MICARDIS®
Telmisartan

DESCRIPTION

MICARDIS 40 MG
White or off-white, oblong tablets; one face marked with 51H, the other with the Boehringer Company symbol.

MICARDIS 80 MG
White or off-white, oblong tablets; one face impressed with "52H"; the other face impressed with the Company symbol

COMPOSITION

1 tablet contains 40 or 80 mg
[1,1'-biphenyl]-2-carboxylic acid, 4'-(1,4'dimethyl-2'-propyl[2,6-bi-1H-benzimidazole]-1'-yl)methyl]
(= telmisartan)

Excipients: * povidone, meglumine, sodium hydroxide, sorbitol, magnesium stearate

Sodium	MICARDIS tablets 40 mg contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Sodium	MICARDIS tablets 80 mg contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

INDICATIONS

Treatment of essential hypertension in adults

DOSAGE AND ADMINISTRATION

The recommended dose is 40 mg once daily. Some patients may already benefit at a daily dose of 20 mg. In cases where the target blood pressure is not achieved, telmisartan dose can be increased to a maximum of 80 mg once daily. When considering raising the dose, it must be borne in mind that the maximum antihypertensive effect is generally attained four to eight weeks after the start of treatment. Alternatively, telmisartan may be used in combination with thiazide-type diuretics such as hydrochlorothiazide or calcium-channel-blockers such as amlodipine, which have been shown to have an additive blood pressure lowering effect with telmisartan.

Special populations

Geriatric patients
No dose adjustment is necessary for geriatric patients.

Paediatric patients
The safety and efficacy of MICARDIS for use in patients aged below 18 years have not been established.

Renal impairment
No posology adjustment is required for patients with renal impairment, including those on haemodialysis.
Telmisartan is not removed from blood by hemofiltration and is not dialyzable.

Hepatic impairment
In patients with mild to moderate hepatic impairment MICARDIS should be administered with caution For telmisartan, the posology should not exceed 40 mg once daily (see Contraindications).

Method of Administration

MICARDIS tablets are for once-daily oral administration and should be swallowed whole with liquid. MICARDIS can be taken with or without food.

HANDLING INSTRUCTIONS

Due to the hygroscopic property of the tablets, they should be taken out of the sealed blister shortly before administration.

CONTRAINDICATIONS

- Hypersensitivity to the active substance or to any of the excipients
- Second and third trimesters of pregnancy
- Lactation
- Biliary obstructive disorders
- Severe hepatic impairment
- The concomitant use of telmisartan with aliskiren is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m^2)

In case of rare hereditary conditions that may be incompatible with an excipient of the product (please refer to "Special warnings and precautions") the use of the product is contraindicated.

SPECIAL WARNINGS AND PRECAUTIONS

Pregnancy

Angiotensin II receptor blockers should not be initiated during pregnancy.
Unless continued angiotensin II receptor blocker therapy is considered essential, patients planning pregnancy should be changed to alternative anti-hypertensive treatments which have an established safety profile for use in pregnancy.
When pregnancy is diagnosed, treatment with angiotensin II receptor blockers should be stopped immediately, and if appropriate, alternative therapy should be started.

Hyperkalaemia

During treatment with medicinal products that affect the renin-angiotensin-aldosterone system hyperkalaemia may occur, especially in the presence of renal impairment and/or heart failure. Monitoring of serum potassium in patients at risk is recommended.
Based on experience with the use of medicinal products that affect the renin-angiotensin system, concomitant use with potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium or other medicinal products that may increase the potassium level (heparin, etc.) may lead to an increase in serum potassium and should therefore be co-administered cautiously with telmisartan.

Volume and/or sodium-depleted patients

Symptomatic hypotension, especially after the first dose, may occur in patients who are volume and/or sodium depleted by e.g. vigorous diuretic therapy, dietary salt restriction, diarrhoea or vomiting. Such conditions, especially volume and/or sodium depletion, should be corrected before the administration of telmisartan.

Hepatic impairment:

Telmisartan is mostly eliminated in the bile. Patients with biliary obstructive disorders or hepatic insufficiency can be expected to have reduced clearance. MICARDIS should be used with caution in these patients.

Renovascular hypertension

There is an increased risk of severe hypotension and renal insufficiency when patients with bilateral renal artery stenosis or stenosis of the artery to a single functioning kidney are treated with medicinal products that affect the renin-angiotensin-aldosterone system.

Renal impairment and kidney transplant

When telmisartan is used in patients with impaired renal function, a periodic monitoring of potassium and creatinine serum levels is recommended. There is no experience regarding the administration of telmisartan in patients with a recent kidney transplant.
Telmisartan is not removed from blood by hemofiltration and is not dialyzable.

Dual blockade of the renin-angiotensin-aldosterone system

As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function (including acute renal failure) have been reported in susceptible individuals, especially if combining medicinal products that affect this system. Dual blockade of the renin-angiotensin-aldosterone system (e.g. by adding an ACE-inhibitor or the direct renin-inhibitor aliskiren to an angiotensin II receptor blocker) is not recommended and should therefore be limited to individually defined cases with close monitoring of renal function (see Contraindications).

