PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

TELMISARTAN 40 TEVA & TELMISARTAN 80 TEVA

Tablets

Telmisartan

Each TELMISARTAN 40 TEVA tablet contains 19,20 mg sorbitol (E420), 135,80 mg mannitol and 4,66 mg sodium hydroxide.

Each TELMISARTAN 80 TEVA tablet contains 38,40 mg sorbitol (E420), 271,60 mg mannitol, and 9,31 mg sodium hydroxide.

Read this entire leaflet carefully before you start taking TELMISARTAN TEVA:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TELMISARTAN TEVA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. WHAT TELMISARTAN TEVA IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TELMISARTAN TEVA

3. HOW TO TAKE TELMISARTAN TEVA

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE TELMISARTAN TEVA

6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT TELMISARTAN TEVA IS AND WHAT IT IS USED FOR:

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

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

TELMISARTAN TEVA 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 TELMISARTAN TEVA:

Do not take TELMISARTAN TEVA:

- if you are allergic to telmisartan or any of the other ingredients of TELMISARTAN TEVA (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 TELMISARTAN TEVA 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 TELMISARTAN TEVA and tell your doctor:

- if you become pregnant while taking TELMISARTAN TEVA. 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 diarrhea
- 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 TELMISARTAN TEVA for use in children below 18 years have not been established.

Other medicines and TELMISARTAN TEVA:

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 TELMISARTAN TEVA:

- 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 TELMISARTAN TEVA** and **Warnings and precautions**)
- Diuretics (water tablets), especially if taken in high doses together with TELMISARTAN TEVA, may lead to excessive loss of body water and low blood pressure (hypotension).

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

TELMISARTAN TEVA with food, drink and alcohol:
TELMISARTAN TEVA 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 TELMISARTAN TEVA.
Do not take TELMISARTAN TEVA 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 TELMISARTAN TEVA. You should not engage in the above activities until you are aware of the extent to which TELMISARTAN TEVA affects you.

TELMISARTAN TEVA contains sorbitol. If you have been told that you have an intolerance to some sugars, you should not take TELMISARTAN TEVA.

One dose (tablet) of TELMISARTAN 40 TEVA contains 4,66 mg sodium (found in table salt). This is equivalent to 0,24 % of the recommended maximum daily intake of sodium for an adult.
One dose (tablet) of TELMISARTAN 80 TEVA contains 9,31 mg sodium (found in table salt). This is equivalent to 0,48 % of the recommended maximum daily intake of sodium for an adult.
To be taken into consideration by patients on a controlled sodium diet.

3. HOW TO TAKE TELMISARTAN TEVA:

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 80 mg in cases where the target blood pressure is not achieved.
Your doctor may prescribe TELMISARTAN TEVA in combination with other blood pressure lowering medicines.
If you have the impression that the effect of TELMISARTAN TEVA is too strong or too weak, tell your doctor or pharmacist.

If you take more TELMISARTAN TEVA 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 TELMISARTAN TEVA:

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

If you stop taking TELMISARTAN TEVA:

Do not stop taking TELMISARTAN TEVA unless your doctor tells you to.

4. POSSIBLE SIDE EFFECTS:

TELMISARTAN TEVA can have side effects.

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

If any of the following happens, stop taking TELMISARTAN TEVA 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 TELMISARTAN TEVA. 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 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) and 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 (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 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 TELMISARTAN TEVA.

5. HOW TO STORE TELMISARTAN TEVA:

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 TELMISARTAN TEVA contains

TELMISARTAN 40 TEVA: The active substance is 40 mg telmisartan.

TELMISARTAN 80 TEVA: The active substance is 80 mg telmisartan.

The other ingredients are:

Hypromellose

Magnesium stearate

Mannitol

Meglumine

Povidone (K-90)

Sodium hydroxide

Sorbitol (E420)

What TELMISARTAN TEVA looks like and contents of the pack:

TELMISARTAN 40 TEVA and TELMISARTAN 80 TEVA is a white to off white, oblong tablet with a decorative break line on one side.

The tablet can be divided into equal halve.

TELMISARTAN TEVA is packaged in Al/Al blisters in outer cardboard carton.

Pack sizes: 7, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100 tablets.

TELMISARTAN TEVA is packaged in HDPE bottles with a white screw cap.

