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290 mm

TESMINOL
40/80 mg
PM03933102

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

TESMINOL 40 mg
Telmisartan 40 mg
Contains sugar (mannitol 104.14 mg)

TESMINOL 80 mg
Telmisartan 80 mg
Contains sugar (mannitol 208.28 mg)

Read this entire leaflet carefully before you start taking TESMINOL.
- 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.
- **TESMINOL** 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 **TESMINOL** is and what it is used for
2. What you need to know before you take **TESMINOL**
3. How to take **TESMINOL**
4. Possible side effects
5. How to store **TESMINOL**
6. Contents of the pack and other information

1. What TESMINOL is and what it is used for

TESMINOL 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. **TESMINOL** blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

TESMINOL tablets are used for the treatment of high blood pressure in adults.
TESMINOL 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.

2. What you need to know before you take TESMINOL

Do not take TESMINOL:
- If you are allergic to telmisartan or any of the other ingredients of **TESMINOL** (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 have 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 **TESMINOL** 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 **TESMINOL** and tell your doctor:
- If you become pregnant while taking **TESMINOL**. 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 from liver problems

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

Other medicines and TESMINOL
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 **TESMINOL**:
- 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 headings "Do not take **TESMINOL**" and "Warnings and precautions"
- Diuretics ('water tablets'), especially if taken in high doses together with **TESMINOL**, may lead to excessive loss of body water and low blood pressure (hypotension).

The effect of **TESMINOL** may be reduced when you take NSAIDs (non-steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen) or corticosteroids.

TESMINOL 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 **TESMINOL** 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 **TESMINOL**.
TESMINOL with food, drink and alcohol
TESMINOL 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 healthcare provider for advice before taking **TESMINOL**.

Do not take TESMINOL if you are pregnant, are considering becoming pregnant or are breastfeeding.
If you are a woman of childbearing age, you must use effective contraception.
If you are pregnant or breastfeeding; think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

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 **TESMINOL**. You should not engage in the above activities until you are aware of the extent to which **TESMINOL** affects you.

3. How to take TESMINOL

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 not sure.
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 80mg in cases where the target blood pressure is not achieved.
Your doctor may prescribe **TESMINOL** in combination with other blood pressure lowering medicines.

If you have the impression that the effect of **TESMINOL** is too strong or too weak, tell your doctor or pharmacist.

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

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

4. Possible side effects

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

If any of the following happens, stop taking **TESMINOL** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Swelling of your 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 **TESMINOL**. 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 signs 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 side effects:
- Coughing

Less frequent side effects:
- 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), joint 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.

Side effects with unknown frequency:
- Increase in certain white blood cells (eosinophilia)
- Low blood sugar levels (in diabetic patients)
- Hives (urticaria)
- 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 Reaction Reporting Form", found online under SAHPRA's publications: www.sahpra.org.za
By reporting side effects, you can help provide more information on the safety of **TESMINOL**.

5. How to store TESMINOL

Store all medicines out of reach of children.
Store at or below 25 ºC.
Store in the original packaging.
Do not take after the expiry date stated on the package.
Return all unused medicine to your pharmacist.
Do not dispose of unused capsules in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TESMINOL contains
TESMINOL 40: The active substance is 40 mg telmisartan.
TESMINOL 80: The active substance is 80 mg telmisartan.

The other ingredients are light magnesium oxide, mannitol (E number: E421), crospovidone, colloidal silicon dioxide, sodium hydroxide, microcrystalline cellulose and magnesium stearate (vegetable grade).

What TESMINOL looks like and contents of the pack
Silver aluminium/aluminium blister strips, packed in an outer carton.
Pack size: 10's, 28's or 30's tablets.
Tablets and sachets of silica gel are packed in white HDPE container with neck finish white closure with pulp and heat seal liner.
Pack size: 90's tablets.
Not all packs and pack sizes are necessarily marketed.

Holder of certificate of registration
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12, Alberton,
South Africa.