Other conditions with stimulation of the renin-angiotensin-aldosterone system

In patients whose vascular tone and renal function depend predominantly on the activity of the renin-angiotensin-aldosterone system (e.g. patients with severe congestive heart failure or underlying renal disease, including renal artery stenosis), treatment with medicinal products that affect this system has been associated with acute hypotension, hyperazotaemia, oliguria, or rarely acute renal failure.

Primary aldosteronism

Patients with primary aldosteronism generally will not respond to antihypertensive medicinal products acting through inhibition of the renin-angiotensin system. Therefore, the use of telmisartan is not recommended.

Aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy

As with other vasodilators, special caution is indicated in patients suffering from aortic or mitral stenosis, or obstructive hypertrophic cardiomyopathy.

Sorbitol

MICARDIS tablets 40 mg contains 168.64 mg sorbitol in each tablet.
MICARDIS tablets 80 mg contains 337.28 mg sorbitol in each tablet.
Sorbitol is a source of fructose. MICARDIS tablets 80mg is not recommended for use in patients with hereditary fructose intolerance (HFI).

Diabetes mellitus

In diabetic patients with an additional cardiovascular risk, i.e. patients with diabetes mellitus and coexistent coronary artery disease (CAD), the risk of fatal myocardial infarction and unexpected cardiovascular death may be increased when treated with blood pressure lowering agents such as ARBs or ACE-inhibitors. In patients with diabetes mellitus CAD may be asymptomatic and therefore undiagnosed. Patients with diabetes mellitus should undergo appropriate diagnostic evaluation, e.g. exercise stress testing, to detect and to treat CAD accordingly before initiating treatment with MICARDIS.

Ethnic differences

As observed for angiotensin converting enzyme inhibitors, angiotensin receptor blockers including telmisartan are apparently less effective in lowering blood pressure in black

people than in non-blacks, possibly because of higher prevalence of low-renin states in the black hypertensive population.

Ischaemic heart disease
As with any antihypertensive agent, excessive reduction of blood pressure in patients with ischaemic cardiopathy or ischaemic cardiovascular disease could result in a myocardial infarction or stroke.

Micardis tablets should not be divided into halves as the tablets have no score line and no studies have been performed on halved tablets.

INTERACTIONS

Telmisartan may increase the hypotensive effect of other antihypertensive agents.

Co-administration of telmisartan did not result in a clinically significant interaction with digoxin, warfarin, hydrochlorothiazide, glibenclamide, ibuprofen, paracetamol, simvastatin and amlodipine. For digoxin a 20% increase in median plasma digoxin trough concentration has been observed (39% in a single case), monitoring of plasma digoxin levels should be considered.

In one study the co-administration of telmisartan and ramipril led to an increase of up to 2.5 fold in the AUC0-24 and Cmax of ramipril and ramiprilat. The clinical relevance of this observation is not known.

Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with angiotensin converting enzyme inhibitors.
Cases have also been reported with angiotensin II receptor blockers including telmisartan. Therefore, serum lithium level monitoring is advisable during concomitant use.

Treatment with NSAIDs (i.e. ASA at anti-inflammatory dosage regimens, COX-2 inhibitors and non-selective NSAIDs) is associated with the potential for acute renal insufficiency in patients who are dehydrated. Compounds acting on the Renin-Angiotensin-System like telmisartan may have synergistic effects. Patients receiving NSAIDs and telmisartan should be adequately hydrated and their renal function should be monitored at the beginning of combined treatment.

A reduced effect of antihypertensive drugs like telmisartan by inhibition of vasodilating prostaglandins has been reported during combined treatment with NSAIDs.

As with other medicinal products acting on the renin-angiotensin-aldosterone system, telmisartan may provoke hyperkalaemia. The risk may increase in case of treatment combination with other medicinal products that may also provoke hyperkalaemia (salt substitutes containing potassium, potassium-sparing diuretics

ACE inhibitors, angiotensin II receptor antagonists, non steroidal antiinflammatory medicinal products (NSAIDs, including selective, COX-2 inhibitors), heparin, immunosupressives (cyclosporin or tacrolimus), and trimethoprim).

The occurrence of hyperkalaemia depends on associated risk factors. The risk is increased in case of the above-mentioned treatment combinations. The risk is particularly high in combination with potassium sparing-diuretics, and when combined with salt substitutescontaining potassium. A combination with ACE inhibitors or NSAIDs, for example, presents as lesser risk provided that precautions for use are strictly followed.

Diuretics (thiazide or loop diuretics):
Prior treatment with high dose diuretics such as furosemide (loop diuretic) and hydrochlorothiazide (thiazide diuretic) may result in volume depletion, and in a risk of hypotensin when initiating therapy with telmisartan.

Potassium sparing diuretics or potassium supplements:
Angiotensin II receptor antagonists such as telmisartan, attenuate diuretic induced potassium oss. Potassium sparing diuretics e.g. spironolactone, eplerenone, triamterene, or amiloride, potassium supplements, or potassium-containing salt substitutes may lead to a significant increase in serum potassium. If concomitant use is indicated because of documented hypokalaemia, they should be used with caution and with frequent monitoring of serum potassium.

Corticosteroids (systemic route):
Reduction of the antihypertensive effect.

