PT. PFIZER INDONESIA
Local Product Document

Generic Name: Olmesartan medoxomil
Trade Name: Olmetec®
CDS Effective Date: April 2020
Supersedes: May 2016

NAME OF THE MEDICINAL PRODUCT

Olmetec® 20 mg film-coated tablet
Olmetec® 40 mg film-coated tablet

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 20 mg of olmesartan medoxomil
Each tablet contains 40 mg of olmesartan medoxomil

For excipients, see section **List of excipients**

PHARMACEUTICAL FORM

Film-coated tablet.

Appearance:
Olmetec® 20 mg tablets: White, circular, film-coated tablets with C14 respectively debossed on one side.

Olmetec® 40 mg tablets: White, oval, film-coated tablets with C15 debossed on one side.

CLINICAL PARTICULARS

Therapeutic indication

Treatment of essential hypertension.

Posology and method of administration

Adults
The recommended starting dose of olmesartan medoxomil is 10 mg once daily. In patients whose blood pressure is not adequately controlled at this dose, the dose of olmesartan medoxomil may be increased to 20 mg once daily as the optimal dose. If additional blood pressure reduction is required, olmesartan medoxomil dose may be increased to a maximum of 40 mg daily or hydrochlorothiazide therapy may be added.

The antihypertensive effect of olmesartan medoxomil is substantially present within 2 weeks of initiating therapy and is maximal by about 8 weeks after initiating therapy. This should be borne in mind when considering changing the dose regimen for any patient.

In order to assist compliance, it is recommended that Olmetec® tablets be taken at about the same time each day, with or without food, for example at breakfast time.

Elderly
The maximum dose in elderly patients is 20 mg olmesartan medoxomil once daily, owing to limited experience of higher dosages in this patient group.

Renal impairment
The maximum dose in patients with mild to moderate renal impairment (creatinine clearance of 20 – 60 mL/min) is 20 mg olmesartan medoxomil once daily, owing to limited experience of higher dosages in this patient group. The use of olmesartan medoxomil in patients with severe renal impairment (creatinine clearance <20 mL/min) is not recommended, since there is only limited experience in this patient group.

Hepatic impairment
The use of olmesartan medoxomil is not recommended in patients with hepatic impairment, since there is only limited experience in this patient group.

Children and adolescents
The safety and efficacy of olmesartan medoxomil have not been established in children and adolescents up to 18 years of age.

Contraindications

Hypersensitivity to the active ingredient or any of the other excipients of Olmetec® tablets (see section **List of excipients**).

Pregnancy. Patient who become pregnant should discontinue the use of olmesartan medoxomil as soon as possible (see section **Pregnancy and lactation**).

Lactation (see section **Pregnancy and lactation**).

Biliary obstruction (see section **Pharmacokinetic properties**).

Do not co-administer aliskiren with olmesartan medoxomil in patients with diabetes (see section **Interaction with other medicinal products and other forms of interaction**).

Special warnings and special precautions for use

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

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 other drugs that affect this system has been associated with acute hypotension, azotaemia, oliguria or, rarely, acute renal failure. The possibility of similar effects cannot be excluded with angiotensin II receptor antagonists.

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.

Sprue-like enteropathy:
Severe, chronic diarrhea with substantial weight loss has been reported in patients taking olmesartan medoxomil months to years after drug initiation. Intestinal biopsies of patients often demonstrated villous atrophy. If a patient develops these symptoms during treatment with olmesartan medoxomil, exclude other etiologies. Consider discontinuation of olmesartan medoxomil in cases where no other etiology is identified.

Electrolyte imbalance:
Olmetec® contains olmesartan, a drug that inhibits the renin-angiotensin system (RAS). Drugs that inhibit the RAS can cause hyperkalaemia. Monitor serum electrolytes periodically.

Renal impairment and kidney transplantation:
When olmesartan medoxomil is used in patients with impaired renal function, periodic monitoring of serum potassium and creatinine levels is recommended. Use of olmesartan medoxomil is not recommended in patients with severe renal impairment (creatinine clearance <20 mL/min) (see sections **Posology and method of administration** and **Pharmacokinetic properties**). There is no experience of the administration of olmesartan medoxomil in patients with a recent kidney transplant or in patients with end-stage renal impairment (i.e., creatinine clearance <12 mL/min).

Hepatic impairment:
There is currently limited experience in patients with mild to moderate hepatic impairment and no experience in patients with severe hepatic impairment, therefore use of olmesartan medoxomil in these patient groups is not recommended (see sections **Posology and method of administration** and **Pharmacokinetic properties**).

Hyperkalaemia:
As with other angiotensin II antagonists and angiotensin converting enzyme (ACE) inhibitors, hyperkalaemia may occur during treatment with olmesartan medoxomil, especially in the presence of renal impairment and/or heart failure (see section **Interaction with other medicinal products and other forms of interaction**). Close monitoring of serum potassium levels in at risk patients is recommended.

