Esamlo®
Levamlodipine Maleate
TABLET

DESCRIPTION
Esamlo® 2.5 Tablet
White convex round tablet with logo and dividing line (the tablet can be divided into two equal parts).
Esamlo® 5 Tablet
White convex round tablet with logo and without dividing line

COMPOSITION
Esamlo® 2.5 Tablet
Each tablet contains Levamlodipine maleate equivalent to 2.5 mg Levamlodipine
Esamlo® 5 Tablet
Each tablet contains Levamlodipine maleate equivalent to 5 mg Levamlodipine

PHARMACOLOGICAL PROPERTIES
Pharmacology
The active ingredient levamlodipine maleate is the maleate salt of levamlodipine, the pharmacologically active isomer of amlodipine, a long-acting calcium channel blocker. It is indicated for the treatment of hypertension in adults, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from a wide variety of pharmacologic classes including Levamlodipine. Levamlodipine may be used alone or in combination with other antihypertensive agents.
Levamlodipine maleate is chemically described as (S)3-ethyl-5-methyl-2-(2 aminoethoxymethyl)-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridine dicarboxylate maleate with a molecular weight of 524.95. Its empirical formula is C24H29CIN2O9.

Pharmacodynamic properties
Pharmacotherapeutic group : Cardiovascular system, selective calcium channel blockers with mainly vascular, dihydropyridine derivatives, ATC Code : C08CA17

Amlodipine is a calcium ion influx inhibitor (slow channel blocker or calcium ion antagonist) and inhibits the transmembrane influx of calcium ions into cardiac and vascular smooth muscle.

The mechanism of the antihypertensive action of amlodipine is due to adirect relaxant effect on vascular smooth muscle.

In patients with hypertension, once-daily dosing provides clinically significant reductions in blood pressure in both the supine and standing positions throughout the 24-hour interval. Due to the slow onset of action, acute hypotension is not a feature of amlodipine administration.

Amlodipine has not been associated with any adverse metabolic effects or changes in plasma lipids and is suitable for use in patients with asthma, diabetes, and gout.

Pharmacokinetics

Clinical studies conducted using Norvask® tablets as the Innovator.

Absorption

After oral administration of therapeutic doses, amlodipine is well absorbed with peak blood levels between 6 and 12 hours post-dose. Absolute bioavailability has been estimated to be between 64% and 80%. The volume of distribution is approximately 21 L/kg. In vitro studies have shown that approximately 97.5% of circulating amlodipines is bound to plasma proteins. Absorption of amlodipine is unaffected by consumption of food.

Biotransformation/Elimination

The terminal plasma elimination half-life is about 35 to 50 hours and is consistent with once-daily dosing. Steady-state plasma levels are reached after 7 to 8 days of consecutive dosing. Amlodipine is extensively metabolized by the liver to inactive metabolites, with 10% of the parent compound and 60% of metabolites excreted in the urine.

Use in the Elderly

The time to reach peak plasma concentrations of amlodipine is similar in elderly and younger subjects. Amlodipine clearance tends to be decreased with resulting increases in AUC and elimination half-life in elderly patients. Increases in AUC and elimination half-life in patients with CHF were as expected for the patient age group studied.

Preclinical Safety Data

Nonclinical studies conducted using Norvask® tablets as the Innovator

Carcinogenesis, Mutagenesis, Impairment of Fertility

Rats and mice treated with amlodipine in the diet for 2 years, at concentrations calculated to provide daily dosage levels of 0.5, 1.25, and 2.5mg/kg/day showed no evidence of carcinogenicity. The highest dose (for mice, similar to, and for rats twice* the maximum recommended clinical dose of 10 mg, on a mg/m2 basis) was close to the maximum tolerated dose for mice but not for rats.

Mutagenicity studies revealed no drug-related effects at either the gene or chromosome levels.

There was no effect on the fertility of rats treated with amlodipine (males for 64 days and females for 14 days prior to mating) at doses up to 10 mg/kg/day (8 times* the maximum recommended human dose of 10mg, on a mg/m2 basis).

*Based on patient weight of 50 kg.