Pregnancy, Lactation and Fertility

Pregnancy
The use of angiotensin II receptor blockers is not recommended during the first trimester of pregnancy and should not be initiated during pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor blockers should be stopped immediately, and, if appropriate, alternative therapy should be started.
Unless continued angiotensin II receptor blocker therapy is considered essential, patients planning pregnancy should be changed to alternative anti-hypertensive treatments which have an established safety profile for use in pregnancy.
Non-clinical studies with telmisartan do not indicate teratogenic effects, but have shown fetotoxicity.
The use of angiotensin II receptor blockers is contraindicated during the second and third trimester of pregnancy.

When used in pregnancy during the second and third trimerters, drug that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus. When pregnancy is detected, Micardis tablets should be discontinued as soon as possible.

Drug that act directly on the renin-angiotensin system can cause fetal and neonatal morbidity and death when administered to pregnant women. Several dozen cases have been reported in the world literature in patients who were taking angiotensin converting enzyme inhibitors. When pregnancy is detected, Micardis tablets should be discontinued as soon as possible. The use of drug that act directly on the renin-angiotensin system during second and third trimesters of pregnancy has been associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Oligohydramnios has also been reported, presumably resulting from decreased fetal renal fiction: oligohydramnios in this setting has been associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Prematurity, intrauterine growth retardation, and patent ductus arteriosus have also been reported, although it is not clear whether these accurrences were due to exposure to the drug.

Angiotensin II receptor blockers exposure during the second and third trimesters is known to induce human fetotoxicity (decreased renal function, oligohydramnios, skull ossification retardation) and neonatal toxicity (renal failure, hypotension, hyperkalaemia).

Should exposure to angiotensin II receptor blockers have occurred from the second trimester of pregnancy, ultrasound check of renal function and skull is recommended.
Infants whose mothers have taken angiotensin II receptor blockers should be closely observed for hypotension.

Lactation
Telmisartan is contraindicated during lactation since it is not known whether it is excreted in human milk. Non-clinical studies have shown excretion of telmisartan in breast milk.

Fertility
No studies on fertility in humans have been performed.
In non-clinical studies, no effects of telmisartan on male and female fertility were observed.

Driving and Using Machines

No studies on the effect on the ability to drive and use machines have been performed. However, when driving vehicles or operating machinery it should be taken into account that syncope or vertigo may occasionally occur when taking antihypertensive therapy.

ADVERSE REACTIONS

Summary of the safety profile
In patients treated for hypertension the overall incidence of adverse events reported with telmisartan (41.4%) was usually comparable to those reported with placebo (43.9%) in

controlled clinical trials. The incidence of adverse events was not dose related and showed no correlation with gender, age or race of the patients.

The adverse drug reactions listed below have been accumulated from controlled clinical trials including 5788 hypertensive patients treated with telmisartan:

Frequency categories:

Very common ≥ 1/10
Common ≥ 1/100 < 1/10
Uncommon ≥ 1/1,000 < 1/100
Rare ≥ 1/10,000 < 1/1,000
Very rare < 1/10,000
Not known cannot be estimated from the available data
Note:
The above mentioned frequency categories are based on the EU SmPC Guideline; therefore, in countries outside the European Union other definitions may be appropriate.

Table 1 Adverse reactions listed in the CCDS and corresponding frequencies according to the EU SmPC Guideline

MedDRA System Organ Class	Adverse reactions	Frequencies according to EU SmPC guideline
Infections and infestations	sepsis (including fatal outcome)	rare
	upper respiratory tract infection	uncommon
	urinary tract infection	uncommon
	cystitis	uncommon
Blood and lymphatic system disorders	thrombocytopenia	rare
	anaemia	uncommon
	eosinophilia	rare
Immune system disorders	anaphylactic reaction	rare
	hypersensitivity	rare
Metabolism and nutrition disorders	hyperkalaemia	uncommon
	hypoglycaemia (in diabetic patients)	rare
	hyponatraemia	rare
Psychiatric disorders	depression	uncommon
	anxiety	rare
	insomnia	uncommon
Nervous system disorders	syncope (faint)	uncommon
Eye disorders	visual impairment	rare

Ear and labyrinth disorders	vertigo	uncommon
Cardiac disorders	bradycardia	uncommon
	tachycardia	rare
Vascular disorders	hypotension	uncommon
	orthostatic hypotension	uncommon
Respiratory, thoracic and mediastinal disorders	dyspnoea	uncommon
Gastrointestinal disorders	abdominal pain	uncommon
	diarrhoea	uncommon
	vomiting	uncommon
	dyspepsia	uncommon
	dry mouth	rare
	flatulence	uncommon
	abdominal discomfort	rare
Hepatobiliary disorders	hepatic function abnormal/ liver disorder* *Most cases of hepatic function abnormal/liver disorder from post-marketing experience with telmisartan occurred in patients in Japan, who are more likely to experience these adverse reactions.	rare
Skin and subcutaneous tissue disorders	angioedema (including fatal outcome)	rare
	drug eruption	rare
	toxic skin eruption	rare
	urticaria	rare
	eczema	rare
	erythema	rare
	rash	uncommon
	pruritus	uncommon
	hyperhidrosis	uncommon
Musculoskeletal and connective tissue disorders	arthralgia	rare
	back pain	uncommon
	pain in extremity (leg pain)	rare
	tendon pain (tendonitis like symptoms)	rare
	muscle spasms (cramps in legs)	uncommon
	myalgia	uncommon
Renal and urinary disorders	renal impairment (including acute kidney injury) (see also under Special precautions and warnings)	uncommon
General disorders and administration site conditions	chest pain	uncommon
	asthenia (weakness)	uncommon
	influenza like illness	rare
Investigations	hepatic enzyme increased	rare
	blood creatinine increased	uncommon

	blood creatine phosphokinase (CPK) increased	rare
	haemoglobin decreased	rare
	blood uric acid increased	rare

Reporting of Suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via following contact:

Telephone: +62 21 21684084 Or Email: IDsafety@zuelligpharma.com

OVERDOSE

Limited information is available with regard to overdose in humans.