Lithium:
As with other angiotensin-II receptor antagonists, the combination of lithium and olmesartan medoxomil is not recommended (see section **Interaction with other medicinal products and other forms of interaction**).

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

Primary aldosteronism:
Patients with primary aldosteronism generally will not respond to antihypertensive drugs acting through inhibition of the renin-angiotensin system. Therefore, the use of olmesartan medoxomil is not recommended in such patients.

Ethnic differences:
As with all other angiotensin II antagonists, the blood pressure lowering effect of olmesartan medoxomil is somewhat less in black patients than in non-black patients, possibly because of a higher prevalence of low-renin status in the black hypertensive population.

Other:
As with any antihypertensive agent, excessive blood pressure decrease in patients with ischaemic heart disease or ischaemic cerebrovascular disease could result in a myocardial infarction or stroke.

Interaction with other medicinal products and other forms of interaction

Effects of other medicinal products on olmesartan medoxomil:

Potassium supplements and potassium sparing diuretics:
Based on experience with the use of other drugs that affect the renin-angiotensin system, concomitant use of potassium-sparing diuretics, potassium supplements, salt substitutes

containing potassium or other drugs that may increase serum potassium levels (e.g. heparin) may lead to increases in serum potassium (see section **Special warnings and special precautions for use**). Such concomitant use is therefore not recommended.

Other antihypertensive medications:
The blood pressure lowering effect of olmesartan medoxomil can be increased by concomitant use of other antihypertensive medications.

Dual blockade of the Renin-Angiotensin System (RAS):
Dual blockade of the RAS with angiotensin receptor antagonists, ACE inhibitors or aliskiren is associated with increased risks of hypotension, hyperkalemia and changes in renal function (including acute renal failure) compared to monotherapy. Monitor blood pressure, renal function and electrolytes in patients on olmesartan and other agents that affect the RAS.

Use with aliskiren:
Do not co-administer aliskiren with olmesartan medoxomil in patients with diabetes (see section **Contraindications**) because dual use is associated with increased risks of hypotension, hyperkalemia, and changes in renal function (including acute renal failure) compared to monotherapy.

Non-steroidal anti-inflammatory drugs (NSAIDs):
NSAIDs (including acetylsalicylic acid at doses >3 g/day and also COX-2 inhibitors) and angiotensin-II receptor antagonists may act synergistically by decreasing glomerular filtration. The risk of the concomitant use of NSAIDs and angiotensin II antagonists is the occurrence of acute renal failure. Monitoring of renal function at the beginning of treatment should be recommended as well as regular hydration of the patient.

Additionally, concomitant treatment can reduce the antihypertensive effect of angiotensin II receptor antagonists, leading to their partial loss of efficacy.

Use with colesevelam hydrochloride:
Concurrent administration of bile acid sequestering agent colesevelam hydrochloride reduces the systemic exposure and peak plasma concentration of olmesartan. Administration of olmesartan at least 4 hours prior to colesevelam hydrochloride decreased the drug interaction effect (see section **Pharmacological properties**).

Other compounds:
After treatment with antacid (aluminium magnesium hydroxide), a modest reduction in bioavailability of olmesartan was observed. Co-administration of warfarin and digoxin had no effect on the pharmacokinetics of olmesartan.

Effects of olmesartan medoxomil on other medicinal products:
Lithium:

Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with angiotensin converting enzyme inhibitors and angiotensin II antagonists. Therefore use of olmesartan medoxomil and lithium in combination is not recommended (see section **Special warnings and special precautions for use**). If use of the combination proves necessary, careful monitoring of serum lithium levels is recommended.

Other compounds:
Compounds which have been investigated in specific clinical studies in healthy volunteers include warfarin, digoxin, an antacid (magnesium aluminium hydroxide), hydrochlorothiazide and pravastatin. No clinically relevant interactions were observed and in particular olmesartan medoxomil had no significant effect on the pharmacokinetics or pharmacodynamics of warfarin or the pharmacokinetics of digoxin.

Olmesartan had no clinically relevant inhibitory effects on *in vitro* human cytochrome P450 enzymes 1A1/2, 2A6, 2C8/9, 2C19, 2D6, 2E1 and 3A4, and had no or minimal inducing effects on rat cytochrome P450 activities. Therefore, *in vivo* interaction studies with known cytochrome P450 enzyme inhibitors and inducers were not conducted, and no clinically relevant interactions between olmesartan and drugs metabolised by the above cytochrome P450 enzymes are expected.

Pregnancy and lactation

Use in pregnancy (see section Contraindications):
There is no experience with the use of olmesartan medoxomil in pregnant women. However, drugs that act directly on the renin-angiotensin system administered during the second and third trimesters of pregnancy have been reported to cause foetal and neonatal injury (hypotension, renal dysfunction, oliguria and/or anuria, oligohydramnios, skull hypoplasia, intrauterine growth retardation, lung hypoplasia, facial abnormalities, limb contracture) and even death.

