APPROVED PATIENT INFORMATION – MICARDIS

PATIENT INFORMATION LEAFLET_____

SCHEDULING STATUS: S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Micardis® 40 mg & 80 mg tablets **ABCD**

Telmisartan

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- MICARDIS 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.

1. WHAT MICARDIS TABLETS CONTAIN

The active ingredient is TELMISARTAN 40 mg or 80 mg per tablet.
The other ingredients are magnesium stearate, meglumine, povidone, sodium hydroxide and sorbitol.
Contains sugar (sorbitol).

2. WHAT MICARDIS IS USED FOR

MICARDIS tablets are used for the treatment of high blood pressure. This is also known as essential hypertension.

MICARDIS tablets can also be used to reduce cardiovascular events and 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.

3. BEFORE YOU TAKE MICARDIS TABLETS

Do not take MICARDIS if you are pregnant, are considering becoming pregnant or are breast-feeding. A switch to a suitable alternative treatment should be carried out in advance of planned pregnancy.

Do not take MICARDIS if you:

- are allergic to telmisartan or any of the other ingredients in the tablets
- suffer from the rare hereditary condition called fructose intolerance
- 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
- suffer from severe liver disease or biliary obstruction (a problem with the drainage of the bile from the gall bladder)
- suffer from obstruction of blood vessels to your heart or kidneys
- suffer from severe kidney function impairment
- suffer from porphyria
- are currently taking lithium
- are currently taking potassium sparing water tablets containing spironolactone, triamterene or amiloride
- are currently taking aliskiren-containing products

Take special care with MICARDIS and tell your doctor if you:

- suffer from kidney disease or have had a kidney transplant
- suffer from liver problems
- have heart problems
- 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
- have high potassium levels in your blood or use salt substitutes containing potassium
- have been told previously that you have raised aldosterone levels
- 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.

Pregnancy and breastfeeding:
Do not take MICARDIS 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 your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery:
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 MICARDIS.

Important information about some of the ingredients of MICARDIS:
Sorbitol is not suitable for patients with hereditary fructose intolerance.

Taking other medicines with MICARDIS:
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

MICARDIS can interfere with some other medicines such as digoxin, lithium, ACE-inhibitors and non-steroidal anti-inflammatory medicines (NSAIDs) like aspirin.

4. HOW TO TAKE MICARDIS

- Do not share medicines prescribed for you with any other person.
- Always take MICARDIS tablets exactly as your doctor has instructed you. Do not take more or less tablets and do not take them more often than

recommended. You should check with your doctor or pharmacist if you are unsure.

- If you have the impression that MICARDIS is too strong or too weak, talk to your doctor or pharmacist. Do not stop taking MICARDIS without first talking to your doctor.
- MICARDIS tablets are only for adults and should not be taken by children and adolescents up to 18 years.

For high blood pressure:

MICARDIS 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 MICARDIS in combination with other blood pressure lowering medicines.

To reduce cardiovascular events and death in patients 55 years or older who are at high risk of cardiovascular disease:

MICARDIS is usually taken in a dose of one 80 mg tablet once daily (preferably at about the same time each day) and swallowed with a drink of water.

When initiating treatment, your doctor may wish to monitor your blood pressure and, if appropriate, adjust your blood pressure lowering medicines.

If you take more MICARDIS than you should:

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

If you forget to take MICARDIS:

If you miss a dose of this medicine, 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.

5. POSSIBLE SIDE EFFECTS

MICARDIS tablets can have side effects.

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

Less frequent:

- anaphylactic reaction (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)
- eczema, facial swelling, severe allergic reactions of the skin (with possible fatal outcome)

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

Frequent:

- changes in the heart-rate, low blood pressure, shortness of breath
- faintness, dizziness for example when standing up quickly
- you pass less urine than is normal for you and you notice that your feet are swollen
- elevated blood potassium levels
- urinary tract infections (including inflammation of the bladder), upper respiratory tract infections (e.g. sore throat or sinusitis)
- anaemia and other changes to the blood chemistry
- back pain, muscle tenderness, cramps in the legs, chest pain, weakness

Less frequent:

- blood poisoning
- low blood sugar in diabetic patients
- liver or kidney problems
- influenza-like symptoms

