PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

TELGEN® 40 Tablets

TELGEN® 80 Tablets

Read all of this leaflet carefully before you start taking TELGEN®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other health care provider.
- TELGEN® 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 TELGEN® is and what it is used for
2. What you need to know before you take TELGEN®
3. How to take TELGEN®
4. Possible side effects
5. How to store TELGEN®
6. Contents of the pack and other information

1. What TELGEN® is and what it is used for

TELGEN® contains telmisartan.

Telmisartan in TELGEN® belongs to a group of medicines called Vascular medicines (other hypotensives), which is used for the treatment of high blood pressure. This is also known as essential hypertension.

TELGEN® is used to reduce cardiovascular events (i.e. heart attack or stroke) death in patients 55 years or older who are at high risk of cardiovascular disease; the benefit of treatment is evident after at least 6 months of continued treatment.

2. What you need to know before you take TELGEN®

Do not take TELGEN® (telmisartan) 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.

Do not take TELGEN®:

- If you are allergic to telmisartan, or any of the other ingredients of TELGEN® (listed in section 6).
- If you have previously been treated with a medication in the same group of medicines as TELGEN® (angiotensin receptor antagonists) or with a medication in the group of medicines known as ACE inhibitors and have had allergic reactions with swelling of the face, lips, tongue, and or throat with difficulty in swallowing or breathing.
- If you suffer from inherited or of unknown cause or spontaneous angioedema (swelling of the face, lips, tongue, and or throat with difficulty in swallowing or breathing).
- If you have obstruction of the heart's blood vessels (left ventricle outflow).

- If you have severe kidney function impairment.
- If you have narrowing of the blood vessel of the kidney on both sides.
- If you have narrowing of the blood vessels in the kidney if you only have one kidney.
- If you have narrowing of the heart's aortic blood vessel.
- If you are taking TELGEN® together with potassium sparing diuretics (water tablets) such as spironolactone, triamterene, amiloride.
- If you have a rare blood pigment disorder called porphyria.
- If you are taking TELGEN® together with lithium, as this may lead to toxic blood concentrations of lithium.
- Pregnancy and breastfeeding (see **Pregnancy and Breastfeeding**).
- If you have severe liver disease or biliary obstruction (a problem with the drainage of the bile from the gall bladder).
- If you have rare hereditary condition called sorbitol intolerance.
- If you are currently taking aliskiren-containing products.
- If you are taking fluoroquinolones (class of medicines used to treat infections).

Warnings and precautions

Take special care with TELGEN®:

- if you suffer from kidney disease or have had a kidney transplant.
- if you suffer from liver problems.
- if you have heart problems.
- if your body could be lacking salt due to a low salt diet, or if you have recently lost a lot of body fluids due to taking strong diuretic medicines (water tablets), vomiting or diarrhea (loose stools).

- if you have high potassium levels in your blood or use salt substitutes containing potassium.
- if you have been told previously that you have raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals).
- if you have diabetes (too much sugar in the blood) symptoms include excessive thirst, increased appetite with weight loss and passing large amounts of urine and/or elderly (>70 years)

TELGEN® may be less effective in lowering the blood pressure in black patients.

If you are taking medicines used to treat high blood pressure (an ACE-inhibitor such as enalapril, lisinopril, ramipril); or fluoroquinolones (class of medicines used to treat infections such as ciprofloxacin, levofloxacin).

Your doctor may check your kidney function at regular intervals.

Other medicines and TELGEN®:

Always tell your healthcare professional if you are taking any other medicine.

(This includes 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 TELGEN®:

- Lithium containing medicines to treat some types of depression.
- Medicines that may increase blood potassium levels such as
  - salt substitutes containing potassium,
  - potassium-sparing diuretics (certain ‘water tablets’),
  - ACE inhibitors (used to treat high blood pressure e.g. enalapril, lisinopril, ramipril),

- angiotensin II receptor antagonists (used to treat high blood pressure e.g. valsartan, losartan),
- NSAIDs (non-steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen),
- heparin (used to thin blood),
- immunosuppressives (used to prevent organ rejection e.g. cyclosporin or tacrolimus), and
- antibiotic trimethoprim (used to treat infection)
- fluoroquinolones (class of medicines used to treat infections e.g. ciprofloxacin, levofloxacin, moxifloxacin).