The use of ARB is contraindicated during pregnancy. 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 antagonists should be stopped immediately, and, if appropriate, alternative therapy should be started.

If pregnancy occurs during therapy, olmesartan medoxomil must be discontinued as soon as possible.

If Olmetec® is used during pregnancy, or if the patient becomes pregnant while taking Olmetec®, the patient should be apprised of the potential hazard to a fetus. Should exposure to Olmetec® have occurred from the second trimester forward, ultrasound examinations of the renal function and of the skull are recommended. Newborns exposed to angiotensin II

antagonists in utero must be closely monitored for the occurrence of hypotension, oliguria, and hyperkalaemia.

Use during lactation (see section Contraindications):
Olmesartan is excreted in the milk of lactating rats but it is not known whether olmesartan is excreted in human milk. Mothers must not breast-feed if they are taking olmesartan medoxomil.

Effects on ability to drive and use machines

The effect of Olmetec® tablets on the ability to drive has not been specifically studied. With respect to driving vehicles or operating machines, it should be taken into account that occasionally dizziness or fatigue may occur in patients taking antihypertensive therapy.

Undesirable effects

In double-blind, placebo-controlled monotherapy studies, the overall incidence of treatment-emergent adverse events was 42.4% on olmesartan medoxomil and 40.9% on placebo. In long-term (2-year) treatment, the incidence of withdrawals due to adverse events on olmesartan medoxomil 10 - 20 mg once daily was 3.7%.

In placebo-controlled monotherapy studies, the only adverse drug reaction that was unequivocally related to treatment was dizziness (2.5% incidence on olmesartan medoxomil and 0.9% on placebo).

Adverse events reported across all clinical trials with olmesartan medoxomil (including trials with active as well as placebo control), irrespective of causality or incidence relative to placebo, included those events listed below. Frequencies are defined as: common (≥1/100, <1/10); uncommon (≥1/1000, <1/100); rare (≥1/10000, <1/1000), very rare (<1/10000).

The adverse events listed include all adverse events reported commonly and other adverse events of potential clinical relevance.

Central nervous system disorders:
Common: Dizziness
Uncommon: Vertigo

Cardiovascular disorders:
Rare: Hypotension

Myo/endo/pericardial and valve disorders:
Uncommon: Angina pectoris

Respiratory system disorders:
Common: Bronchitis, cough, pharyngitis, rhinitis

Gastro-intestinal disorders:
Common: Abdominal pain, diarrhea, dyspepsia, gastroenteritis, nausea

Skin and appendages disorders:
Uncommon: Rash

Musculoskeletal disorders:
Common: Arthritis, back pain, skeletal pain

Urinary system disorders:
Common: Haematuria, urinary tract infection

General disorders:
Common: Chest pain, fatigue, influenza-like symptoms, peripheral oedema, pain

Post-launch experience:
In addition, as with other angiotensin II antagonists, headache has been observed, in very rare cases hypersensitivity reactions (pruritus, urticaria, angioedema), peripheral oedema, vomiting, diarrhea, sprue-like enteropathy, anaphylactic reaction, acute renal failure, hyperkalemia, rhabdomyolysis, increase blood creatinine levels, alopecia, myalgia and asthenic condition such as asthenia, fatigue, lethargy, malaise have been reported.

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:
Pusat Farmakovigilans/MESO Nasional
Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif
Badan Pengawas Obat dan Makanan
Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560
Email: pv-center@pom.go.id
Phone: +62-21-4244691 Ext.1079
Website: https://e-meso.pom.go.id/ADR

PT Pfizer Indonesia
Email: IDN.AEReporting@pfizer.com
Website: www.pfizersafetyreporting.com

Laboratory parameters

In placebo-controlled monotherapy studies, the incidence was somewhat higher on olmesartan medoxomil compared with placebo for hypertriglyceridaemia (2.0% vs. 1.1%) and for raised creatine phosphokinase (1.3% vs. 0.7%).

Laboratory adverse events reported across all clinical trials with olmesartan medoxomil (including trials without a placebo control), irrespective of causality or incidence relative to placebo, included:

Metabolic and nutritional disorders:
Common: Increased creatine phosphokinase, hypertriglyceridaemia, hyperuricaemia
Rare: Hyperkalaemia

Liver and biliary disorders:
Common: Liver enzyme elevations

Overdose

Only limited information is available regarding overdosage in humans. The most likely effect of overdosage is hypotension. In the event of overdosage, the patient should be carefully monitored and treatment should be symptomatic and supportive.

No information is available regarding the dialysability of olmesartan.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmaco-therapeutic group:
Angiotensin II antagonists, ATC code CO9C A.