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

Tell your doctor if you notice any of the following:

Frequent:

- feeling sad (depression), difficulty sleeping
- abdominal pain, loose/runny stools, indigestion, flatulence, vomiting
- cough

Less frequent:

- increased sweating, skin rashes and itching
- abnormal vision
- joint pain, leg pain
- sore tendons
- stomach upset, dry mouth
- anxiety
- hives (itchy rash)
- hypersensitivity (allergy)

Not all side effects reported for MICARDIS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MICARDIS, please consult your doctor, pharmacist, or other healthcare professional for advice.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF MICARDIS

Store MICARDIS tablets in a cool place (at or below 30 °C). The tablets should be kept in the original blister foil until required for administration in order to protect them from moisture.

Store all medicines out of reach of children.

Do not take this medicine after the expiry date stated on the blister strips and carton. Return unused or expired medicines to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF MICARDIS

Carton containing 28 tablets packed in aluminium blister strips of 7 tablets per strip.

8. IDENTIFICATION OF MICARDIS

MICARDIS 40 mg: White to off-white, oblong tablets; one face marked with 51H and the other with the Boehringer Company symbol.
MICARDIS 80 mg: White to off-white, oblong tablets; one face marked with 52H and the other with the Boehringer Company symbol.

9. REGISTRATION NUMBERS

MICARDIS 40 mg tablets : 33/7.1.3/0020
MICARDIS 80 mg tablets : 33/7.1.3/0021

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Date of registration: 20 August 1999
Revised: 20 August 2019

INLIGTINGSBLAD VIR
PASIËNTE_____

SKEDULERINGSTATUS S3

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM

Micardis® 40 mg & 80 mg tablette **ABCD**

Telmisartan

Lees die hele pamflet deeglik deur voordat jy MICARDIS neem.

- Hou hierdie pamflet. Dit is moontlik dat jy dit weer sal wil deurlees.
- Indien jy verdere vrae het, raadpleeg asseblief jou dokter of apteker.
- MICARDIS is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.

1. WAT MICARDIS-TABLETTE BEVAT

Die aktiewe bestanddeel is TELMISARTAN 40 mg of 80 mg per tablet.
Die ander bestanddele is magnesiumstearaat, meglumien, povidoon, natriumhidroksied en sorbitol.
Bevat suiker (sorbitol).

2. WAARVOOR MICARDIS GEBRUIK WORD

MICARDIS tablette word gebruik vir die behandeling van hoë bloeddruk. Dit staan ook bekend as essensiële hipertensie.

MICARDIS tablette kan ook gebruik word om hartaanvalle en sterftes te verminder by pasiënte van 55 jaar of ouer met 'n hoë risiko vir kardiovaskulêre siektes. Die voordeel van die behandeling is duidelik na 6 maande van onafgebroke behandeling.

3. VOORDAT JY MICARDIS TABLETTE NEEM

Moet nie MICARDIS 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.

Moet nie MICARDIS neem nie as jy:

- allergies is vir telmisartan, of enige ander bestanddeel in die tablette
- ly aan die seldsame oorerflike toestand bekend as fruktose-onverdraagsaamheid
- voorheen met medisyne, bekend as angiotensien-omskakelingsensiem (AOE) inhibeerders of angiotensien-reseptorblokkeerders (ARBs) swelling van die gesig, lippe, mond, tong of keel en reuse galbulte op jou vel ontwikkel het - jy moet nooit weer hierdie medisyne neem nie
- ly aan ernstige lewersiekte of galwegobstruksie ('n probleem met die dreinering van gal uit die galblaas)
- obstruksie van die bloedvate na jou hart of niere het
- ly aan ernstige belemmerde nierfunksie
- ly aan porfirie
- tans litium neem
- tans kaliumsparende "water"-tablette neem wat spironolaktoon, triamtereen of amiloried bevat
- tans medisyne neem wat aliskiren bevat.