- Diuretics ('water tablets'), especially if taken in high doses together with TELGEN, may lead to excessive loss of body water and low blood pressure (hypotension).
- Alskiren (used to treat high blood pressure)
- Medicines for heart problems, high blood pressure that your doctor does not know about (e.g. digoxin)

The effect of TELGEN® may be reduced when you take NSAIDs (non-steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen) or corticosteroids (used to provide relief for inflammation).

TELGEN® 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). Furthermore, low blood pressure may be aggravated by alcohol, barbiturates, narcotics or antidepressants. 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 TELGEN®.

Pregnancy and Breastfeeding:

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.

Do not take TELGEN® if you are pregnant or breastfeeding. If you become pregnant while taking TELGEN®, stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking TELGEN® by using suitable contraception.
TELGEN® can cause toxicity in the embryo, foetal and neonatal deaths when given to pregnant women. Women of childbearing age should use effective contraception.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:

When driving vehicles or operating machinery, it should be borne in mind that dizziness or drowsiness may occasionally occur when taking blood pressure lowering medication, including TELGEN®.

TELGEN® contains sorbitol:

TELGEN® tablets contain sorbitol. If you have been told that you have an intolerance to some sugars, you should not take TELGEN®.

3. How to take TELGEN®

Do not share medicines prescribed for you with any other person.
Always take TELGEN® tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that TELGEN® is too strong or too weak, talk to your doctor or pharmacist.

TELGEN® tablets are only for adults should not be taken by children and adolescents up to 18 years.

TELGEN® is usually taken in a dose of one 40 mg or 80 mg tablet once daily, preferably at about the same time each day, and swallowed with a drink of water.

Your doctor may prescribe TELGEN® in combination with other blood pressure lowering medicines.

If you take more TELGEN® than you should:

In the event of overdosage or accidental intake, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take TELGEN®:

If you miss a dose of TELGEN®, take it as soon as you remember on the same day. If you do not take your tablet on that same day, take your normal dose on the next day. Do not double the dose to make up for forgotten individual doses.

4. Possible side effects

TELGEN® can have side effects.

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

If any of the following happens, stop taking TELGEN® and tell your doctor immediately

or go to the casualty department at your nearest hospital:

- sudden allergic reaction including signs like rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath or trouble breathing (anaphylactic reaction)
- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing (angioedema),
- sepsis (often called "blood poisoning", is a severe infection with whole-body inflammatory response which can lead to death)
- allergic reaction

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TELGEN®. 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:

- urinary tract infections (including inflammation of the bladder),
- upper respiratory tract infections (e.g. sore throat or feeling of tension or fullness in the nose)
- bleeding or bruising more easily than normal due to low blood platelet count (thrombocytopenia)
- dizziness on standing up, especially when getting up from a sitting or lying position (orthostatic hypotension)
- progressive scarring of lung tissue (interstitial lung disease)
- skin rash with inflammation of the skin, marked by itching and rash and often including blisters that weep and become crusted (eczema)
- flu-like symptoms, such as high temperature, sore throat, runny nose, cough

and chills (influenza-like symptoms)

- low blood sugar levels (in diabetic patients)
- kidney problems including symptoms, little or no urine, drowsiness, nausea, vomiting, breathlessness

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

Tell your doctor if you notice any of the following:

Frequent:

- cough

Less frequent:

- chest pain
- a condition in which the amount of oxygen-carrying pigment (haemoglobin) in the blood is below normal due to decreased number of red blood cells, symptoms includes tiredness, headaches, being short of breath when exercising, dizziness and looking pale (anaemia)
- abdominal pain, diarrhea (loose stools), indigestion, stomach discomfort vomiting; loss of taste, dry mouth, flatulence
- joint pain, muscle tenderness, back pain, cramps in the legs or leg pain;
- anxiety, depression, difficulty sleeping;
- fainting drowsiness, abnormal vision, dizziness;
- changes in the heart-rate, low blood pressure, shortness of breath
- increased sweating, skin rashes and itching, hives, severe drug rash, redness of the skin (erythema)
- sore tendons, weakness.