Result and Conclusion of Bioequivalence Study of Levamlodipine 5 Mg Tablet Produced By PT Pratapa Nirmala In Comparison With Conjupri® tablets as the Innovator

Result

- AUC_{0-t}

  Means (SDs) AUC_{0-t} of Levamlodipine after single dose administration of the test drug and reference drugs were 77731.64 (43495.32) ng/mL.h and 70031.27 (36576.68) ng/mL.h, respectively. Statistical comparison of geometric means of Test drug versus Reference drug was 107.78% and 90% confidence intervals was 96.30 – 120.62%. CV intra subject was 19.34%.
- $AUC_{0-\infty}$

  Means (SDs) $AUC_{0-\infty}$ of Levamlodipine after single dose administration of the test drug and reference drugs were 84732.26 (46471.21) ng/mL.h and 76068.11 (39922.52) ng/mL.h, respectively. Statistical comparison of geometric means of Test drug versus Reference drug was 108.75% and 90% confidence intervals was 96.85 – 122.10%. CV intra subject was 19.90%.

- C_{max}
  Means (SDs) C_{max} of Levamlodipine after single dose administration of the test drug and reference drugs were 4767.85 (1629.71) ng/mL and 4723.03 (1661.98) ng/mL. respectively. Statistical comparison of geometric means of Test drug versus Reference drug was 100.09% and 90% confidence intervals was 91.70 – 109.23%. CV intra subject was 15.00%.
- $T_{1/2}$ and T_{max}
  Means (SDs) $T_{1/2}$ of Levamlodipine after single dose administration of the test drug and reference drugs were 17.09 (5.20) h and 16.96 (6.53) h, respectively. Means (SDs) T_{max} of Levamlodipine after single dose administration of the test drug and reference drugs were 6.83 (1.10) and 5.72 (1.02) h, respectively. Based on Wilcoxon Sign Rank test, statistically there was a significant difference between the T_{max} data of Test and Reference drug, while there was no significant difference between the $T_{1/2}$ data of Test drug and Reference.
- Adverse event There were no adverse events in this study.

Conclusion

From the result of study, it was concluded that Levamlodipine 5 mg tablet produced by PT Pratapa Nirmala was bioequivalent to its reference Conjupri® tablets as the Innovator

INDICATIONS

Levamlodipine Maleate is calcium channel blocker and may be used alone in combination with other antihypertensive agents for the treatment of hypertension in adults, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

POSOLOGY AND METHOD OF ADMINISTRATIONS

Posology

Adults

The usual initial antihypertensive oral dose of levamlodipine is 2.5 mg once daily, and the maximum dose is 5 mg once daily.

Small, fragile, or elderly patients, or patients with hepatic insufficiency may be started on 1.25 mg once daily and this dose may be used when adding levamlodipine to other antihypertensive therapy.

Adjust dosage according to blood pressure goals. In general, wait 7 to 14 days between titration steps. Titrate more rapidly, however, if clinically warranted, provided the patient is assessed frequently.

Method of Administrations

Esamlo® is given orally.

CONTRAINDICATIONS

Levamlodipine is contraindicated in patients with known hypersensitivity to dihydropyridines* or any of the inert ingredients.

*Amlodipine is a dihydropyridine calcium channel blocker

WARNING AND PRECAUTIONS

Use in Patients with Impaired Hepatic Function

As with all calcium antagonists, amlodipine's half-life is prolonged in patients with impaired liver function and dosage recommendations have not been established in these patients. The drug should therefore, be administered with caution in these patients.

ADVERSE REACTIONS

Clinical trials conducted using Norvask® tablets as the Innovator

Amlodipine is well tolerated. In placebo-controlled clinical trials involving patients with hypertension or angina, the most commonly observed side effects were:

MedDRA System Organ Class	**Undesirable Effects**
Nervous System Disorders	headaches, dizziness, somnolence
Cardiac Disorders	palpitations
Vascular Disorders	flushing
Gastrointestinal Disorders	abdominal pain, nausea
General Disorders and Administration Site Condition	oedema, fatigue

In these clinical trials, no pattern of clinically significant laboratory test abnormalities related to amlodipine has been observed.