Neem spesiale sorg met MICARDIS en vertel vir jou dokter indien jy:

- ly aan niersiekte of 'n nieroorplanting gehad het
- ly aan lewermoeilikheid
- hartprobleme het
- dalk te min soute in jou liggaam hetm as gevolg van 'n lae-sout dieet, of as jy onlangs baie van jou liggaamsvloeistof verloor het as gevolg van diuretiese medisyne ("water"-tablette), braking of diaree
- hoë kaliumvlakke in jou bloed het, of as jy kaliumbevattende soutvervangers gebruik
- voorheen ingelig is dat jou aldosteroonvlakke te hoog is
- reeds 'n medisyne neem wat bekend staan as 'n angiotensien-omskakelingsensiem (AOE) inhibeerder

- Kontak jou dokter om jou behandling te herevalueer indien jy behandel word met Angiotensien-omskakelingsensiem (AOE) inhibeerders/Angiotensien reseptor blokkeerders (ARBs) tesame met 'n fluorokinoloon antibiotika.

Swangerskap en borsvoeding:

Moet nie MICARDIS neem as jy swanger is, oorweeg om swanger te raak of as jy borsvoed nie.

Indien jy 'n vrou in die ouderdomsgroep vir swangerskap is moet jy doeltreffende voorbehoeding gebruik.

Indien jy swanger is, of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgkundige om advies voordat jy hierdie medisyne gebruik.

Bestuur en gebruik van masjinerie:

Wanneer voertuie bestuur of masjinerie gebruik word moet daar in gedagte gehou word dat duiseligheid en lomerigheid soms kan voorkom met bloeddrukverlagende medisyne, insluitend MICARDIS.

Belangrike inligting oor sommige van die bestanddele van MICARDIS:

Sorbitol is nie geskik vir pasiënte met oorerflike fruktose-onverdraagsaamheid nie.

Inname van ander medisyne met MICARDIS:

Lig altyd jou gesondheidsorgkundige in as jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

MICARDIS tablette kan inwerk op sekere ander medisynes, soos digoksien, litium, AOE-inhibeerders'n en nie-steroïed anti-inflammatoriese middels (NSAIMs) soos aspirien.

4. HOE OM MICARDIS TE NEEM

- Moet nie medisyne wat vir jou voorgeskryf is met ander mense deel nie.

- Neem MICARDIS tablette altyd presies soos jou dokter dit vir jou voorgeskryf het. Moet nie meer of minder tablette neem nie en moet dit nie meer dikwels neem as wat aanbeveel word nie. As jy onseker is, vra jou dokter of apteker.
- Indien jy die indruk kry dat die effek van MICARDIS te sterk of te swak is, lig jou dokter of apteker in. Moet nie ophou om MICARDIS te neem sonder dat jy eers met jou dokter gepraat het nie.
- MICARDIS tablette is slegs vir volwassenes en moet nie deur kinders en adolessente jonger as 18 jaar geneem word nie.

Vir hoë bloeddruk:

Die gewone dosis van MICARDIS is een 40 mg of 80 mg tablet een keer daagliks (verkieslik op dieselfde tyd elke dag) en gesluk met water.
Jou dokter kan MICARDIS in kombinasie met ander bloeddrukverlagende medisyne voorskryf.

Om hartaanvalle en sterftes te verminder by pasiënte 55 jaar of ouer met 'n hoë risiko vir kardiovaskulêre siektes:

MICARDIS word gewoonlik geneem as 'n dosis van een 80 mg tablet een keer daagliks (verkieslik op dieselfde tyd elke dag) en gesluk met water.

Wanneer die behandeling begin, sal jou dokter moontlik jou bloeddruk wil kontroleer en, indien toepaslik, jou bloeddrukverlagende medisyne aanpas.

Indien jy meer MICARDIS neem as wat jy moet:

In die geval van 'n oordosering of as dit per ongeluk ingeneem word, raadpleeg jou dokter of apteker. Indien geeneen beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet het om MICARDIS te neem:

Indien jy 'n dosis van hierdie medisyne oorgeslaan het, neem dit sodra jy daarvan onthou, op dieselfde dag. Indien jy nie jou tablet op dieselfde dag neem nie, moet jy jou normale dosis die volgende dag volg. Moet nie die dosis verdubbel om op te maak vir vergete individuele dosisse nie.

5. MOONTLIKE NEWE-EFFEKTE

MICARDIS tablette kan newe-effekte hê.