Olmesartan medoxomil is a potent, orally active, selective angiotensin II receptor (type AT_1) antagonist. It is expected to block all actions of angiotensin II mediated by the AT_1 receptor, regardless of the source or route of synthesis of angiotensin II. The selective antagonism of the angiotensin II (AT_1) receptors results in increases in plasma renin levels and angiotensin I and II concentrations, and some decrease in plasma aldosterone concentrations.

Angiotensin II is the primary vasoactive hormone of the renin-angiotensin-aldosterone system and plays a significant role in the pathophysiology of hypertension via the type 1 (AT_1) receptor.

In hypertension, olmesartan medoxomil causes a dose-dependent, long-lasting reduction in arterial blood pressure. There has been no evidence of first-dose hypotension, of

tachyphylaxis during long-term treatment, or of rebound hypertension after cessation of therapy.

Once daily dosing with olmesartan medoxomil provides an effective and smooth reduction in blood pressure over the 24-hour dose interval. Once daily dosing produced similar decreases in blood pressure as twice daily dosing at the same total daily dose.

With continuous treatment, maximum reductions in blood pressure are achieved by 8 weeks after the initiation of therapy, although a substantial proportion of the blood pressure lowering effect is already observed after 2 weeks of treatment. When used together with hydrochlorothiazide, the reduction in blood pressure is additive and co-administration is well tolerated.

The effect of olmesartan on mortality and morbidity is not yet known.

Pharmacokinetic properties

Absorption and distribution

Olmesartan medoxomil is a prodrug. It is rapidly converted to the pharmacologically active metabolite, olmesartan, by esterases in the gut mucosa and in portal blood during absorption from the gastrointestinal tract.

No intact olmesartan medoxomil or intact side chain medoxomil moiety have been detected in plasma or excreta. The mean absolute bioavailability of olmesartan from a tablet formulation was 25.6%.

The mean peak plasma concentration (C_{max}) of olmesartan is reached within about 2 hours after oral dosing with olmesartan medoxomil, and olmesartan plasma concentrations increase approximately linearly with increasing single oral doses up to about 80 mg.

Food had minimal effect on the bioavailability of olmesartan and therefore olmesartan medoxomil may be administered with or without food.

No clinically relevant gender-related differences in the pharmacokinetics of olmesartan have been observed.

Olmesartan is highly bound to plasma protein (99.7%), but the potential for clinically significant protein binding displacement interactions between olmesartan and other highly bound co-administered drugs is low (as confirmed by the lack of a clinically significant interaction between olmesartan medoxomil and warfarin). The binding of olmesartan to blood cells is negligible. The mean volume of distribution after intravenous dosing is low (16 – 29 L).

Metabolism and elimination
Total plasma clearance was typically 1.3 L/h (CV, 19%) and was relatively slow compared to hepatic blood flow (ca 30 L/h). Following a single oral dose of ^{14}C-labelled olmesartan medoxomil, 10% - 16% of the administered radioactivity was excreted in the urine (the vast majority within 24 hours of dose administration) and the remainder of the recovered radioactivity was excreted in the faeces. Based on the systemic availability of 25.6%, it can be calculated that absorbed olmesartan is cleared by both renal excretion (ca 40%) and hepato-biliary excretion (ca 60%). All recovered radioactivity was identified as olmesartan. No other significant metabolite was detected. Enterohepatic recycling of olmesartan is minimal. Since a large proportion of olmesartan is excreted via the biliary route, use in patients with biliary obstruction is contraindicated (see section **Contraindications**).

The terminal elimination half-life of olmesartan varied between 10 and 15 hours after multiple oral dosing. Steady-state was reached after the first few doses, and no further accumulation was evident after 14 days of repeated dosing. Renal clearance was approximately 0.5-0.7 L/h and was independent of dose.

Pharmacokinetics in special populations
Elderly:
In hypertensive patients, the AUC at steady-state was increased by ca 35% in elderly patients (65 – 75 years old) and by ca 44% in very elderly patients (≥75 years old) compared with the younger age group (see section **Posology and method of administration**).

Renal impairment:
In renally impaired patients, the AUC at steady-state increased by 62%, 82% and 179% in patients with mild, moderate and severe renal impairment, respectively, compared to healthy controls (see sections **Posology and method of administration** and **Special warnings and special precautions for use**).

Hepatic impairment:
After single oral administration, olmesartan AUC values were 6% and 65% higher in mildly and moderately hepatically impaired patients, respectively, than in their corresponding matched healthy controls. The unbound fraction of olmesartan at 2 hours post-dose in healthy subjects, in patients with mild hepatic impairment and in patients with moderate hepatic impairment was 0.26%, 0.34% and 0.41%, respectively. Olmesartan medoxomil has not been evaluated in patients with severe hepatic impairment (see sections **Posology and method of administration** and **Special warnings and special precautions for use**).