Effect on laboratory tests

There may be changes in the results of certain laboratory tests.

- high potassium levels in the blood (hyperkalaemia)
- Increase in some white blood cells (eosinophilia)
- abnormal liver function or enzyme levels/liver problem, increased hepatic enzymes or creatine phosphokinase in the blood
- decreased haemoglobin level in blood
- increased level of creatinine in the blood
- increased levels of uric acid

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 TELGEN®.

5. How to store TELGEN®

Store at or below 25 °C in the original package, protected from light and moisture. Do not remove the blister strips from the carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not store in bathrooms in order to protect from moisture.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems e.g. toilets.

6. Contents of the pack and other information

What TELGEN® contains

TELGEN® 40

The active substance is telmisartan 40 mg

Contains sugar: sorbitol 174,64 mg per tablet.

Contain sodium hydroxide 3,36 mg per tablet.

TELGEN® 80

The active substance is telmisartan 80 mg

Contains sugar: sorbitol 349,28 mg per tablet.

Contains sodium hydroxide 6,72 mg per tablet.

TELGEN® also contains the following inactive ingredients:

Magnesium stearate, meglumine, povidone, sodium hydroxide and sorbitol.

Carton contains 30 tablets packed in desiccant embedded silver cold form blisters or silver cold form blisters of 10 tablets each.

What TELGEN® looks like and contents of the pack

TELGEN® 40

Off white to light yellow coloured, oblong tablets, debossed with **'T12'** on one side and plain on other side.

TELGEN® 80

Off white to light yellow coloured, oblong tablets, debossed with **'T13'** on one side and

plain on other side.

Holder of Certificate of Registration

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PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS S3

TELGEN 40 Tablette

TELGEN 80 Tablette

Telmisartan

Bevat suiker (Sorbitol)

TELGEN 40: sorbitol (174,64 mg/tablet)

TELGEN 80: sorbitol (349,28 mg/tablet)

Lees die hele pasiëntinligtingstuk noukeurig deur voordat jy begin om TELGEN te neem

- Hou hierdie inligtingstuk. Dit mag vir jou nodig wees om dit weer te lees.
- Vra asseblief jou dokter, apteker, verpleegster of ander verskaffer van gesondheidsorg as jy verdere vrae het.
- TELGEN is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met ander persone deel nie. Dit mag hulle benadeel, selfs as hulle simptome dieselfde is as joune.

Wat is in hierdie pasiëntinligtingstuk

1. Wat TELGEN is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy TELGEN gebruik
3. Hoe om TELGEN te gebruik
4. Moontlike newe-effekte
5. Hoe om TELGEN te bewaar
6. Inhoud van die verpakking en ander inligting

1. Wat TELGEN is en waaroor dit gebruik word

TELGEN bevat telmisartan.

Telmisartan in **TELGEN** behoort aan 'n groep medisyne wat vaskulêre medisyne (ander hipotensiewe middels) genoem word, wat gebruik word vir die behandeling van hoë bloeddruk. Dit is ook bekend as essensiële hipertensie.

TELGEN word gebruik om kardiovaskulêre gebeure (d.w.s. hartaanval of beroerte) sterftes te verminder by pasiënte 55 jaar of ouer wat 'n hoë risiko van kardiovaskulêre siekte het; die voordeel van behandeling is duidelik na ten minste 6 maande van voortgesette behandeling.