Pack sizes: 100, 500 tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration:

Teva Pharmaceuticals (Pty) Ltd.

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PASIëNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S3

TELMISARTAN 40 TEVA & TELMISARTAN 80 TEVA

Tablette

Telmisartaan

Elke TELMISARTAN 40 TEVA tablet bevat 19,20 mg sorbitol (E420), 135,80 mg mannitol en 4,66 mg natrium hidroksied.

Elke TELMISARTAN 80 TEVA tablet bevat 38,40 mg sorbitol (E420), 271,60 mg mannitol, en 9,31 mg natrium hidroksied.

Lees hierdie blad noukeurig deur voordat u begin om TELMISARTAN TEVA te gebruik:

- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vrae het, moet u asseblief vir u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vra.
- TELMISARTAN TEVA is vir u persoonlik voorgeskryf en u moet nie u medisyne vir ander mense gee nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as u s'n.

Wat in hierdie blad is:

1. WAT TELMISARTAN TEVA IS EN WAARVOOR DIT GEBRUIK WORD.

2. WAT U MOET WEET VOORDAT U TELMISARTAN TEVA DRINK.

3. HOE OM TELMISARTAN TEVA TE DRINK.

4. MOONTLIKE NEWE-EFFEKTE.

5. HOE OM TELMISARTAN TEVA TE BÊRE.

6. INHOUD VAN DIE PAK EN ANDER INLIGTING.

1. WAT TELMISARTAN TEVA IS EN WAARVOOR DIT GEBRUIK WORD:

TELMISARTAN TEVA behoort aan ’n klas geneesmiddels bekend as angiotensien II-reseptorantagoniste.

Angiotensien II is ’n stof wat in die liggaam gemaak word wat veroorsaak dat bloedvate toetrek, en u bloeddruk dus verhoog. TELMISARTAN TEVA blokkeer die effek van angiotensien II sodat die bloedvate verslap en u bloeddruk verlaag.

TELMISARTAN TEVA-tablette word gebruik vir die behandeling van hoë bloeddruk in volwassenes.

TELMISARTAN TEVA-tablette kan ook gebruik word om kardiovaskulêre voorvalle (d.w.s. hartaanval of beroerte) en sterftes te verminder in pasiënte van 55 jaar en ouer wat ’n hoë risiko vir kardiovaskulêre siektes het.

2. WAT U MOET WEET VOORDAT U TELMISARTAN TEVA DRINK:

Moenie TELMISARTAN TEVA drink nie:

- as u allergies vir kalsium of vir enige van die ander bestanddele van TELMISARTAN TEVA is (sien **afdeling 6**)
- as u swelling in die gesig, lippe, mond, tong of keel ervaar en reuse galbulte op u vel ontwikkel het toe u voorheen medisyne genaamd angiotensien-omskakelingsensiemremmers (AOER’s) of angiotensienreseptorblokkers (ARB's) gebruik het, moet u hierdie medisyne nooit weer gebruik nie
- as u dokter vir u gesê het dat die dikte van u hartspier abnormaal groter geword het (hipertrofiese obstruktiewe kardiomiopatie (HOKM))
- as u aan obstruksie van die bloedvate in u hart of niere ly
- as u ernstige probleme met nierfunksie het
- as u tans kaliumsparende diuretika (watertablette) gebruik wat spironolaktoon, triamtereen of amiloried bevat
- as u porfirie het (’n skaars genetiese siekte)
- as u tans litium gebruik (vir die behandeling van sekere tipes depressie)
- Moenie TELMISARTAN TEVA drink as u swanger is, dit oorweeg om swanger te raak of borsvoed nie. Voor ’n beplande swangerskap moet na geskikte alternatiewe behandeling oorgeskakel word

- as u aan ’n erge lewersiekte of galobstruksie (’n probleem met die dreinering van die gal vanaf die galblaas) ly
- as u tans produkte wat aliskiren bevat, gebruik
- as u ’n fluoorkinoloonantibiotikum gebruik (gebruik om verskillende siektes soos respiratoriese en urienweginfeksies te behandel)
- as u nierprobleme het of bejaard is.