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Registration number
TESMINOL 40 mg: 47/7.1.3/1120
TESMINOL 80 mg: 47/7.1.3/1121

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169.

335 mm

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PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS S3

TESMINOL 40 mg
Telmisartan 40 mg
Bevat suiker (104,14 mg mannitol)

TESMINOL 80 mg
Telmisartan 80 mg
Bevat suiker (208,28 mg mannitol)

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy TESMINOL begin neem.
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy verdere vrae het.
- **TESMINOL** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

Wat in hierdie inligtingstuk is

1. Wat **TESMINOL** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **TESMINOL** neem
3. Hoe om **TESMINOL** te neem
4. Moontlike newe-effekte
5. Hoe om **TESMINOL** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat TESMINOL is en waarvoor dit gebruik word

TESMINOL behoort aan 'n klas van medisyne bekend as angiotensien II reseptor antagoniste.
Angiotensien II is 'n stof wat in jou liggaam geproduseer word wat veroorsaak dat jou bloedvate vernou en sodoende verhoog jou bloeddruk. **TESMINOL** blokkeer die effek van angiotensien II sodat die bloedvate ontspan, en jou bloeddruk verlaag word.

TESMINOL tablette word gebruik vir die behandeling van hoë bloeddruk in volwassenes.
TESMINOL tablette kan ook gebruik word om kardiovaskulêre gebeure (d.w.s. hartaanval of beroerte) en sterftes te verminder in pasiënte van 55 jaar of ouer met 'n hoë risiko vir kardiovaskulêre siekte.

2. Wat jy behoort te weet voordat jy TESMINOL neem

Moet nie TESMINOL neem nie:
- Indien jy allergies vir telmisartan, of enige van die ander bestanddele van **TESMINOL** (sien afdeling 6)
- Indien jy swelling van die gesig, lippe, mond, tong of keel en reuse swelsels op jou vel ontwikkel het wanneer jy voorheen medisyne geneem het bekend as angiotensien omskakeling ensien (AOE) inhibeerders of angiotensien reseptor blokkeerders (ARBs) - jy moet nooit weer hierdie medisyne neem nie
- Indien jou dokter vir jou gesê het dat die dikte van jou hartspier abnormaal vergroot is (hipertrofiese obstruktiewe kardiomiopatie (HOKM)
- Indien jy ly aan obstruksie van bloedvate na jou hart of niere
- Indien jy ernstige nierfunksieprobleme het
- Indien jy tans kaliumsparende diuretika ('water tablette') neem wat spironolaktoon, triamtereen of amiloried bevat
- Indien jy porfirie het ('n seldsame oorerflike siekte)
- Indien jy tans litium gebruik (word gebruik om sommige tipes depressie te behandel)
- Moet nie **TESMINOL** neem as jy swanger is, oorweeg om swanger te raak of as jy borsvoed nie. 'n Oorskakeling na 'n geskikte alternatiewe behandeling moet betyds gedoen word voor 'n beplande swangerskap.
- Indien jy aan ernstige lewersiekte of galobstruksie ly ('n probleem met die dreinering van die gal vanuit die galblaas)
- Indien jy tans aliskiren bevattende produkte gebruik
- Indien jy 'n fluorokinoloon antibiotika neem (wat gebruik word om 'n verskeidenheid van siektes soos bv. respiratoriese en urienweginfeksies te behandel), indien jy nierprobleme het of bejaard is.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met **TESMINOL** en vertel jou dokter:
- Indien jy swanger raak terwyl jy **TESMINOL** neem. Jy moet onmiddellik met die behandeling staak en jou dokter kontak om jou medisyne te verander.
- Indien jy aan niersiekte ly of 'n nieroorplanting gehad het
- Indien jy dalk 'n tekort aan soute in jou liggaam het as gevolg van 'n lae sout dieet, of as jy onlangs baie liggaamsvloeistowwe verloor het as gevolg van die neem van diuretiese medisyne (water tablette), braking of diaree
- Indien jy alreeds 'n middel naamlik 'n angiotensien omskakeling ensiem (AOE) inhibeerder gebruik
- Kontak jou dokter om jou behandeling te herevalueer as jy reeds met angiotensien omskakeling ensiem (AOE) inhibeerders/angiotensien reseptor blokkeerders (ARB's) saam met 'n fluorokinoloon antibiotika behandel word
- Indien jy voorheen ingelig is dat jou aldosteroonvlakke te hoog is
- Indien jy hartprobleme het
- Indien jy diabetes het
- Indien jy hoë kaliumvlakke in jou bloed het of as jy kaliumbevattende soutvervangers gebruik
- Indien jy lewerprobleme het.