Less commonly observed side effects in marketing experience include:

MedDRA System Organ Class	**Undesirable Effects**
Blood and Lymphatic System Disorders	leukopenia, thrombocytopenia
Metabolism and Nutrition Disorders	hyperglycaemia
Psychiatric Disorders	insomnia, mood altered
Nervous System Disorders	hypertonia, hypoaesthesia/paresthesia, neuropathy peripheral, syncope, dysgeusia, tremor, extrapyramidal disorder
Eye Disorders	visual impairment
Ear and Labyrinth Disorders	tinnitus
Vascular Disorders	hypotension, vasculitis
Respiratory, Thoracic, and Mediastinal Disorders	cough, dyspnoea, rhinitis
Gastrointestinal Disorders	change in bowel habits, dry mouth, dyspepsia (including gastritis), gingival hyperplasia, pancreatitis, vomiting
Skin and Subcutaneous Tissue Disorders	alopecia, hiperhidrosis, purpura, skin discoloration, urticaria
Musculoskeletal and Connective Tissue Disorders	Arthralgia, back pain, muscle spasms, myalgia
Renal and Urinary Disorders	pollakiuria, micturition disorder, nocturia
Reproductive System and Breast Disorders	gynaecomastia, erectile dysfunction
General Disorders and Administration Site Conditions	asthenia, malaise, pain
Investigations	weight increased/decreased

Rarely reported events were: allergic reaction including pruritus, rash, angioedema, and erythema multiforme.

Hepatitis, jaundice and hepatic enzyme elevations have also been reported very infrequently (mostly consistent with cholestasis). Some cases severe enough to require hospitalization have been reported in association with use of amlodipine. In many instances, causal association is uncertain.

As with other calcium channel blockers, the following adverse events have been rarely reported and cannot be distinguished from the natural history of the underlying disease: myocardial infarction, arrhythmia (including bradycardia, ventricular tachycardia, and atrial fibrillation) and chest pain.

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 at:
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,
Website: https://e-meso.pom.go.id/ADR
Reporting can also be done through our Pharmacovigilance Center at :
Email : pharmacovigilance@fahrenheit.co.id, pv@omegaresearch.id; Telepon : +62-21-3905831

DRUG INTERACTIONS
Amlodipine has been safely administered with thiazide diuretics, alpha-blockers, beta-blockers, ACE inhibitors, long-acting nitrates, sublingual nitroglycerine, non steroidal anti-inflammatory drugs, antibiotics, and oral hypoglycemic drugs.
In vitro data from studies with human-plasma indicate that amlodipine has no effect on protein binding of the drugs tested (digoxin, phenytoin, warfarin, or indomethacin).

Simvastatin
Co-administration of multiple doses of 10 mg amlodipine with 80 mg simvastatin resulted in a 77% increase in exposure to simvastatin compared to simvastatin alone. Limit the dose of simvastatin in patients on amlodipine to 20 mg daily.

Grapefruit Juice
Co-administration of 240 mL grapefruit juice with a single oral dose of 10 mg amlodipine in 20 healthy volunteers had no significant effect on the pharmacokinetics of amlodipine. The study did not allow examination of the effect of genetic polymorphism in CYP3A4, the primary enzyme responsible for metabolism of amlodipine; therefore, administration of amlodipine with grapefruit or grapefruit juice is not recommended as bioavailability may be increased in some patients,resulting in increased blood pressure lowering effects.

CYP3A4 Inhibitors

Co-administration of a 180 mg daily dose of diltiazem with 5 mg amlodipine in elderly hypertensive patients (69 to 87 years of age) resulted in a 57% increase in amlodipine systemic exposure. Co-administration of erythromycin in healthy volunteers (18 to 43 years of age) changed amlodipine systemic exposure (22% increase in area under the concentration versus time curve [AUC]). Although the clinical relevance of these findings is uncertain, pharmacokinetic variations may be more pronounced in the elderly. Strong inhibitors of CYP3A4 (e.g., ketoconazole, itraconazole, ritonavir) may increase the plasma concentrations of amlodipine to a greater extent than diltiazem. Amlodipine should be used with caution when administered with CYP3A4 inhibitors.

Clarithromycin

Clarithromycin is an inhibitor of CYP3A4. There is an increased risk of hypotension in patients receiving clarithromycin with amlodipine. Close observation of patients is recommended when amlodipine is co-administered with clarithromycin.

CYP3A4 Inducers

There is no data available regarding the effect of CYP3A4 inducers on amlodipine. Concomitant use of CYP3A4 inducers (e.g., rifampicin, hypericum perforatum) may decrease the plasma concentrations of amlodipine. Amlodipine should be used with caution when administered with CYP3A4 inducers.

In the following studies, there were no significant changes in the pharmacokinetics of either amlodipine or another drug within the study, when co-administered.