2. Wat jy moet weet voordat jy TELGEN neem

Moenie TELGEN (telmisartan) neem as jy swanger is, dit oorweeg om swanger te raak of borsvoed nie. Daar moet oorgeskakel word na 'n geskikte alternatiewe behandeling voor die beplande swangerskap.

Moenie TELGEN neem nie:

- as jy allergies vir telmisartan is, of vir enige van die ander bestanddele van TELGEN.
- as jy voorheen met ‘n middel in dieselfde groep van middels as TELGEN (angiotensien-reseptor antagoniste), of met ‘n middel in die groep van medisyne wat bekend staan as AOE-inhibeerders, behandel is en ‘n allergiese reaksie gehad het met swelling van die gesig, lippe, tong, en of keel met probleme om te sluk of asem te haal.
- as jy aan oorerflike angio-edeem ly, óf van onbekende óf spontane oorsaak (swelling van die gesig, lippe, tong, en of keel met probleme om te sluk of asem te haal).

- as jy obstruksie het van die uitvloei vanuit die hart se bloedvate (uitvloei vanuit die linker ventrikel).
- as jy ernstige belemmering van nierfunksie het.
- as jy vernouing van die bloedvate van die nier aan beide kante het.
- as jy vernouing van die bloedvate van die nier het as jy net een nier het.
- as jy vernouing van die aortiese bloedvat het.
- as jy TELGEN neem saam met kaliumbesparende diuretika soos **s**pironolaktoon, triamtereen, amiloried.
- as jy ‘n rare bloedpigment oorerflike toestand het wat porfirie genoem word.
- as jy TELGEN saam met litium neem, aangesien dit mag lei tot toksiese konsentrasies van litium in die bloed.
- swangerskap en borsvoeding (sien **Swangerskap en Borsvoeding**).
- as jy ernstige lewersiekte of galversperring het ('n probleem met die dreinering van die gal vanuit die galblaas).
- as jy 'n seldsame oorerflike toestand het wat sorbitolintoleransie genoem word.
- as jy tans produkte wat aliskiren bevat, gebruik.
- as jy fluorokinolone gebruik (‘n soort medisyne wat gebruik word om infeksies te behandel).

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met TELGEN:

- as jy aan ‘n niersiekte ly of ‘n nieroorplanting gehad het
- as jy aan lewerprobleme ly
- as jy hartprobleme het
- jou liggaam ‘n souttekort het as gevolg van ‘n lae soutdieet, of as jy onlangs ‘n klomp liggaamsvloeistowwe verloor het as gevolg van die neem van sterk diuretiese middels (watertablette), braking of diaree (los stoelgange).

- as jy hoë kaliumvlakke in jou bloed het of soutvervangers gebruik wat kalium bevat
- as jy voorheen ingelig is dat jy verhoogde aldosteroonvlakke het (water- en soutretensie in die liggaam, tesame met die wanbalans van verskillende bloedminerale).
- as jy suikersiekte het (te veel suiker in die bloed), simptome sluit in oormatige dors, verhoogde eetlus met gewigsverlies en passering van groot hoeveelhede urine en / of bejaard is (> 70 jaar).

TELGEN kan minder effektief wees om bloeddruk by swart pasiënte te verlaag.

As jy medisyne gebruik vir die behandeling van hoë bloeddruk ('n AOE-remmer soos enalapril, lisinopril, ramipril); of fluorokinolone (soort medisyne wat gebruik word vir die behandeling van infeksie soos siprofloksasien, levofloksasien).

Jou dokter kan jou nierfunksie met gereelde tussenposes kontroleer.

Ander medisyne en TELGEN:

Lig jou gesondheidsorgverskaffer altyd in as jy ander medisyne gebruik. (Dit sluit aanvullende of tradisionele medisyne in.)

Jou dokter moet moontlik die dosis van hierdie ander medisyne verander of ander voorsorgmaatreëls tref. In sommige gevalle sal jy miskien moet ophou om een van die medisyne te gebruik.