Waarskuwings en voorsorgmaatreëls:

Wees veral versigtig met TELMISARTAN TEVA en sê vir u dokter:

- as u swanger raak terwyl u TELMISARTAN TEVA drink. U moet die behandeling onmiddellik staak en u dokter skakel om u medisyne te verander
- as u aan niersiekte ly of ’n nieroorplanting gehad het
- as u as gevolg van ’n laesoutdieet ’n tekort aan sout in u liggaam het, of as u onlangs as gevolg van die gebruik van diuretika (watertablette), braking of diarree baie liggaamsvloeistof verloor het
- as u reeds medisyne gebruik wat ’n angiotensienomskakelingsensiem- (AOE) remmer genoem word
- skakel u dokter om u behandeling te herevalueer as u met ’n angiotensienomskakelingsensiem- (AOE) remmer /angiotensienreseptorblokker (ARB) saam met ’n fluoorkinoloon-antibiotikum behandel word
- as vroeër vir u gesê het dat u aldosteroonvlakke hoog is
- as u hartprobleme het
- as u diabetes het
- as u hoë kaliumvlakke in u bloed het of soutvervangers gebruik wat kalium bevat
- as u lewerprobleme het.

Kinders en adolessente:

Die veiligheid en effektiwiteit van TELMISARTAN TEVA vir kinders jonger as 18 jaar is nie bepaal nie.

Ander medisyne en TELMISARTAN TEVA:

Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik (waaronder aanvullende of tradisionele medisyne).
U dokter moet moontlik die dosis van hierdie ander medisyne verander of ander voorsorgmaatreëls tref. In sommige gevalle moet u dalk een van hierdie medisyne staak. Dit geld veral die onderstaande medisyne wat saam met TELMISARTAN TEVA gebruik word:

- Digoksien (vir verskeie harttoestande)
- Medisyne wat kaliumvlakke in die bloed kan verhoog, soos soutvervangers wat kalium bevat, kaliumsparende diuretika (sekere watertablette), AOE-remmers, angiotensien II-reseptorantagoniste, NSAIM's (nie-steroïed anti-inflammatoriese middels, bv. aspirien of ibuprofeen), heparien, immuunonderdrukkers (bv. siklosporien of takrolimus) en die antibiotikum trimetopriem
- Litiumbevattende medisyne (vir behandeling van sekere tipes depressie)
- As u ’n AOE-remmer of aliskiren gebruik (lees ook die inligting onder die opskrifte Moenie TELMISARTAN TEVA drink nie en Waarskuwings en voorsorgmaatreëls)
- Diuretika ('watertablette'), veral as dit in hoë dosisse saam met TELMISARTAN TEVA gedrink word, kan tot oormatige verlies aan liggaamsvog en lae bloeddruk (hipotensie) lei.

Die effek van TELMISARTAN TEVA kan verlaag word as u NSAIM's (nie-steroïed anti-inflammatoriese middels, bv. aspirien of ibuprofeen) of kortikosteroïede gebruik.
TELMISARTAN TEVA kan die bloeddrukverlagende effek versterk van ander medisyne wat vir die behandeling van hoë bloeddruk gebruik word of van medisyne met bloeddrukverlagende potensiaal (bv. baklofeen, amifostien).
Gelyktydige gebruik van fluoorkinolone en TELMISARTAN TEVA kan akute nierskade veroorsaak.
Verder kan alkohol, barbiturate, verdowingsmiddels of antidepressante lae bloeddruk vererger. U kan dit ervaar as duiseligheid wanneer u opstaan. U moet u dokter raadpleeg as u die dosis van u ander medisyne moet aanpas terwyl u TELMISARTAN TEVA gebruik.

Gebruik van TELMISARTAN TEVA saam met kos, drank en alkohol:

TELMISARTAN TEVA kan met of sonder voedsel gedrink word.

Swangerskap, borsvoeding en vrugbaarheid:

As u swanger is of borsvoed, dink dat u dalk swanger kan wees of beplan om ’n baba te hê, moet u u dokter, apteker of ander gesondheidsorgverskaffer asseblief om advies raadpleeg voordat u TELMISARTAN TEVA drink.

Moenie TELMISARTAN TEVA drink as u swanger is, dit oorweeg om swanger te raak of borsvoed nie.

As u ’n vrou van vrugbare ouderdom is, moet u effektiewe voorbehoeding gebruik.

