polyethylene flow reducer.

Pack sizes of:

5 /5: 10, 30, 90 (30 x 3) tablets

5/10, 10/5, 10/10: 30, 90 (30 x 3) tablets

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

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