Dit geld veral vir die onderstaande medisyne wat terselfdertyd as TELGEN geneem word:

- Litiumbevattende medisyne om sommige soorte depressie te behandel.
- Medisyne wat die kaliumvlakke in die bloed kan verhoog:
    - soutvervangers wat kalium bevat;
    - kaliumbesparende diuretika (sekere 'watertablette');
    - AOE-remmers (word gebruik om hoë bloeddruk te behandel, bv. enalapril, lisinopril, ramipril);

- angiotensien II-reseptorantagoniste (gebruik vir die behandeling van hoë bloeddruk, bv. valsartan, losartan);
- NSAIMs (nie-steroïdale anti-inflammatoriese medisyne, bv. aspirien of ibuprofeen);
- heparien (gebruik om bloed te verdun)
- immuunonderdrukkers (word gebruik om orgaanverwerping te voorkom, bv. siklosporien of takrolimus);
- antibiotiese trimetoprim (word gebruik om infeksie te behandel)
- fluorokinolone (soort medisyne wat gebruik word vir die behandeling van infeksie, bv. siprofloksasien, levofloksasien, moksifloksasien);

- Diuretika ('watertablette'), veral as dit saam met TELGEN in hoë dosisse geneem word, kan lei tot oormatige verlies aan liggaamsvloeistof en lae bloeddruk (hipotensie);
- Alskiren (word gebruik om hoë bloeddruk te behandel);
- Medisyne vir hartprobleme, hoë bloeddruk waarvan jou dokter nie weet nie (bv. digoksien).

Die effek van TELGEN kan verminder word as jy NSAIMs (nie-steroïdale anti-inflammatoriese medisyne, bv. aspirien of ibuprofeen) of kortikosteroïede gebruik (wat gebruik word om ontsteking te verlig).

TELGEN kan die bloeddrukverlagende effek verhoog van ander medisyne wat gebruik word vir die behandeling van hoë bloeddruk of van medisyne met bloeddrukverlagende potensiaal (bv. baklofen, amifostien). Verder kan lae bloeddruk vererger word deur alkohol, barbiturate, verdowingsmiddels of antidepressante. Jy kan dit waarneem as duiseligheid wanneer jy opstaan. Jy moet jou dokter raadpleeg as jy die dosis van jou ander medisyne moet aanpas terwyl jy TELGEN gebruik.

Swangerskap en Borsvoeding:

As jy swanger is of borsvoed, dink dat jy swanger is of van plan is om 'n baba te kry, raadpleeg jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy hierdie medisyne gebruik.

Moenie TELGEN neem as jy swanger is of borsvoed nie. As jy swanger raak terwyl jy TELGEN neem, moet jy dit onmiddellik staak en jou dokter inlig. Vrouens moet dit vermy om swanger te raak terwyl hulle TELGEN neem deur geskikte voorbehoeding te gebruik. TELGEN kan toksisiteit in die embrio, fetale en neonatale sterftes veroorsaak as dit aan swanger vrouens gegee word. Vrouens van kinderbarende ouderdom moet doeltreffende voorbehoeding gebruik.

Vra jou dokter of apteker vir advies voordat jy enige medisyne neem.

Bestuur en gebruik van masjiene:

Wanneer voertuie bestuur word of masjiene hanteer word, moet dit in gedagte gehou word dat duiseligheid of lomerigheid soms kan voorkom as bloeddrukverlagende medisyne, insluitend **TELGEN,** geneem word.

TELGEN bevat sorbitol:

TELGEN tablette bevat sorbitol. As aan jou gesê is dat jy sommige suikers nie kan verdra nie, moet jy nie TELGEN neem nie.

3. Hoe om TELGEN te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem TELGEN tablette altyd presies soos jou dokter jou beveel het. As jy nie seker is nie, moet jy dit met jou dokter of apteker bespreek.

As jy onder die indruk is dat TELGEN te sterk of te swak is, praat dan met jou dokter of apteker.

