PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S3**

TESAMOLOT™ 40/5, tablets

TESAMOLOT™ 40/10, tablets

TESAMOLOT™ 80/5, tablets

TESAMOLOT™ 80/10, tablets

Telmisartan and amlodipine

Contains sugar (mannitol)

TESAMOLOT™ 40/5

Contains approximately 351,605 mg sugar (mannitol) per tablet.

TESAMOLOT™ 40/10

Contains approximately 344,67 mg sugar (mannitol) per tablet.

TESAMOLOT™ 80/5

Contains approximately 519,945 mg sugar (mannitol) per tablet.

TESAMOLOT™ 80/10

Contains approximately 513, 01 mg sugar (mannitol) per tablet.

Read all of this leaflet carefully before you start taking TESAMOLOT™ tablets

- 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.
- TESAMOLOT™ 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 TESAMOLOT™ is and what it is used for
2. What you need to know before you take TESAMOLOT™
3. How to take TESAMOLOT™
4. Possible side effects
5. How to store TESAMOLOT™
6. Contents of the pack and other information

1. What TESAMOLOT™ is and what it is used for

The active substances are called telmisartan and amlodipine.

TESAMOLOT™ is used to treat and control high blood pressure (also known as essential hypertension) in adult patients:

- who already receive telmisartan and amlodipine as separate tablets and who wish to take instead the same doses in one tablet for convenience.
- who are not adequately controlled with amlodipine alone.

Telmisartan belongs to a group of substances called "angiotensin-II receptor antagonists". Angiotensin II is a substance produced in the body which causes blood vessels to narrow, thus increasing blood pressure. Telmisartan works by blocking the effect of angiotensin II.

Amlodipine belongs to a group of substances called "calcium channel blockers". Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening.

This means that both of these active substances work together to help stop your blood vessels tightening. As a result, the blood vessels relax and blood pressure is lowered.

2. What you need to know before you take TESAMOLOT™

Do not take TESAMOLOT™ if you:

- are allergic (hypersensitive) to telmisartan and/or amlodipine or any of the other ingredients of TESAMOLOT™ (See Section 6)
- if you are allergic to other medicines of the dihydropyridine type (one type of calcium channel blocker)
- if you have developed swelling and red swollen marks on your skin when you have previously taken medicines called angiotensin converting enzyme inhibitors (ACE inhibitors) or angiotensin receptor blockers (ARBs)
- if you are taking medicines called fluoroquinolones and have serious kidney problems
- if you have hereditary swelling problems or swelling that occurs without a known cause
- if you have a condition known as Hypertrophic Obstructive Cardiomyopathy (HOCM)
- if you have severe kidney problems
- if blood vessels to the kidneys are narrowed
- if you have a narrowing of the aortic blood vessel
- if you are currently taking lithium and potassium sparing water tablets containing spironolactone, triamterene or amiloride
- if you are currently taking aliskiren-containing medicines
- if you suffer from porphyria
- if you have problems with drainage of the bile from the liver and gall bladder
- if you have severe liver problems
- if you suffer from low heart output because of a serious heart problem
- if you are or may potentially be pregnant
- if you are breast-feeding or may breast feed

Warnings and precautions

Take special care with TESAMOLOT™

Before treatment with TESAMOLOT™, tell your doctor if any of the following applies to you before and while taking TESAMOLOT™, as your dose may need to be adjusted:

- if you are pregnant
- if you already take a medicine called an angiotensin-converting enzyme (ACE) inhibitor
- if you have low blood pressure (hypotension), which is likely to occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy ('water tablets'), low-salt diet, diarrhoea or vomiting
- if you have impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- if you have liver problems
- if you have kidney problems or if you have had a kidney transplant
- if you have been told by a doctor that you have raised aldosterone levels (which leads to water and salt retention in the body along with imbalance of various blood minerals)
- if you are taking medicines called fluoroquinolones
- if you have chest pain and heart problems
- if you have high potassium levels in your blood or use salt substitutes that contain potassium
- if you have diabetes
- if you have been told by your doctor you have an intolerance to some sugars (see Section 6)

Blood monitoring

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

Other medicines and TESAMOLOT™

Always tell your health care provider if you are taking any other medicine.

(This includes complementary or traditional medicines).