Motorbestuur en gebruik van masjinerie:

As u voertuie bestuur of masjinerie gebruik, moet u in ag neem dat duiseligheid of lomerigheid kan voorkom as u bloeddrukverlagende medisyne, soos TELMISARTAN TEVA, gebruik. Totdat u weet hoe TELMISARTAN TEVA u beïnvloed, moet nie ’n voertuig bestuur of masjiene hanteer nie.

TELMISARTAN TEVA bevat sorbitol. As vir u gesê is dat u ’n onverdraagbaarheid vir sekere suikers het, moet u nie TELMISARTAN TEVA drink nie.

Een dosis (tablet) TELMISARTAN 40 TEVA bevat 4,66 mg natrium (gevind in tafelsout). Dit is gelykstaande aan 0,24 % van die aanbevole maksimum daaglikse inname van natrium vir 'n volwassene.

Een dosis (tablet) TELMISARTAN 80 TEVA bevat 9,31 mg natrium (gevind in tafelsout). Dit is gelykstaande aan 0,48 % van die aanbevole maksimum daaglikse inname van natrium vir 'n volwassene.

Natrium inhoud moet in ag geneem te word deur pasiënte met 'n beheerde natriumdieet.

3. HOE OM TELMISARTAN TEVA TE DRINK:

Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie. Gebruik hierdie medisyne altyd presies soos wat u dokter vir u gesê het. Raadpleeg u dokter of apteker as u nie seker is nie.

Volwassenes:

Die gewone dosis is een tablet van 40 mg een keer per dag (verkieslik ongeveer dieselfde tyd elke dag) afgesluk met water. Die dosis kan tot 80 mg verhoog word in gevalle waar die teikenbloeddruk nie bereik word nie.
U dokter kan TELMISARTAN TEVA voorskryf saam met ander medisyne wat bloeddruk verlaag.
Praat met u dokter of apteker as u die indruk het dat die effek van TELMISARTAN TEVA te sterk of te swak is.

As u meer TELMISARTAN TEVA gedrink het as wat u moes:
Raadpleeg u dokter of apteker in geval van oordosering. As nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

As u vergeet om TELMISARTAN TEVA te drink:
Drink TELMISARTAN TEVA altyd soos voorgeskryf. As u ’n dosis oorgeslaan het, drink dit sodra as wat u onthou. Moenie ’n dubbele dosis TELMISARTAN TEVA drink om vir die vergete individuele dosisse op te maak nie.

As u ophou om TELMISARTAN TEVA te drink:
U moet nie ophou om TELMISARTAN TEVA te drink tensy u dokter vir u sê om dit te doen nie.

4. MOONTLIKE NEWE-EFFEKTE:
TELMISARTAN TEVA kan newe-effekte hê.
Nie al die newe-effekte wat vir TELMISARTAN TEVA aangemeld is, is in hierdie blad opgeneem nie.
As u algemene gesondheidstoestand versleg of as u newe-effekte ervaar terwyl u TELMISARTAN TEVA drink, moet u u gesondheidsorgverskaffer om advies raadpleeg.

Indien enige van die volgende voorkom, moet u ophou om TELMISARTAN TEVA te drink en onmiddellik vir u dokter sê of na die ongevalle-afdeling van u naaste hospitaal gaan:

- swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat probleme met sluk of asemhaling kan veroorsaak
- veluitslag of jeuk

- floutes.

Dit is almal baie ernstige newe-effekte. As u dit ervaar, kan dit wees dat u ’n ernstige reaksie op TELMISARTAN TEVA het. Dit mag wees dat u dringende mediese aandag of hospitalisasie nodig het.

Sê dadelik vir u dokter of gaan na die ongevalle-afdeling van u naaste hospitaal as u enige van die volgende opmerk:

- ernstige, lewensbedreigende infeksie (sepsis, ook bekend as bloedvergiftiging) met moontlike dodelike uitkoms
- veranderinge in die manier waarop u hart klop, as u byvoorbeeld opmerk dat dit vinniger, stadiger of onreëlmatig klop
- geel verkleuring van die vel, donker urien, voel moeg of swak wat simptome van lewerprobleme of lewerversaking kan wees
- produseer minder urien as wat normaal is vir u, wat tekens van ernstige nierprobleme of nierversaking kan wees.

Hierdie is almal ernstige newe-effekte. Dit mag wees dat u dringende mediese aandag nodig het.

Sê vir u dokter as u enige van die volgende opmerk:

Newe-effekte wat dikwels voorkom:

- Hoes.