Drug interaction with bile acid sequestering agent colesevelam:
Concomitant administration of 40 mg olmesartan medoxomil and 3,750 mg colesevelam hydrochloride in healthy subjects resulted in 28% reduction in C_{max} and 39% reduction in AUC of olmesartan. Lesser effects, 4% and 15% reduction in C_{max} and AUC, respectively, were observed when olmesartan medoxomil was administered 4 hours prior to colesevelam

hydrochloride (see section **Interaction with other medicinal products and other forms of interaction**).

Preclinical safety data

In chronic toxicity studies in rats and dogs, olmesartan medoxomil showed similar effects to other AT_1 receptor antagonists and ACE inhibitors: raised blood urea (BUN) and creatinine (through functional changes to the kidneys caused by blocking AT_1 receptors); reduction in heart weight; a reduction of red cell parameters (erythrocytes, haemoglobin, haematocrit); histological indications of renal damage (regenerative lesions of the renal epithelium, thickening of the basal membrane, dilatation of the tubules). These adverse effects caused by the pharmacological action of olmesartan medoxomil have also occurred in preclinical trials on other AT_1 receptor antagonists and ACE inhibitors and can be reduced by simultaneous oral administration of sodium chloride.

In both species, increased plasma renin activity and hypertrophy/hyperplasia of the juxtaglomerular cells of the kidney were observed. These changes, which are a typical effect of the class of ACE inhibitors and other AT_1 receptor antagonists, would appear to have no clinical relevance.

Like other AT_1 receptor antagonists olmesartan medoxomil was found to increase the incidence of chromosome breaks in cell cultures *in vitro*. No relevant effects were observed in several *in vivo* studies using olmesartan medoxomil at very high oral doses of up to 2000 mg/kg. The overall data of a comprehensive genotoxicity testing suggest that olmesartan is very unlikely to exert genotoxic effects under conditions of clinical use.

Olmesartan medoxomil was not carcinogenic, neither in rats in a 2-year study nor in mice when tested in two 6-month carcinogenicity studies using transgenic models.

In reproductive studies in rats, olmesartan medoxomil did not affect fertility and there was no evidence of a teratogenic effect. In common with other angiotensin II antagonists, survival of offspring was reduced following exposure to olmesartan medoxomil, and pelvic dilatation of the kidney was seen after exposure of the dams in late pregnancy and lactation. In common with other antihypertensive agents, olmesartan medoxomil was shown to be more toxic to pregnant rabbits than to pregnant rats; however, there was no indication of a fetotoxic effect.

Clinical trials

The Randomised Olmesartan And Diabetes Microalbuminuria Prevention (ROADMAP) clinical study included 4447 patients with type 2 diabetes, normoalbuminuria and at least one additional cardiovascular risk factor. Patients were randomized to olmesartan 40 mg daily or placebo. The trial met its primary endpoint, delayed onset of microalbuminuria. For the secondary endpoints, which the study was not designed to formally assess, cardiovascular events occurred in 96 patients (4.3%) with olmesartan and in 94 patients (4.2%) with placebo.

The incidence of cardiovascular mortality was higher with olmesartan compared to placebo treatment (15 patients [0. 67%] vs. 3 patients [0.14%] [HR=4.94, 95% CI=1.43-17.06]), but the risk of non-fatal myocardial infarction was lower with olmesartan (HR 0.64, 95% CI 0.35, 1.18).

PHARMACEUTICAL PARTICULARS

List of excipients

Tablet core
Microcrystalline cellulose
Lactose monohydrate
Hydroxypropylcellulose
Magnesium stearate

Tablet coat
Titanium dioxide (E 171)
Talc
Hypromellose

Incompatibilities

Not applicable

Shelf-life

3 years

Special precautions for storage

Store below 30°C.

Prescription Only
HARUS DENGAN RESEP DOKTER

Supply
Olmetec® 20 mg film-coated tablet;
Box contains of 3 blisters @ 10 film-coated tablet;
Reg. No. DKI1890701717A1
Olmetec® 40 mg film-coated tablet;
Box contains of 3 blisters @ 10 film-coated tablet;
Reg. No. DKI1890701717B1

Manufactured by
Daiichi Sankyo Europe GmbH,
Germany

Packed and released by
Pfizer Manufacturing Deutschland GmbH,
Freiburg Im Breisgau, Germany

Imported by
PT. Pfizer Indonesia,
Jakarta,
Indonesia

Nama Generik: Olmesartan medoksomil
Nama Dagang: Olmetec®
Tanggal Berlaku CDS: April 2020
Menggantikan: Tidak Ada
Disetujui oleh BPOM:

Leaflet kemasan: Informasi bagi pengguna

Olmetec®
20 mg tablet salut selaput
40 mg tablet salut selaput
Olmesartan medoksomil

Baca semua bagian leaflet ini dengan cermat sebelum mulai menggunakan obat ini karena berisi informasi penting bagi Anda.
- Simpan leaflet ini. Anda mungkin perlu membacanya kembali.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter, apoteker, atau perawat Anda.
- Obat ini telah diresepkan hanya untuk Anda. Jangan berikan kepada orang lain. Obat ini dapat membahayakan mereka, sekali pun tanda-tanda penyakit mereka sama dengan Anda.
- Jika Anda mengalami efek samping apa pun, konsultasikan dengan dokter atau perawat Anda. Termasuk setiap kemungkinan efek samping yang tidak tercantum dalam leaflet ini. Lihat bagian 13.