Indien enige van die volgende gebeur, staak MICARDIS en vertel jou dokter dadelik daarvan, of gaan na die ongevalle-afdeling by jou naaste hospitaal:

Minder dikwels:

- anafilaktiese reaksie ('n skielike allergiese reaksie, wat tekens kan insluit soos 'n veluitslag, jeuk of bort op die vel, swelling van die gesig, lippe, tong of ander dele van die liggaam, kortasem of probleme met asemhaling)
- ekseem, geswelde gesig, ernstige allergiese reaksies op die vel (met 'n moontlik noodlottige gevolg)

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

Lig jou dokter dadelik in as jy enige van die volgende tekens waarneem, of gaan na die ongevalleafdeling by jou naaste hospitaal:

Dikwels:

- veranderinge in die tempo van die hartklop, lae bloeddruk, kortasem
- swakheid, duiseligheid - byvoorbeeld as jy vinnig opstaan
- jy minder urien passeer as gewoonlik en jy agterkom dat jou voete geswel is
- verhoogde kaliumvlakke in jou bloed
- urienweginfeksies (insluitend inflammasie in die blaas), boonste lugweginfeksies (bv. 'n seer keel of sinusitis)
- anemie en ander veranderinge in die bloedchemie
- rugpyn, teer spiere, krampe in die bene, borspyn, swakheid

Minder dikwels:

- bloedvergiftiging
- lae bloedsuiker by diabetiese pasiënte
- lewer- of niermoeilikheid
- griepagtige simptome

Al hierdie newe-effekte is ernstig. Jy mag dringende mediese aandag benodig.

Sê vir jou dokter as jy enige van die volgende waarneem:

Dikwels:

- hartseer gevoel (depressie), sukkel om aan die slaap te raak
- buikpyn, los/loperige stoelgange, slegte spysvertering, winderigheid, braking
- hoes

Minder dikwels:

- verhoogde sweetafskeiding, veluitslag en jeuk
- abnormale visie
- gewrigspyn, beenpyn
- seer tendons
- omgekrapte maag, droë mond
- angs
- bort (jeukerige uitslag)
- hipersensitiwiteit (allergie)

Nie alle newe-effekte wat vir MICARDIS aangemeld is, word in hierdie inligtingsblad genoem nie. Indien jou algemene gesondheid verswak of jy enige ongunstige effek ervaar terwyl jy MICARDIS neem, moet jy asseblief jou dokter, apteker of ander gesondheidsorgkundige raadpleeg.
Indien jy enige newe-effekte waarneem wat nie in hierdie pamflet vermeld word nie, lig asseblief jou dokter of apteker in.

6. BERGING EN WEGDOENING VAN MICARDIS

Bewaar MICARDIS tablette op 'n droë, koel plek (teen of benede 30 ˚C). Die tablette moet in die oorspronklike foelie stolpverpakking gehou word totdat dit benodig word, om dit teen vog te beskerm.

Bêre alle medisyne buite bereik van kinders.

Moet nie hierdie medisyne na die vervaldatum wat op die stolpstrokies en kartonhouer verskyn, neem nie. Neem ongebruikte medisyne na jou apteker terug vir die veilige wegdoen daarvan. Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

7. AANBIEDING VAN MICARDIS

'n Kartonhouer met 28 tablette, verpak in aluminium stolpstroke met 7 tablette per strokie.

8. IDENTIFIKASIE VAN MICARDIS

MICARDIS 40 mg: Wit tot effewit, langwerpige tablette; een kant gemerk met 51H en die ander kant met die Boehringer maatskappysimbool.

MICARDIS 80 mg: Wit tot effewit, langwerpige tablette; een kant gemerk met 52H en die ander kant met die Boehringer maatskappysimbool.

9. REGISTRASIENOMMERS

MICARDIS 40 mg tablette: 33/7.1.3/0020

MICARDIS 40 mg tablette: 33/7.1.3/0021

10. NAAM, BESIGHEIDSADRES EN TELEFOONNOMMER VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

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11. DATUM VAN PUBLIKASIE VAN HIERDIE PASIËNTINLIGTINGSBLAD

20 Augustus 2019