Newe-effekte wat minder dikwels voorkom:

- urienweginfeksies, infeksies in die boonste lugweë (bv. seer keel, ontsteekte sinusse, verkoue)
- tekort aan rooibloedselle (bloedarmoede), lae plaatjietelling (trombositopenie)
- hoë vlakke kalium in u bloed
- probleem om aan die slaap te raak, voel hartseer (depressie), voel angstig
- floute (sinkopee), voel lomerig (slaperigheid)
- probleme met u visie
- sensasie van rotasie (vertigo)

- lae bloeddruk (hipotensie) in gebruikers wat vir hoë bloeddruk behandel word, duiseligheid wanneer opgestaan word (ortostatiese hipotensie)
- kortasemheid, progressiewe littekens in longweefsel (interstisiële longsiekte)
- buikpyn, diarree, ongemak in die buik, opgeblasenheid, braking, droë mond, omgekrapte maag, smaakstoornis (disgeusie)
- meer sweet, jeuk, geneesmiddeluitslag, ekseem (velafwyking), rooi vel
- rugpyn, spierkrampe, spierpyn (mialgie), gewrigspyn (artralgie), pyn in die ledemate
- pyn op die bors, gevoel van swakheid (astenie), griepagtige siekte
- hoër vlakke kreatinien in die bloed, laer vlakke hemoglobien (’n bloedproteïen), hoër vlakke uriensuur, hoër vlakke lewerensieme of kreatienfosfokinase in die bloed.

Newe-effekte met onbekende frekwensie:

- styging in die aantal witbloedselle (eosinofilie)
- lae bloedsuikervlakke (in diabetiese pasiënte)
- galbulte (urtikarie)
- pyn in die tendons.

As u enige newe-effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apteker asseblief in kennis stel.

Aanmeld van newe-effekte:

Praat met u dokter of apteker as u newe-effekte ervaar.
U kan newe-effekte ook by SAHPRA aanmeld via die vorm vir die aanmeld van nadelige geneesmiddelreaksies, naamlik **6.04 Adverse Drug Reaction Reporting Form** wat aanlyn onder SAHPRA se publikasies gekry kan word: https://www.sahpra.org.za/Publications/Index/8..
Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van TELMISARTAN TEVA te gee.

5. HOE OM TELMISARTAN TEVA TE BÊRE:

Hou alle medisyne buite bereik van kinders.

Bêre by of onder 25 ºC.

Bêre in die oorspronklike verpakking.

Moenie na die vervaldatum op die pakkie gebruik nie.

Gee alle ongebruikte medisyne terug aan u apteker.

Moenie ongebruikte tablette in dreinering- of rioolstelsels (bv. toilette) gooi nie.

6. INHOUD VAN DIE PAK EN ANDER INLIGTING:

Wat TELMISARTAN TEVA bevat

TELMISARTAN 40 TEVA: Die aktiewe bestanddeel is 40 mg telmisartaan.

TELMISARTAN 80 TEVA: Die aktiewe bestanddeel is 80 mg telmisartaan.

Die ander bestanddele is:

Hipromellose

Magnesiumstearaat

Mannitol

Meglumien

Povidoon (K-90)

Natriumhidroksied

Sorbitol (E420)

Hoe TELMISARTAN TEVA lyk en die inhoud van die pakkie:

TELMISARTAN 40 TEVA en TELMISARTAN 80 TEVA is ’n wit tot spierwit, langwerpige tablet met ’n dekoratiewe breeklyn aan die een kant.

Die tablet kan in gelyke helftes verdeel word.

TELMISARTAN TEVA is in Al/Al-stulpstroke in ’n buitenste kartondoos verpak.

Pakgroottes: 7, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100 tablette

TELMISARTAN TEVA is in HDPE-bottels met ’n wit skroefdop verpak.

Pakgroottes: 100, 500 tablette

Nie al die pakgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat:

Teva Pharmaceuticals (Pty) Ltd.

Maxwell Kantoorpark

Magwasingelwes

Waterfall City

Midrand

Gauteng

2090.

Tel.: +27 (0)11 055 0200

Hierdie blad is laas hersien op:

21 January 2021

Registrasienommers:

TELMISARTAN 40 TEVA: 48/7.1.3/0824

TELMISARTAN 80 TEVA: 48/7.1.3/0825