Isi leaflet ini:

1. Nama obat
2. Bentuk sediaan
3. Deskripsi obat
4. Apa kandungan obat ini?
5. Kekuatan obat
6. Apa kegunaan obat ini?
7. Berapa banyak dan seberapa sering Anda seharusnya menggunakan obat ini? Apa yang harus dilakukan jika ada dosis terlewat?
8. Kapan seharusnya Anda tidak menggunakan obat ini?
9. Apa yang harus dipertimbangkan saat menggunakan obat ini?
10. Apa saja obat lain atau makanan yang harus dihindari selama menggunakan obat ini?
11. Apakah obat ini aman untuk perempuan hamil dan menyusui?
12. Apakah pasien diperbolehkan mengemudi dan mengoperasikan mesin selama menggunakan obat ini?
13. Apa saja potensi efek yang tidak diinginkan karena menggunakan obat ini?
14. Tanda-tanda dan gejala-gejala overdosis
15. Apa yang harus dilakukan jika Anda menggunakan lebih dari dosis yang dianjurkan?
16. Bagaimana cara menyimpan obat ini?
17. Petunjuk penggunaan/penanganan
18. Nomor otorisasi pemasaran
19. Nama dan alamat pemohon dan/atau pemilik obat sesuai dengan ketentuan yang berlaku
20. Tanggal revisi PIL
21. Peringatan khusus

1. Nama obat
Olmetec®

2. Bentuk sediaan
Tablet salut selaput.

3. Deskripsi obat

Olmetec® 20 mg tablet: Tablet salut selaput bulat berwarna putih dengan cap C14 dicetak tenggelam pada satu sisi.
Olmetec® 40 mg tablet: Tablet salut selaput lonjong berwarna putih dengan cap C15 dicetak tenggelam pada satu sisi.

4. Apa kandungan obat ini?

Setiap tablet mengandung 20 mg/40 mg olmesartan medoksomil.

Olmesartan medoksomil termasuk dalam golongan obat yang disebut “antagonis reseptor angiotensin-II”.

Daftar zat tambahan:
Tablet inti
Mikrokristalin selulosa
Laktos monohidrat
Hikdroksipropil selulosa
Magnesium stearate

Tablet salut
Titanium dioksida (E 171)
Talk
Hipromelosa

5. Kekuatan obat

20 mg; 40 mg.

6. Apa kegunaan obat ini?

Olmetec® digunakan untuk mengobati hipertensi esensial.

7. Berapa banyak dan seberapa sering Anda seharusnya menggunakan obat ini? Apa yang harus dilakukan jika ada dosis terlewat?

Selalu gunakan obat ini dengan tepat sesuai anjuran dokter atau apoteker Anda. Konsultasikan dengan
dokter atau apoteker Anda jika Anda tidak yakin.

Dewasa
Dosis awal yang dianjurkan untuk pasien dewasa adalah 10 mg setiap hari. Namun demikian, jika tekanan darah Anda tidak terkendali, dokter dapat memutuskan untuk mengubah dosis Anda hingga 20 atau 40 mg satu kali sehari atau meresepkan obat tambahan.

Lansia
Dosis maksimum pada pasien lansia adalah 20 mg olmesartan medoksomil satu kali sehari.

Anak-anak dan Remaja
Olmetec® tidak dianjurkan untuk anak-anak dan remaja berusia di bawah 18 tahun.

Jika Anda lupa meminum Olmetec®

Jika Anda lupa meminum satu dosis, minum dosis normal Anda pada keesokan harinya seperti biasa. Jangan meminum dosis ganda untuk mengejar dosis yang terlupa.

Penting kiranya Anda melanjutkan meminum Olmetec® kecuali jika dokter memerintahkan Anda untuk menghentikannya.

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

8. Kapan seharusnya Anda tidak menggunakan obat ini?

Jangan menggunakan Olmetec®

- jika Anda alergi terhadap olmesartan medoksomil atau terhadap bahan-bahan lain dalam obat ini
- jika Anda hamil atau menyusui
- jika Anda menderita diabetes dan Anda diberi obat yang mengandung aliskiren
- jika Anda mengalami gangguan hati atau penyumbatan empedu

9. Apa yang harus dipertimbangkan saat menggunakan obat ini?

Konsultasikan dengan dokter Anda sebelum menggunakan Olmetec®.