Kinders en adolessente
Die veiligheid en doeltreffendheid van **TESMINOL** vir gebruik in kinders jonger as 18 jaar oud is nie vasgestel nie.

Ander medisyne en TESMINOL
Vertel altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in).
Jou dokter sal moontlik die dosis van hierdie ander medisyne moet verander, of ander voorsorgmaatreëls moet tref. In sommige gevalle sal jy dalk moet ophou om een van hierdie middels te neem. Dit geld veral vir die medisyne hieronder gelys indien dit saam met **TESMINOL** geneem word:
- Digoksien (gebruik om verskeie harttoestande te behandel)
- Medisyne wat kaliumvlakke in die bloed kan verhoog, soos kaliumbevattende soutvervangers, kaliumsparende diuretika (sekere 'water tablette'), AOE inhibeerders, angiotensien II reseptor antagoniste, NSAIM's (nie-steroïed anti-inflammatoriese medisyne, bv. aspirien of ibuprofen), heparien, immuunonderdrukkende middels (bv. siklosporien of takrolimus), en die antibiotikum trimetoprim.
- Medisyne wat litium bevat (word gebruik om sommige tipes depressie te behandel).
- Indien jy 'n AOE inhibeerder of aliskiren neem (sien ook inligting onder die opskrifte "Moet nie **TESMINOL** neem nie" en "Waarskuwings en voorsorgmaatreëls").
- Diuretika ('water tablette'), veral wanneer dit in hoë dosisse saam met **TESMINOL** geneem word, kan dit lei tot oormatige verlies van liggaamsvloeistowwe en lae bloeddruk (hipotensie).

Die effek van **TESMINOL** kan verminder word wanneer jy NSAIM's (nie-steroïed anti-inflammatoriese medisyne, bv. aspirien of ibuprofen) of kortikosteroïede neem.

TESMINOL kan die bloeddrukverlagende effek verhoog van ander medisyne wat gebruik word om hoë bloeddruk te behandel, of van medisyne met bloeddrukverlagende potensiaal (bv. baklofen, amifostien).

Gelyktydige gebruik van fluorokinolone en **TESMINOL** kan akute nierbesering presipiteer.

Verder kan alkohol, barbiturate, narkotiese middels of antidepressante lae bloeddruk vererger. Jy kan dit as duiseligheid ervaar wanneer jy opstaan. Jy moet jou dokter raadpleeg indien jy nodig het om die dosis van jou ander medisyne aan te pas terwyl jy **TESMINOL** neem.

TESMINOL met voedsel, drank en alkohol
TESMINOL kan met of sonder kos geneem word.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of borsvoed, vermoed dat jy moontlik swanger kan wees of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy **TESMINOL** neem.

Jy moet nie TESMINOL gebruik indien jy swanger is, oorweeg om swanger te raak of as jy borsvoed nie.
Indien jy 'n vrou van vrugbare ouderdom is, moet jy effektiewe voorbehoeding gebruik.
Indien jy swanger is of borsvoed, vermoed dat jy moontlik swanger kan wees of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne neem.

Bestuur en gebruik van masjinerie
Wanneer jy voertuie bestuur of masjinerie hanteer, moet daar in ag geneem word dat duiseligheid of lomerigheid kan voorkom wanneer bloeddrukverlagende medikasie, insluitend **TESMINOL**, geneem word. Jy moet nie by bogenoemde aktiwiteite betrokke raak voordat jy seker is van die mate waarin **TESMINOL** jou affekteer nie.