TELGEN tablette is slegs vir volwassenes en moenie deur kinders en adolessente tot op 18-jarige ouderdom geneem word nie.

TELGEN word gewoonlik as ‘n dosis van een 40 mg of 80 mg tablet een keer per dag geneem, verkieslik op dieselfde tyd elke dag, en met water ingesluk.

Jou dokter mag TELGEN in kombinasie met ander bloeddrukverlagende middels voorskryf.

As jy meer TELGEN geneem het as wat jy behoort te neem:

Raadpleeg jou dokter of apteker in die geval van oordosering of by toevallige inname.

Indien nie een van hulle beskikbaar is nie, soek hulp by die naaste hospitaal of gifbeheersentrum.

As jy vergeet het om TELGEN te neem

As jy ‘n dosis TELGEN oorgeslaan het, neem dit op dieselfde dag so gou as wat jy onthou. As jy nie jou tablet op dieselfde dag neem nie, neem die gewone dosis op die volgende dag. Moenie ‘n dubbele dosis neem om te vergoed vir die individuele dosisse wat jy vergeet het nie.

4. Moontlike newe-effekte

TELGEN kan newe-effekte hê.

Nie alle newe-effekte wat vir TELGEN aangemeld word, is in hierdie inligtingstuk ingesluit nie. Raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgdeskundige vir advies indien jou algemene gesondheid versleg terwyl jy TELGEN neem.

Indien enige van die volgende gebeur, staak die gebruik van TELGEN en lig jou dokter onmiddellik in of gaan na die noodgevalle afdeling by jou naaste hospitaal:

- skielike allergiese reaksie insluitend tekens soos uitslag, jeuk of plaaslike jeukende verhewendheid van die vel, swelling van die gesig, lippe, tong of ander liggaamsdele, kortasemigheid of asemhalingsprobleme (anafilaktiese reaksie)
- swelling van die hande, voete, enkels, gesig, lippe, mond, of keel wat probleme om te sluk of asem te haal kan veroorsaak (angio-edeem)
- sepsis (dikwels "bloedvergiftiging" genoem) is 'n ernstige infeksie met inflammatoriese reaksie van die hele liggaam wat tot die dood kan lei)
- allergiese reaksie.

Hierdie is almal baie ernstige newe-effekte. As jy dit het, kon jy ‘n ernstige allergiese reaksie teenoor TELGEN gehad het. Jy mag dringende mediese aandag of hospitalisasie benodig.

Lig jou dokter dadelik in of gaan na die noodgevalle afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- urienweginfeksie (insluitend blaasontsteking)
- boonste lugweginfeksie (bv. seerkeel of gespanne gevoel of volgevoel in die neus)
- makliker as gewoonlik bloeding of kneusing as gevolg van lae bloedplaatjie-telling (trombositopenie)
- duiseligheid as jy opstaan, veral as jy uit 'n sittende of lêende posisie opstaan (ortostatiese hipotensie)
- progressiewe littekens van longweefsel (interstisiële longsiekte)

- veluitslag met ontsteking van die vel, wat gekenmerk word deur jeuk en uitslag en dikwels blase insluit wat drup en ‘n kors vorm (ekseem)
- griepagtige simptome, soos hoë koors, seerkeel, loopneus, hoes en kouekoors (griepagtige simptome)
- lae bloedsuikervlakke (by diabetiese pasiënte)
- nierprobleme, insluitend simptome soos min of geen urine, lomerigheid, naarheid, braking, uitasemigheid.

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese hulp benodig.