Beri tahu dokter Anda jika Anda sedang meminum obat-obatan berikut yang digunakan untuk mengobati tekanan darah tinggi:

- penghambat ACE
- aliskiren

Dokter Anda dapat memeriksa fungsi ginjal, tekanan darah, dan kadar elektrolit (misalnya kalium) dalam darah Anda secara rutin.

Beri tahu dokter Anda jika Anda mengalami gangguan kesehatan berikut ini:

- jika Anda menderita gangguan ginjal atau menjalani transplantasi ginjal
- jika Anda menderita penyakit liver
- jika Anda mengalami gagal jantung atau ada masalah dengan katup jantung atau otot jantung Anda
- jika Anda mengalami muntah yang parah, diare, menjalani pengobatan dengan “tablet air” (diuretik) dosis tinggi atau jika Anda tengah menjalani diet rendah garam
- jika Anda mengalami peningkatan kadar kalium dalam darah
- jika Anda mengalami gangguan pada kelenjar adrenal (kelenjar penghasil hormon di bagian atas ginjal)

Hubungi dokter Anda jika Anda mengalami diare yang parah, berkelanjutan, dan menyebabkan penurunan berat badan yang signifikan. Dokter dapat mengevaluasi gejala Anda dan memutuskan cara melanjutkan pengobatan tekanan darah Anda.

Seperti halnya obat lain yang bekerja menurunkan tekanan darah, penurunan tekanan darah secara berlebihan pada pasien dengan gangguan aliran darah di jantung atau otak dapat menyebabkan serangan jantung atau stroke. Oleh karena itu, dokter akan memeriksa tekanan darah Anda secara cermat.

Pasien kulit hitam
Seperti halnya obat-obatan sejenis, efek penurunan tekanan darah yang ditimbulkan Olmetec® bisa jadi agak kurang pada pasien kulit hitam.

Olmetec® mengandung laktosa
Obat ini mengandung laktosa (sejenis gula). Jika Anda telah diberi tahu oleh dokter bahwa Anda menderita intoleransi terhadap beberapa jenis gula, hubungi dokter Anda sebelum meminum produk obat ini.

10. Apa saja obat lain atau makanan yang harus dihindari selama menggunakan obat ini?

Beri tahu dokter atau apoteker Anda jika Anda sedang menggunakan, baru-baru ini menggunakan, atau mungkin akan menggunakan obat-obatan lain.

Beri tahu dokter atau apoteker Anda jika Anda sedang menggunakan, baru-baru ini menggunakan, atau mungkin akan menggunakan obat mana pun berikut ini:

- **Obat-obatan penurun tekanan darah lainnya**, karena dapat meningkatkan efek Olmetec® . Dokter Anda mungkin dapat mengubah dosis Anda dan/atau mengambil tindakan pencegahan lainnya: Jika Anda meminum penghambat ACE atau aliskiren
- **Suplemen kalium, pengganti garam yang mengandung kalium, “tablet air”** (diuretik) atau **heparin** (untuk mengencerkan darah dan mencegah bekuan darah.). Menggunakan obat-obatan ini bersamaan dengan Olmetec® dapat meningkatkan kadar kalium dalam darah Anda.
- **Litium** yang digunakan bersamaan dengan Olmetec® dapat meningkatkan toksisitas litium. Jika Anda harus meminum litium, dokter akan mengukur kadar litium dalam darah Anda.
- **Obat Antiinflamasi Nonsteroid** (OAINS) yang digunakan bersamaan dengan Olmetec® dapat meningkatkan risiko gagal ginjal. Efek Olmetec® dapat menurun dengan adanya OAINS.
- **Kolesevelam hidroklorida**, karena dapat menurunkan efek Olmetec®. Dokter dapat menyarankan Anda untuk meminum Olmetec® setidaknya 4 jam sebelum kolesevelam hidroklorida.
- **Antasida tertentu** (aluminium magnesium hidroksida), karena dapat sedikit menurunkan efek Olmetec®.

Olmetec® dengan makanan dan minuman
Olmetec® dapat diminum sebelum atau sesudah makan. Telan tablet dengan bantuan cairan (misalnya segelas air). Bila memungkinkan, minum dosis harian Anda pada waktu yang sama setiap hari, misalnya pada waktu sarapan.

11. Apakah obat ini aman untuk perempuan hamil dan menyusui?

Kehamilan
Jangan meminum Olmetec® jika Anda merasa sedang (atau mungkin saja) hamil. Jika terjadi kehamilan selama terapi, Olmetec® harus dihentikan sesegera mungkin.

Menyusui
Jangan meminum Olmetec® jika Anda sedang menyusui.

Jika Anda hamil atau menyusui, menduga bahwa diri Anda hamil, atau sedang merencanakan kehamilan, mintalah saran dari dokter atau apoteker Anda sebelum menggunakan obat ini.