Symptoms

The most prominent manifestations of telmisartan overdose were hypotension, tachycardia; bradycardia also occurred.

Therapy

If symptomatic hypotension should occur, supportive treatment should be instituted.
Telmisartan is not removed by hemofiltration and is not dialyzable.

PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Angiotensin II receptor blocker

ATC code:

C09CA07

Mode of Action

Telmisartan is an orally effective and specific angiotensin II receptor (type AT1) blocker. Telmisartan displaces angiotensin II with very high affinity from its binding site at the AT1 receptor subtype, which is responsible for the known actions of angiotensin II. Telmisartan does not exhibit any partial agonist activity at the AT1 receptor. Telmisartan selectively binds the AT1 receptor. The binding is long lasting.

Telmisartan does not show affinity for other receptors, including AT2 and other less characterised AT receptors. The functional role of these receptors is not known, nor is the effect of their possible overstimulation by angiotensin II, whose levels are increased by telmisartan. Plasma aldosterone levels are decreased by telmisartan. Telmisartan does not inhibit human plasma renin or block ion channels. Telmisartan does not inhibit angiotensin converting enzyme (kininase II), the enzyme which also degrades bradykinin. Therefore it is not expected to potentiate bradykinin-mediated adverse effects.
In man, an 80 mg dose of telmisartan almost completely inhibits the angiotensin II evoked blood pressure increase. The inhibitory effect is maintained over 24 hours and still measurable up to 48 hours.

Pharmacodynamics

Treatment of essential hypertension
After the first dose of telmisartan, the antihypertensive activity gradually becomes evident within 3 hours. The maximum reduction in blood pressure is generally attained 4 weeks after the start of treatment and is sustained during long-term therapy.

The antihypertensive effect persists constantly over 24 hours after dosing and includes the last 4 hours before the next dose as shown by ambulatory blood pressure measurements. This is confirmed by trough to peak ratios consistently above 80% seen after doses of 40 and 80 mg of telmisartan in placebo controlled clinical studies.

There is an apparent trend to a dose relationship to a time to recovery of baseline SBP. In this respect data concerning DBP are inconsistent.

In patients with hypertension telmisartan reduces both systolic and diastolic blood pressure without affecting pulse rate. The antihypertensive efficacy of telmisartan has been compared to agents representative of other classes of antihypertensive drugs (in clinical trials comparing telmisartan to agents such as amlodipine, atenolol, enalapril, hydrochlorothiazide, losartan, lisinopril, ramipril and valsartan.

Upon abrupt cessation of treatment with telmisartan, blood pressure gradually returns to pre-treatment values over a period of several days without evidence of rebound hypertension.
Telmisartan treatment has been shown in clinical trials to be associated with statistically significant reductions in Left Ventricular Mass and Left Ventricular Mass Index in patients with hypertension and Left Ventricular Hypertrophy.

Telmisartan treatment has been shown in clinical trials (including comparators like losartan, ramipril and valsartan) to be associated with statistically significant reductions in proteinuria (including microalbuminuria and macroalbuminuria) in patients with hypertension and diabetic nephropathy.

The incidence of dry cough was significantly lower in patients treated with telmisartan than in those given angiotensin converting enzyme inhibitors in clinical trials directly comparing the two antihypertensive treatments.

Pharmacokinetics

Absorption
Absorption of telmisartan is rapid although the amount absorbed varies. The mean absolute bioavailability for telmisartan is about 50%.

When telmisartan is taken with food, the reduction in the area under the plasma concentration-time curve (AUC) of telmisartan varies from approximately 6% (40 mg dose) to approximately 19% (160 mg dose). By 3 hours after administration plasma concentrations are similar whether telmisartan is taken fasting or with food.

The small reduction in AUC is not expected to cause a reduction in the therapeutic efficacy.

Distribution
Telmisartan is largely bound to plasma protein (> 99.5%), mainly albumin and alpha-1 acid glycoprotein. The mean steady state apparent volume of distribution (Vss) is approximately 500 L.

Biotransformation
Telmisartan is metabolised by conjugation to the glucuronide of the parent compound. No pharmacological activity has been shown for the conjugate.

Elimination
Telmisartan is characterised by biexponential decay pharmacokinetics with a terminal elimination half-life of >20 hours.
After oral (and intravenous) administration telmisartan is nearly exclusively excreted with the faeces, exclusively as unchanged compound. Cumulative urinary excretion is < 2% of dose.
Total plasma clearance (CLtot) is high (approximately 900 mL/min compared with hepatic blood flow (about 1500 mL/min).