Tell your doctor if you take:

- medicines that may increase blood potassium levels such as salt substitutes containing potassium or potassium-sparing diuretics (certain 'water tablets' e.g., spironolactone, triamterene, or amiloride)
- baclofen, amifostine, neuroleptics or antidepressants, alcohol, barbiturates, narcotics
- medicines used to treat pain and arthritis called NSAIDs (non-steroidal anti-inflammatory medicines, e.g., aspirin or ibuprofen) or corticosteroids
- ramipril or other medicines that may be used to treat high blood pressure or a heart problem.
- digoxin and diltiazem (medicines used to treat the heart)
- lithium containing medicines used to treat some types of depression
- anticonvulsant medicines (e.g., carbamazepine, phenobarbitone, phenytoin, fosphenytoin, primidone)
- rifampicin (type of antibiotic)
- erythromycin (antibiotic)
- medicines used for HIV/AIDS (e.g., ritonavir) or for treatment of fungal infections (e.g., ketoconazole, itraconazole)
- aliskiren (medicines use to treat high blood pressure)
- simvastatin (medicines used to treat high cholesterol levels)
- heparin, immunosuppressives (e.g., cyclosporin or tacrolimus), and the antibiotic trimethoprim

Taking TESAMOLOT™ with food and drink

- You can take TESAMOLOT™ with water or other non-alcoholic drink and with or without food.
- Grapefruit juice and grapefruit should not be consumed when you take TESAMOLOT™. This is because grapefruit and grapefruit juice may lead to increased blood levels of the active ingredient amlodipine in some patients and may increase the blood pressure lowering effect of TESAMOLOT™.

Pregnancy and Breastfeeding

Pregnancy

You must tell your doctor if you think you might be pregnant or are planning to have a baby. Your doctor will normally advise you to stop taking TESAMOLOT™ before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of TESAMOLOT™.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. TESAMOLOT™ is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

No information is available on the effect of TESAMOLOT™ on the ability to drive or operate machinery. Some people may experience side effects such as fainting, sleepiness, dizziness or a feeling of spinning (vertigo) when taking TESAMOLOT™. If you experience these side effects, do not drive or use machines.

Important information about some of the ingredients of TESAMOLOT™

TESAMOLOT™ contains mannitol (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking TESAMOLOT™.

Use in children and adolescents

TESAMOLOT™ is not recommended for use in children and adolescents up to the age of 18 years.

3. HOW TO TAKE TESAMOLOT™

Your doctor will decide on the most suitable treatment for you including on:

- the correct dose
- how often and for how long you should be treated and
- whether you should also receive other medicines with TESAMOLOT™ or not.

Your doctor will give you all the necessary information on your treatment plan.

The recommended dose is one tablet a day.

If your liver is not working properly, the usual dose should not exceed one 40 mg/5 mg tablet or one 40 mg/10 mg tablet per day.

You can take TESAMOLOT™ with or without food. The tablets should be swallowed with some water or other non-alcoholic drink.

If you take more TESAMOLOT™ 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.

You might experience low blood pressure and rapid heartbeat. Slow heartbeat, dizziness, reduced kidney function including kidney failure, marked and prolonged low blood pressure including shock and death have also been reported.

If you forget to take TESAMOLOT™

- If you forget to take a dose, take it as soon as you remember and then carry on as before. If you do not take your tablet on one day, take your normal dose on the next day. Do not take a double dose to make up for forgotten individual doses.

If you stop taking TESAMOLOT™

- Unless your doctor instructs you to stop treatment, it is important to continue taking TESAMOLOT™.
- If you stop and your original symptoms come back tell your doctor or pharmacist immediately
- If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

TESAMOLOT™ can have side effects.

Not all side effects reported for TESAMOLOT™ are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TESAMOLOT™, please consult your doctor, pharmacist or other health care professional for advice.

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

- Allergic reactions include swelling of the hands, feet, ankles, face, mouth, lips, gums, tongue, throat and neck which may cause difficulty in swallowing or breathing
- throat tightness, shortness of breath and wheezing
- rash, "hives" (raised bumps), blisters or itching
- Sepsis (often called "blood poisoning", is a severe infection of the whole-body with high fever and the feeling of being severely ill), rapid swelling of the skin and mucosa (angioedema). If these effects are not treated they could be fatal
- Heart problems or heart attack

  Heart problems may get worse in people that already have heart disease. This may happen when you start TESAMOLOT™ tablets or when there is an increase in your dose of TESAMOLOT™.

These are all very serious side effects.

You may need urgent medical attention or hospitalisation.