12. Apakah pasien diperbolehkan mengemudi dan mengoperasikan mesin selama menggunakan obat ini?
Anda dapat merasa pusing atau lelah selama menjalani pengobatan untuk tekanan darah tinggi. Jika hal ini terjadi, jangan mengemudi atau menggunakan mesin hingga gejala-gejalanya mereda. Mintalah saran dari dokter Anda.

13. Apa saja potensi efek yang tidak diinginkan karena menggunakan obat ini?
Seperti semua obat-obatan yang ada, obat ini bisa menimbulkan efek samping, meskipun tidak semua orang mengalaminya.

Jika gejala-gejala berikut ini terjadi, hentikan meminum Olmetec® dan segera beri tahu dokter Anda atau datangi Unit Gawat Darurat di rumah sakit terdekat Anda:
- Pembengkakan wajah, bibir, mulut, lidah, atau tenggorok yang dapat menyebabkan kesulitan menelan atau bernapas
- Tekanan darah turun terlalu rendah

Beri tahu dokter Anda sesegera mungkin jika Anda mengalami yang berikut ini:
- ruam kulit atau gatal-gatal, hives
- otot terasa sakit, nyeri tekan, atau lemah yang bukan disebabkan oleh olahraga
- nyeri persendian
- nyeri jantung
- nyeri dada
- sesak napas atau dada terasa ketat, kesulitan bernapas
- pembengkakan tangan, kaki, atau pergelangan kaki
- gejala-gejala yang mungkin menunjukkan kadar kalium tinggi dalam darah, seperti mual, diare.

Efek samping lain:
Beri tahu dokter atau apoteker Anda jika Anda mengalami yang berikut ini:
- kepala terasa ringan, pusing, atau pingsan
- batuk
- sakit kepala
- merasa mual atau muntah
- diare
- perut terasa tidak nyaman
- rasa letih yang tidak biasa atau rasa lemah, kelelahan
- pilek atau hidung tersumbat, atau bersin
- gejala 'mirip flu'
- bronkitis
- radang tenggorok dan tidak nyaman saat menelan (faringitis)
- pembengkakan tangan, kaki, atau pergelangan kaki
- nyeri punggung
- infeksi saluran kemih, darah di dalam urine
- rambut rontok dalam patch
- perubahan hasil tes laboratorium

Beri tahu dokter atau perawat Anda jika teramati adanya efek samping yang tercantum di atas.

Melaporkan efek samping
Jika Anda mengalami efek samping apa pun, konsultasikan dengan dokter, apoteker, atau perawat Anda. Termasuk setiap kemungkinan efek samping yang tidak tercantum dalam leaflet ini. Dengan melaporkan efek samping, Anda bisa membantu memberikan informasi lebih lanjut mengenai keamanan obat ini.

Untuk melaporkan efek samping, hubungi www.pfizersafetyreporting.com atau email di IDN.AEReporting@pfizer.com.

14. Tanda-tanda dan gejala-gejala overdosis
Jika Anda meminum tablet melebihi dosis yang seharusnya, Anda dapat mengalami tekanan darah rendah dengan gejala seperti pusing.

15. Apa yang harus dilakukan jika Anda menggunakan lebih dari dosis yang dianjurkan?
Jika Anda meminum tablet melebihi dosis yang seharusnya, segera datangi dokter atau unit gawat darurat terdekat dan bawa serta kemasan obat Anda atau leaflet ini.

16. Bagaimana cara menyimpan obat ini?
Jauhkan obat ini dari pandangan dan jangkauan anak-anak.

Jangan gunakan obat ini setelah melewati tanggal kedaluwarsa yang tertera pada wadahnya.

Simpan pada suhu di bawah 30 °C.

Waktu kedaluwarsa: 3 tahun

17. Petunjuk penggunaan/penanganan
Olmetec® dapat diminum sebelum atau sesudah makan. Telan tablet dengan bantuan cairan (misalnya segelas air). Bila memungkinkan, minum dosis harian Anda pada waktu yang sama setiap hari, misalnya pada waktu sarapan.

18. Nomor otorisasi pemasaran
Olmetec® 20 mg tablet salut selaput; Dus berisi 3 blister @ 10 tablet salut selaput; No. Reg. DKI1890701717A1
Olmetec® 40 mg tablet salut selaput; Dus berisi 3 blister @ 10 tablet salut selaput; No. Reg. DKI1890701717B1

19. Nama dan alamat pemohon dan/atau pemilik obat sesuai dengan ketentuan yang berlaku
Diproduksi oleh:
Daiichi Sankyo Europe GmbH, Pfaffenhofen, Germany

Dikemas dan Diedarkan oleh:
Pfizer Manufacturing Deutschland GmbH, Freiburg Im Breisgau, Germany

Diimpor oleh:
PT. Pfizer Indonesia
Jakarta, Indonesia.

20. Tanggal revisi PIL
04/2025

21. Peringatan khusus
HARUS DENGAN RESEP DOKTER