Linearity
The maximum plasma concentration (Cmax) and, to a smaller extent, area under the plasma concentration-time curve (AUC) increase disproportionately with dose. There is no evidence of clinically relevant accumulation of telmisartan.

PK in specific populations

Gender differences
Gender differences in plasma concentrations were observed, Cmax and AUC being approximately 3-and 2-fold higher, respectively, in females compared to males without relevant influence on efficacy.

Geriatric patients
The pharmacokinetics of telmisartan do not differ between younger and geriatric patients.

Renal impairment
Lower plasma concentrations were observed in patients with renal insufficiency undergoing dialysis. Telmisartan is highly bound to plasma protein in renal-insufficient subjects and cannot be removed by dialysis. The elimination half-life is not changed in patients with renal impairment.

Hepatic impairment
Pharmacokinetic studies in patients with hepatic impairment showed an increase in absolute bioavailability up to nearly 100%. The elimination half-life is not changed in patients with hepatic impairment.

TOXICOLOGY

In non-clinical safety studies doses producing exposure comparable to that in the clinical therapeutic range caused reduced red cell parameters (erythrocytes, haemoglobin, haematocrit) and changes in renal haemodynamics (increased blood urea nitrogen and creatinine), as well as increased serum potassium in normotensive animals. In dogs renal tubular dilation and atrophy were observed. Gastric mucosal injury (erosion, ulcers or inflammation) also was noted in rats and dogs. These pharmacologically mediated side effects, known from non-clinical studies with both angiotensin converting enzyme inhibitors and angiotensin II blockers, were prevented by oral saline supplementation.

In both species increased plasma renin activity and hypertrophy/hyperplasia of the renal juxtaglomerular cells were observed. These changes, also a class effect of ACE-inhibitors and other angiotensin II blockers, do not appear to have clinical significance.

No clear evidence of a teratogenic effect was observed; at toxic doses levels, however, non-clinical studies indicated some hazardous potential of telmisartan to foetal development (increased number of late resorptions in rabbits) and to the postnatal development of the offspring: lower body weight, delayed eye opening and higher mortality.
No effects of telmisartan on male or female fertility were observed.
There was no evidence of mutagenicity and relevant clastogenic activity in in vitro studies and no evidence of carcinogenicity in rats and mice.

Availabilty

Tablet 40 mg Box, contains 2 alu blisters of 10 tablets	Reg. No. DKI2355200310A1
Tablet 80 mg Box, contains 2 alu blisters of 10 tablets	Reg. No. DKI2355200310B1

Storage Conditions:
Store in the original package in order to protect from moisture.
Store below 30°C, in a safe place, out of the reach of children.

Only on doctor's prescription
Harus dengan resep dokter.

Manufactured by:
Boehringer Ingelheim Hellas Single Member S.A.
Koropi, Greece

Package and released by:
Boehringer Ingelheim Shanghai Pharmaceuticals Co., Ltd.
Shanghai, China

For:
Boehringer Ingelheim International GmbH
Ingelheim am Rhein, Germany

Imported by:
PT Tunggal Idaman Abdi
Jakarta, Indonesia

Version: 17-0226

B. LEMBAR INFORMASI OBAT

Lembar informasi obat: Informasi untuk pasien
Micardis 40 mg dan 80 mg
telmisartan

Bacalah lembar informasi ini sebelum mulai mengkonsumsi obat ini. Informasi dalam lembar ini penting bagi Anda.
- Simpanlah lembar informasi ini. Anda mungkin akan perlu membacanya lagi.
- Jika Anda membutuhkan informasi lebih lanjut, tanyakanlah pada dokter ataupun apoteker Anda.
- Obat ini diresepkan hanya untuk Anda. Jangan berikan pada orang lain karena dapat membahayakan mereka walaupun tanda dan gejala yang dialami serupa dengan Anda.
- Jika Anda mengalami efek samping, konsultasikan dengan dokter Anda atau apoteker Anda, termasuk jika efek samping yang dialami belum ada dalam daftar pada leaflet ini. Lihat bagian 4.

Apa saja yang ada pada leaflet ini

1. Apa itu Micardis dan indikasi pemberiannya
2. Apa yang perlu Anda ketahui sebelum mengonsumsi Micardis
3. Bagaimana cara mengonsumsi Micardis
4. Efek samping yang mungkin terjadi
5. Bagaimana cara penyimpanan Micardis yang baik
6. Isi kemasan dan informasi lainnya

1. Apa itu Micardis dan indikasi pemberiannya
Micardis termasuk dalam golongan obat yang dikenal sebagai penghambat reseptor angiotensin II. Angiotensin II adalah zat yang diproduksi dalam tubuh Anda yang menyebabkan pembuluh darah menyempit, sehingga meningkatkan tekanan darah Anda. Micardis menghalangi efek angiotensin II sehingga pembuluh darah menjadi rileks, dan tekanan darah Anda menurun.

Micardis digunakan untuk mengobati hipertensi esensial (tekanan darah tinggi) pada orang dewasa. 'Esensial' berarti tekanan darah tinggi tidak disebabkan oleh kondisi lain.