3. Hoe om TESMINOL te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Neem altyd hierdie medisyne presies soos jou dokter vir jou gesê het. Vra jou dokter of apteker indien jy nie seker is nie.
Volwassenes:
Die gewone dosis is 40 mg tablet een keer per dag (verkieslik op ongeveer dieselfde tyd elke dag) en gesluk met 'n glas water. Die dosis kan verhoog word tot 80 mg in gevalle waar die teiken bloeddruk nie bereik word nie.
Jou dokter kan **TESMINOL** in kombinasie met ander bloeddrukverlagende medisyne voorskryf.

Indien jy onder die indruk is dat die effek van **TESMINOL** te sterk of te swak is, lig jou dokter of apteker in.

Indien jy meer TESMINOL geneem het as wat jy behoort te neem
In die geval van 'n oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
Indien jy vergeet om TESMINOL te neem
Neem altyd **TESMINOL** soos voorgeskryf. Indien jy 'n dosis oorgeslaan het, neem dit sodra jy daarvan onthou. Moet nie 'n dubbele dosis van **TESMINOL** neem om vir 'n vergete individuele dosis op te maak nie.
Indien jy ophou om TESMINOL te neem
Moet nie ophou om **TESMINOL** te gebruik nie, tensy jou dokter jou beveel om dit te doen nie.

4. Moontlike newe-effekte

TESMINOL kan newe-effekte hê.
Nie al die newe-effekte wat vir **TESMINOL** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of jy enige ongewenste effekte ervaar terwyl jy **TESMINOL** gebruik, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om **TESMINOL** te gebruik en vertel jou dokter onmiddellik daarvan, of gaan na die ongevalle afdeling van jou naaste hospitaal:
- Swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat dit moeilik kan maak om te sluk of asem te haal,
- Uitslag of jeuk
- Floutes.

Al hierdie newe-effekte is baie ernstig. Indien jy dit ervaar, het jy moontlik 'n ernstige reaksie op **TESMINOL** gehad. Jy mag dringende mediese aandag of hospitalisasie benodig.

Vertel onmiddellik vir jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:
- Ernstige, lewensgevaarlike infeksie (sepsis, ook bekend as 'bloedvergiftiging') met moontlike noodlottige uitkoms.
- Veranderinge in die manier waarop jou hart klop, byvoorbeeld, wanneer jy agterkom dit klop vinniger, stadiger of onreëlmatig.
- Vergeling van die vel en oë, donkerkleurige uriene, voel moeg of swak, wat simptome van lewerprobleme of lewerversaking kan wees
- Om minder uriene te passeer as wat jy normaalweg doen, wat kan dui op ernstige nierprobleme of nierversaking.

Al hierdie newe-effekte is ernstig. Jy mag moontlik dringende mediese aandag nodig hê.

Vertel vir jou dokter indien jy enige van die volgende opmerk:
Gereelde newe-effekte:
- Hoes

Minder gereelde newe-effekte:
- Urienweginfeksies, boonste lugweginfeksies (bv. seer keel, ontsteekte sinusse, algemene verkoue)
- Tekort aan rooibloedselle (anemie), lae bloedplaatjietelling (trombositopenie)
- Hoë kaliumvlakke in jou bloed
- Sukkel om aan die slaap te raak, voel hartseer (depressie), voel angstig
- Floute (sinkopee), voel slaperig (somnolensie)
- Probleme met jou sig
- Gevoel van spin (vertigo)
- Lae bloeddruk (hipotensie) in gebruikers wat behandel word vir hoë bloeddruk, duiseligheid wanneer jy opstaan (ortostatiese hipotensie)
- Kortasem, progressiewe verlittekening van longweefsel (interstisiële longsiekte)
- Abdominale pyn, diaree, ongemak in die buik, opgeblasenheid, braking, droë mond, omgekrapte maag, smaakversteuring (disgeusie)
- Verhoogde sweetafskeiding, jeuk, veluitslag, ekseem ('n vel afwyking), rooiheid van die vel
- Rugpyn, spierkrampe, spierpyn (mialgie), gewrigspyn (artralgie), pyn in ledemate
- Borskaspyn, gevoel van swakheid (astenie), griepagtige siekte
- Verhoogde kreatinienvlak in die bloed, verlaagde hemoglobien ('n bloedproteïen), verhoogde vlakke van uriensuur, verhoogde lewerensieme of kreatienfosfokinase in die bloed.