Lig jou dokter in as jy enige van die volgende opmerk:

Dikwels:

- hoes

Minder dikwels:

- borspyn
- ‘n Toestand waarin die hoeveelheid suurstofdraende pigment (hemoglobien) in die bloed laer as normaal is as gevolg van die verminderde aantal rooibloedselle. Simptome sluit moegheid, hoofpyn, kortasemigheid tydens oefening, duiseligheid en bleekheid (bloedarmoede) in
- buikpyn, diaree (los stoelgang), slegte spysvertering, braking, maagongemak, smaakverlies, droë mond, winderigheid
- gewrigspyn, spiergevoeligheid, rugpyn, krampe in die bene of beenpyn
- angs, depressie, sukkel om te slaap
- flouheid, lomerigheid, abnormale sig, duiseligheid
- veranderinge in die hartklop, lae bloeddruk, kortasemigheid
- verhoogde sweet, veluitslag en jeuk, plaaslike jeukende verhewendheid van die vel, erge geneesmiddel-uitslag, rooiheid van die vel (eriteem)
- seer tendons, swakheid.

Effek op laboratoriumtoetse

Die resultate van sekere laboratoriumtoetse kan verander.

- hoë kaliumvlakke in die bloed (hiperkalemie)
- toename in sommige witbloedselle (eosinofilie)
- abnormale lewerfunksie of ensiemvlakke / lewerprobleem, verhoogde lewerensieme of kreatienfosfokinase in die bloed
- verlaagde hemoglobienvlak in bloed
- verhoogde vlak van kreatinien in die bloed
- verhoogde vlakke van uriensuur.

As jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, moet jy jou dokter of apteker daarvan in kennis stel.

Aanmelding van newe-effekte

As jy newe-effekte ervaar, moet jy jou dokter, apteker of verpleegster inlig.

Jy kan ook newe-effekte aan SAHPRA rapporteer via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn beskikbaar is onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van TELGEN te verskaf.

5. Hoe om TELGEN te bewaar

Bewaar by of onder 25 °C in die oorspronklike verpakking, beskerm teen lig en vog.

Moenie die stulpstroke uit die karton verwyder tot benodig vir gebruik nie.

BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

Moenie in badkamers bewaar nie ten einde teen vog te beskerm.

Moenie ná die vervaldatum soos op die etiket aangebring, gebruik nie.

Bring alle ongebruikte medisyne terug na jou apteker toe.

Moenie van ongebruikte medisyne in dreinering- of rioleringstelsels, bv. toilette, ontslae raak nie.

6. Inhoud van die verpakking en ander inligting

Wat TELGEN bevat

TELGEN 40

Die aktiewe bestanddeel is telmisartan 40 mg.

Bevat suiker: soritol 174,64 mg per tablet

Bevat natriumhidroksied 3,36 mg per tablet.

TELGEN 80

Die aktiewe bestanddeel is telmisartan 80 mg.

Bevat suiker: soritol 349,28 mg per tablet

Bevat natriumhidroksied 6,72 mg per tablet.

TELGEN bevat ook die volgende onaktiewe bestanddele:

Magnesiumstearaat, meglumien, povidoon, natriumhidroksied en sorbitol.

Karton bevat 30 tablette verpak in droogmiddelingelegde silwer kouevorm stulpstroke of silwer kouevorm stulpstroke van 10 tablette elk.

Hoe TELGEN lyk en die inhoud van die verpakking:

TELGEN 40

Naaswit tot liggeel gekleurde, langwerpige tablette, gepers met ‘T12’ op een kant en skoon op die ander kant.

TELGEN 80

Naaswit tot liggeel gekleurde, langwerpige tablette, gepers met ‘T13’ op een kant en skoon op die ander kant.

Houer van die Registrasiesertifikaat

RANBAXY SA (Pty) Ltd (‘n Sun Pharma maatskappy)

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Hierdie inligtingstuk is laas hersien op

Datum van registrasie: 10 Oktober 2013

Datum van vorige goedkeuring: 20 Maart 2024

Registrasienommers

TELGEN 40: 45/7.1.3/0610

TELGEN 80: 45/7.1.3/0611

Namibië: NS2 Telgen 40: Reg nr.: 14/7.1.3/0002
Telgen 80: Reg nr.: 14/7.1.3/0001