Tekanan darah tinggi, jika tidak diobati, dapat merusak pembuluh darah di beberapa organ, yang terkadang dapat menyebabkan serangan jantung, gagal jantung atau ginjal, stroke, atau kebutaan. Biasanya tidak ada gejala tekanan darah tinggi sebelum kerusakan terjadi. Oleh karena itu, penting untuk mengukur tekanan darah secara teratur untuk memverifikasi apakah tekanan darah berada dalam kisaran normal.

2. Apa yang perlu Anda ketahui sebelum mengonsumsi Micardis
Jangan konsumsi Micardis:
- jika Anda memiliki alergi terhadap telmisartan atau komponen lain yang terkandung dalam obat ini (diuraikan dalam bagian 6)
- jika Anda sedang hamil lebih dari 3 bulan. (Lebih baik menghindari Micardis pada awal kehamilan – lihat bagian kehamilan.)
- jika Anda sedang menyusui
- jika Anda memiliki masalah hati yang parah seperti kolestasis atau obstruksi bilier (masalah dengan drainase empedu dari hati dan kantung empedu) atau penyakit hati parah lainnya.

- jika Anda memiliki diabetes atau gangguan fungsi ginjal dan Anda sedang diobati dengan obat penurun tekanan darah yang mengandung aliskiren.

Jika salah satu hal di atas berlaku untuk Anda, beri tahu dokter atau apoteker Anda sebelum mengonsumsi Micardis

Peringatan dan hal yang perlu diperhatikan
Bicaralah dengan dokter Anda sebelum mengonsumsi Micardis jika Anda menderita atau pernah menderita salah satu kondisi atau penyakit berikut:
- Penyakit ginjal atau transplantasi ginjal
- Stenosis arteri ginjal (penyempitan pembuluh darah ke satu atau kedua ginjal)
- Penyakit hati
- Penyakit jantung
- Meningkatnya kadar aldosteron (retensi air dan garam dalam tubuh disertai ketidakseimbangan berbagai mineral darah)
- Tekanan darah rendah (hipotensi), kemungkinan terjadi jika Anda mengalami dehidrasi (kehilangan cairan tubuh berlebihan) atau kekurangan garam akibat misalnya terapi diuretik ('tablet air'), diet rendah garam, diare, atau muntah.
- Meningkatnya kadar kalium dalam darah Anda
- Diabetes

Bicaralah dengan dokter Anda sebelum mengonsumsi Micardis:
- jika Anda mengonsumsi salah satu obat berikut yang digunakan untuk mengobati tekanan darah tinggi:
  - ACE-inhibitor (misalnya enalapril, lisinopril, ramipril), khususnya jika Anda memiliki masalah ginjal terkait diabetes.
  - aliskiren.

    Dokter Anda mungkin akan memeriksa fungsi ginjal, tekanan darah, dan jumlah elektrolit (misalnya kalium) dalam darah Anda secara berkala. Lihat juga informasi di bawah judul "Jangan konsumsi Micardis".
- Jika Anda sedang menggunakan digoxin

Bicaralah dengan dokter jika Anda mengalami sakit perut, mual, muntah, atau diare setelah mengonsumsi Micardis. Dokter akan memutuskan perawatan lebih lanjut. Jangan hentikan penggunaan Micardis sendiri.

Anda harus memberi tahu dokter jika Anda merasa sedang (atau mungkin) hamil. Micardis tidak direkomendasikan pada awal kehamilan, dan tidak boleh dikonsumsi jika Anda hamil lebih dari 3 bulan, karena dapat membahayakan bayi Anda jika digunakan pada tahap tersebut (lihat bagian kehamilan).

Jika akan menjalani operasi atau anestesi, Anda harus memberi tahu dokter bahwa Anda sedang mengonsumsi Micardis.

Micardis mungkin kurang efektif dalam menurunkan tekanan darah pada pasien berkulit hitam.

Seperti halnya obat antihipertensi lainnya, penurunan tekanan darah yang berlebihan pada pasien dengan kardiomiopati iskemik atau penyakit kardiovaskular iskemik dapat mengakibatkan infark miokard atau stroke.

Penggunaan obat lain beserta Micardis
Beritahukan kepada dokter atau apoteker bila anda sedang menggunakan, akhir-akhir ini menggunakan atau mungkin menggunakan obat apapun. Dokter Anda mungkin perlu mengubah dosis obat-obatan lain ini atau mengambil tindakan pencegahan lainnya. Dalam beberapa kasus, Anda mungkin harus berhenti mengonsumsi salah satu obat. Hal ini berlaku khususnya untuk obat-obatan yang tercantum di bawah ini yang dikonsumsi bersamaan dengan Micardis:

- Penggunaan dengan digoxin, warfarin, hydrochlorothiazide, glibenclamide, ibuprofen, paracetamol, simvastatin dan amlodipine. Khusus pada digoxin, pemantauan kadar digoxin plasma perlu dipertimbangkan.
- Penggunaan dengan ramipril, kemungkinan dapat meningkatkan kadar ramipril dalam plasma.
- Penggunaan dengan lithium. Peningkatan konsentrasi lithium pada penggunaan Bersama Micardis pernah dilaporkan. Pemantauan kadar lithium serum dianjurkan selama penggunaan bersamaan.
- Penggunaan dengan Obat Antiinflamasi Nonsteroid (OAINS) dapat menurunkan efek dari Micardis.
- Penggunaan dengan Obat-obatan yang dapat meningkatkan kadar kalium dalam darah, seperti pengganti garam yang mengandung kalium, diuretik hemat kalium, penghambat ACE, penghambat reseptor angiotensin II, OAINS, heparin, cyclosporin atau tacrolimus dan trimethoprim, dapat menyebabkan resiko hiperkalemia.
- Pengobatan sebelumnya dengan diuretik dosis tinggi seperti furosemide dan hydrochlorothiazide dapat mengakibatkan deplesi volume, dan meningkatkan risiko hipotensi saat memulai terapi dengan telmisartan.
- Penggunaan bersamaan dengan diuretik hemat kalium seperti spironolactone, eplerenone, triamterene, atau amiloride, suplemen kalium atau pengganti garam yang mengandung kalium dapat meningkatkan kadar kalium dalam darah. Jika penggunaan bersamaan diindikasikan karena hipokalemia yang terbukti, obat-obatan tersebut harus digunakan dengan hati-hati dan dengan pemantauan kadar kalium serum secara berkala.
- Penggunaan bersama kortikosteroid dapat menyebabkan penurunan efek antihipertensi dari Micardis.

Anda harus berkonsultasi dengan dokter jika Anda perlu menyesuaikan dosis obat lain saat mengonsumsi Micardis.

Kehamilan dan menyusui
Kehamilan
Anda harus memberi tahu dokter jika Anda merasa sedang (atau mungkin) hamil. Dokter biasanya akan menyarankan Anda untuk berhenti mengonsumsi Micardis sebelum hamil atau segera setelah Anda tahu bahwa Anda hamil dan akan menyarankan Anda untuk mengonsumsi obat lain sebagai pengganti Micardis. Micardis tidak direkomendasikan pada awal kehamilan, dan tidak boleh dikonsumsi saat hamil lebih dari 3 bulan, karena dapat membahayakan bayi Anda jika digunakan setelah bulan ketiga kehamilan.

Menyusui

Beri tahu dokter jika Anda sedang menyusui atau akan mulai menyusui. Micardis tidak direkomendasikan untuk ibu yang sedang menyusui, dan dokter Anda mungkin akan memilih perawatan lain jika Anda ingin menyusui, terutama jika bayi Anda baru lahir atau lahir prematur.

Anak dan dewasa
Penggunaan Micardis pada anak-anak dan remaja hingga usia 18 tahun tidak direkomendasikan

Mengemudikan kendaraan bermotor dan mengoperasikan mesin
Beberapa orang mungkin mengalami efek samping seperti pingsan atau perasaan berputar (vertigo) saat mengonsumsi Micardis. Jika Anda mengalami efek samping ini, jangan mengemudi atau mengoperasikan mesin.

Micardis mengandung sorbitol
Obat ini mengandung sorbitol di setiap tabletnya

Micardis mengandung garam
Obat ini mengandung kurang dari 1 mmol garam (23 mg) per tablet, yang berarti pada dasarnya 'bebas natrium'

3. Bagaimana cara mengonsumsi Micardis

Selalu minum obat ini sesuai petunjuk dokter. Konsultasikan dengan dokter atau apoteker jika Anda tidak yakin.

Dosis yang dianjurkan adalah satu tablet sehari. Usahakan untuk minum tablet pada waktu yang sama setiap hari.
Anda dapat minum Micardis dengan atau tanpa makanan. Tablet harus ditelan utuh dengan air atau minuman nonalkohol lainnya. Penting bagi Anda untuk minum Micardis setiap hari sampai dokter memberi tahu sebaliknya. Jika Anda merasa efek Micardis terlalu kuat atau terlalu lemah, konsultasikan dengan dokter atau apoteker Anda.

Untuk pengobatan tekanan darah tinggi, dosis Micardis yang umum bagi kebanyakan pasien adalah satu tablet 40 mg sekali sehari untuk mengendalikan tekanan darah selama periode 24 jam. Namun, terkadang dokter Anda mungkin menyarankan dosis yang lebih rendah yaitu 20 mg atau dosis yang lebih tinggi yaitu 80 mg. Sebagai alternatif, Micardis dapat digunakan dalam kombinasi dengan diuretik ('tablet air') seperti hidroklorotiazid yang telah terbukti memiliki efek penurun tekanan darah tambahan dengan Micardis.

Jika hati Anda tidak berfungsi dengan baik, dosis umumnya tidak boleh melebihi 40 mg sekali sehari.

Bila anda menggunakan Micardis lebih banyak dari yang seharusnya
Jika Anda tidak sengaja mengonsumsi terlalu banyak tablet, segera hubungi dokter, apoteker, atau unit gawat darurat rumah sakit terdekat.

Bila anda lupa menggunakan Micardis
Jika Anda lupa minum satu dosis, jangan khawatir. Minumlah segera setelah Anda ingat, lalu lanjutkan seperti sebelumnya. Jika Anda tidak minum tablet pada satu hari, minumlah dosis normal pada hari berikutnya. **Jangan** minum dosis ganda untuk mengganti dosis yang terlupa.

Tablet Micardis tidak boleh dibagi menjadi dua karena tablet tersebut tidak memiliki garis pemisah dan belum ada penelitian yang dilakukan pada tablet yang telah dibagi dua.