Newe-effekte met onbekende frekwensie:
- Toename in hoeveelheid van sekere witbloedselle (eosinofilie)
- Lae bloedsuikervlakke (in diabetiese pasiënte)
- Galbulte (urtikariaal)
- Seer tendon.

Stel asseblief jou dokter of apteker in kennis, indien jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

Aanmelding van newe-effekte
Indien jy newe-effekte kry praat met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die "**6.04 Adverse Drug Reaction Reporting Form**", wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za.
Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **TESMINOL**.

5. Hoe om TESMINOL te bewaar

Bewaar alle medisyne buite bereik van kinders.
Bewaar by of benede 25 °C.
Bewaar in die oorspronklike verpakking.
Moet nie gebruik na die vervaldatum wat op die verpakking aangebring is nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat TESMINOL bevat
TESMINOL 40: Die aktiewe bestanddeel is 40 mg telmisartan.
TESMINOL 80: Die aktiewe bestanddeel is 80 mg telmisartan.

Die ander bestanddele is ligte magnesiumoksied, mannitol (E-nommer: E421), krospovidoon, kolloïdale silikondioksied, natriumhidroksied, mikrokristallyne sellulose en magnesiumstearaat (groentegraad).

Hoe TESMINOL lyk en inhoud van die pak
Silwer aluminium/aluminium stulpstroke wat, verpak in 'n buitenste karton.
Verpakkingsgrootte: 10's, 28's en 30's tablette.
Tablette en sakkies silikagel word verpak in wit HDPE-houer met 'n nekafwerking wit sluiting met pulp en hitteseëlvoering.
Verkpakkingsgrootte: 90's tablette.
Nie alle verpakkings en verpakkingsgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Weg 1, Bassonia Rock, Uitbr. 12,Alberton,
Suid Afrika

Hierdie inligtingstuk was hersien in
28 Februarie 2022

Registrasienommers
TESMINOL 40 mg: 47/7.1.3/1120
TESMINOL 80 mg: 47/7.1.3/1121

Vir die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodspharma.com of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169

335 mm

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : **Removal of English PI and inclusion of Access to the corresponding professional information as per Latest communication from MAHoder along with Change in the dimensions**

1. Product : TESMINOL 40/80 mg (Telmisartan Tablets 40 / 80 mg)	
2. Country: South Africa (Private Market)	**3. Packaging component: Patient Information Leaflet**
4. No. of Colours: 1 Colour	**5. Pantone Shade No.: Black**
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	**8. Dimensions: 335 (L) x 290 (W) mm**
9. Design / Style: Booklet type	**10. Item code No.: PM03933102**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 34660 mini**
13. Barcode/NDC No: NA	**14. Supersedes Item code No: PM03933101**
15. Revision No: 01	**16. A/W File name:Z:\Telmisartan Tablets\SA Private Market\02\Telmisartan Tablets 40 and 80 mg PIL - PM03933102.cdr**
Approved By:	**17. Location: Baddi**

PRD	M.A. HOLDER	RAD/MEDICAL	QC	PRODN	QA
	09/01/2025				

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

Reason for revision :	Item code	Artwork Send for Prnting Date	Artwork Implementation Date
1) New Artwork for South Africa - (Private Market)	**PM03933101**	**19/10/22**	**08/02/23**
2) Removal of English PI and inclusion of Access to the corresponding professional information as per Latest communication from MAHoder along with Change in the dimensions	**PM03933102**		