Other side effects include:

Frequent side effects:

- Dizziness
- Nose, throat and urinary tract infections

Less frequent side effects:

- Bladder infection (cystitis)
- Low levels of iron in your blood (anaemia), high levels of a type of white blood cell called eosinophils (eosinophilia), low levels of platelets (thrombocytopaenia), low levels of white blood cells called leukocytes (leukocytopenia)
- Swelling (angioedema), allergic reactions, hypersensitivity
- Feeling sad (depression), feeling anxious, problems sleeping (insomnia)
- Sleepiness (somnolence), migraine, headache, tingling or numbness of the hands or feet (paraesthesia), fainting (syncope), reduced sense of touch (hypoaesthesia), distortion of taste (dysgeusia), shaking (tremor)
- Feeling of spinning (vertigo)
- Slow heart rate (bradycardia), fast heart rate (tachycardia), feeling that your heart is beating too hard or too fast (palpitations)
- Low blood pressure (hypotension), low blood pressure on standing up (orthostatic hypotension), flushing
- Cough, shortness of breath (dyspnoea), runny nose (rhinitis)
- Stomach pain (abdominal pain), excessive gas in your stomach (flatulence), runny tummy/ loose stools (diarrhoea), feeling sick (nausea), throwing up (vomiting), gum problems, indigestion (dyspepsia), dry mouth, change in bowel habits, inflammation of the pancreas (pancreatitis) and

stomach (gastritis)

- Itching, dry, red, inflammed skin, rash, increased sweating (hyperhidrosis), hives (urticaria), hair loss (alopecia), skin sensitivity to light
- High levels of potassium in blood (hyperkalaemia), low levels of sugar in blood (hypoglycaemia) (in diabetic patients), high sugar levels (hyperglycaemia)
- Heart problems, increased heart rate
- Ringing in the ear (tinnitus)
- Eye problems
- Liver problems
- Joint pain (arthralgia), muscle cramps, muscle pain (myalgia), back pain, pain in your arms and legs, tendon pain
- Excessive urination at night (nocturia), kidney problems
- Inability to obtain an erection (erectile dysfunction), swelling of breasts in men (gynaecomastia)
- Swelling (oedema), weakness (asthenia), chest pain, tiredness (fatigue), flu-like sickness, weight increase or decrease
- Pain, increase or decrease in weight
- Increased levels of liver enzymes and uric acid in blood (picked up in blood tests)

If you notice any side effects not on 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 TESAMOLOT™.

5. How to store TESAMOLOT™

Store at or below 25 °C.

Keep blisters in original packaging until required for use.

Keep all medicines out of reach and sight of children.

Do not dispose medicines in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What TESAMOLOT™ contains

The active substances are called telmisartan and amlodipine.

TESAMOLOT™ 40/5: Each tablet contains 40 mg telmisartan and 5 mg amlodipine base (as besylate salt).

TESAMOLOT™ 40/10: Each tablet contains 40 mg telmisartan and 10 mg amlodipine base (as besylate salt).

TESAMOLOT™ 80/5: Each tablet contains 80 mg telmisartan and 5 mg amlodipine base (as besylate salt).

TESAMOLOT™ 80/10: Each tablet contains 80 mg telmisartan and 10 mg amlodipine base (as besylate salt).

The other ingredients of TESAMOLOT™ are ferric oxide red, ferric oxide yellow, magnesium stearate, meglumine, polysorbate 80, povidone, purified water and sodium hydroxide.

What TESAMOLOT™ looks like and contents of the pack

TESAMOLOT™ 40/5: Oblong shaped, uncoated, biconvex, bilayered tablet with off white to white layer on one side and pale pink to pink layer with mottled appearance on the other side.

TESAMOLOT™ 40/10: Oblong shaped, uncoated, biconvex, bilayered tablet with off white to white layer on one side and pale yellow to yellow layer with mottled appearance on the other side.

TESAMOLOT™ 80/5: Oblong shaped, uncoated, biconvex, bilayered tablet with off white to white layer on one side and pale pink to pink layer with mottled appearance on the other side.

TESAMOLOT™ 80/10: Oblong shaped, uncoated, biconvex, bilayered tablet with off white to white layer on one side and pale yellow to yellow layer with mottled appearance on the other side.

TESAMOLOT™ tablets are packed in Alu-Alu blisters in pack sizes of 28.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd.

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2057

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TESAMOLOT™ 40/5: 53/7.1.3/0250

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TESAMOLOT™ 80/5: 53/7.1.3/0252

TESAMOLOT™ 80/10: 53/7.1.3/0253

Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. website:

http://www.drreddys.co.za

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100