Jika Anda memiliki pertanyaan lebih lanjut tentang penggunaan obat ini, tanyakan kepada dokter atau apoteker Anda.

4. Efek samping yang mungkin terjadi

Seperti obat-obatan lainnya, obat ini memiliki efek samping, walaupun tidak semuanya terjadi pada setiap orang.

Kemungkinan efek samping dari penggunaan Micardis:

Efek samping yang jarang terjadi (*rare*):
Sepsis* (sering disebut "keracunan darah", adalah infeksi parah dengan respons peradangan seluruh tubuh yang dapat menyebabkan kematian), jumlah trombosit rendah (trombositopenia), peningkatan sel darah putih tertentu (eosinofilia), reaksi alergi parah (reaksi anafilaksis), reaksi alergi/hipersensitif (misalnya ruam, gatal, kesulitan bernapas, mengi, pembengkakan wajah atau tekanan darah rendah), kadar gula darah rendah (pada pasien diabetes), merasa cemas, gangguan penglihatan, detak jantung cepat (takikardia), mulut kering, ketidaknyamanan di perut, fungsi hati abnormal (pasien Jepang lebih mungkin mengalami efek samping ini), pembengkakan cepat pada kulit dan mukosa yang juga dapat menyebabkan kematian (angioedema termasuk hasil yang fatal), eksim (kelainan kulit), kemerahan pada kulit, gatal-gatal (urtikaria), ruam obat parah, kulit merah dan meradang (erythema), *toxic skin eruption,* nyeri sendi (artralgia), nyeri pada ekstremitas, nyeri tendon, penyakit seperti flu, penurunan hemoglobin (protein darah), peningkatan kadar asam urat, peningkatan enzim hati atau kreatin fosfokinase dalam darah, rendahnya kadar natrium

Efek samping yang tidak umum terjadi (*uncommon*):
Infeksi saluran kemih, infeksi saluran pernapasan atas (misalnya sakit tenggorokan, radang sinus, flu biasa), peradangan di kandung kemih yang menimbulkan nyeri ketika buang air kecil (cystitis) kekurangan sel darah merah (anemia), kadar kalium tinggi, kesulitan tidur, merasa sedih (depresi), pingsan (sinkop), perasaan berputar (vertigo), denyut jantung lambat (bradikardia), tekanan darah rendah (hipotensi) pada pengguna yang dirawat karena tekanan darah tinggi, pusing saat berdiri (hipotensi ortostatik), sesak napas, batuk, sakit perut, diare, nyeri di perut, kembung (dyspepsia), muntah, gas dalam perut (flatulence), gatal, peningkatan keringat, ruam obat, sakit punggung, kram otot, nyeri otot (mialgia), gangguan ginjal (termasuk gagal ginjal akut), nyeri di dada, perasaan lemah, dan peningkatan kadar kreatinin dalam darah.

Pelaporan efek samping

Jika Anda mengalami efek samping, beritahukan dokter atau apoteker Anda. Hal ini termasuk efek samping yang mungkin terjadi yang belum tercantum di leaflet ini. Anda dapat juga melaporkan keluhan efek samping atau kondisi tidak nyaman tersebut secara langsung ke Industri Farmasi melalui kontak berikut:
Telepon: +62 21 21684084 atau Email IDsafety@zuelligpharma.com

Dengan melaporkan efek samping tersebut, Anda membantu mengumpulkan informasi mengenai keamanan dari obat ini.

5. Bagaimana cara penyimpanan Micardis

Jauhkan obat ini dari jangkauan anak-anak.

Jangan menggunakan obat ini setelah tanggal kadaluarsa yang tertulis pada karton “EXP”. Tanggal kadaluarsa merujuk pada hari terakhir dari bulan tersebut.

Obat ini tidak memerlukan kondisi penyimpanan suhu khusus. Simpan dalam kemasan asli untuk melindungi dari kelembaban. Keluarkan tablet Micardis dari blister hanya sebelum dikonsumsi.

Jangan membuang obat-obatan melalui air limbah atau limbah rumah tangga. Tanyakan kepada apoteker Anda cara membuang obat-obatan yang tidak lagi Anda gunakan. Langkah-langkah ini akan membantu melindungi lingkungan.

6. Isi kemasan dan informasi lainnya

Kandungan Micardis

Bahan aktif Micardis adalah telmisartan.

Bahan lainnya adalah povidone (K25), meglumine, sodium hydroxide, sorbitol (E420) and magnesium stearate.

Tampilan Micardis 40 mg dan isi kemasan

Tablet Micardis 40 mg berwarna putih, berbentuk lonjong, dan terukir dengan nomor kode ‘51H’ di satu sisi dan logo perusahaan di sisi lainnya.

Tampilan Micardis 80 mg dan isi kemasan

Tablet Micardis 80 mg berwarna putih, berbentuk lonjong, dan terukir dengan nomor kode ‘52H’ di satu sisi dan logo perusahaan di sisi lainnya

Kemasan yang tersedia:

Tablet 40 mg
Dus, 2 Alublister @ 10 Tablet Reg. No: DKI2355200310A1

Tablet 80 mg
Dus, 2 Alublister @ 10 Tablet Reg. No: DKI2355200310B1

Diproduksi oleh :
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Koropi, Greece

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Jakarta, Indonesia

Harus dengan resep dokter.

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