Special Studies: Effect of Other Agents on Amlodipine

Cimetidine

Co-administration of amlodipine with cimetidine did not alter the pharmacokinetics of amlodipine.

Aluminum/Magnesium (Antacid)

Co-administration of aluminum/magnesium (antacid) with a single dose of amlodipine had no significant effect on the pharmacokinetics of amlodipine.

Sildenafil

A single 100 mg dose of sildenafil in subjects with essential hypertension had no effect on the pharmacokinetic parameters of amlodipine. When amlodipine and sildenafil were used in combination, each agent independently exerted its own blood pressure lowering effect.

Special Studies: Effect of Amlodipine on Other Agents

Atorvastatin

Co-administration of multiple 10 mg doses of amlodipine with 80 mg atorvastatin resulted in no significant change in the steady-state pharmacokinetic parameters of atorvastatin.

Digoxin

Co-administration of amlodipine with digoxin did not change serum digoxin levels or digoxin renal clearance in healthy volunteers.

Ethanol (Alcohol)
Single and multiple 10 mg doses of amlodipine had no significant effect on the pharmacokinetics of ethanol.

Warfarin
Co-administration of amlodipine with warfarin did not change the warfarin prothrombin response time.

Cyclosporin
No drug interaction studies have been conducted with cyclosporin and amlodipine in healthy volunteers or other populations, with the exception of renal transplant patients. Various studies in renal transplant patients report that co-administration of amlodipine with cyclosporin affects the trough concentrations of cyclosporin, from no change up to an average increase of 40%. Consideration should be given for monitoring cyclosporin levels in renal transplant patients on amlodipine.

Tacrolimus
There is a risk of increased tacrolimus blood levels when co-administered with amlodipine. In order to avoid toxicity of tacrolimus, administration of amlodipine in a patient treated with tacrolimus requires monitoring of tacrolimus blood levels and dose adjustment of tacrolimus when appropriate.

Mechanistic Target of Rapamycin (mTOR) Inhibitors
mTOR inhibitors such as sirolimus, temsirolimus, and everolimus are CYP3A substrates. Amlodipine is a weak CYP3A inhibitor. With concomitant use of mTOR inhibitors, amlodipine may increase exposure of mTOR inhibitors.

Pregnancy and Lactation
The safety of amlodipine in human pregnancy or lactation has not been established. Amlodipine does not demonstrate toxicity in animal reproductive studies other than delay in parturition and prolongation of labor in rats at a dose level 50 times the maximum recommended dose in humans. Accordingly, use in pregnancy is only recommended when there is no safer alternative and when the disease itself carries greater risk for the mother and fetus. There was no effect on the fertility of rats treated with amlodipine (see section **Preclinical Safety Data**).

Experience in humans indicates that amlodipine is transferred into human breast milk. The median amlodipine concentration ratio of milk/plasma in 31 lactating women with pregnancy-induced hypertension was 0.85 following amlodipine administration at an initial dose of 5 mg once daily which was adjusted as needed (mean daily dose and body weight adjusted daily dose: 6 mg and 98.7 mcg/kg, respectively). The estimated daily dose of amlodipine in the infant via breast milk was 4.17 mcg/kg.

Effects on Ability to Drive and Use Machines
Clinical experience with amlodipine indicates that it is unlikely to impair a patient's ability to drive or use machinery.

OVERDOSAGE
Available data suggest that gross overdose could result in excessive peripheral vasodilatation and possibly reflex tachycardia. Marked and probably prolonged systemic hypotension, up to and including shock with fatal outcome, have been reported.

Administration of activated charcoal to healthy volunteers immediately after or up to 2 hours after amlodipine 10 mg ingestion has been shown to significantly decrease amlodipine absorption. Gastric lavage may be worthwhile in some cases. Clinically significant hypotension due to amlodipine overdose calls for active cardiovascular support, including frequent monitoring of cardiac and respiratory function, elevation of extremities, and attention to circulating fluid volume and urine output. A vasoconstrictor may be helpful in restoring vascular tone and blood pressure, provided there is no contraindication to its use. Intravenous calcium gluconate may be beneficial in reversing the effects of calcium channel blockade. Since amlodipine is highly protein-bound, dialysis is not likely to be of benefit.

LIST OF EXCIPIENTS
Sodium Starch Glycolate, Microcrystalline Cellulose, Beta Cyclodextrin, Colloidal Silicon Dioxide, Magnesium Stearate

STORAGE
Store below 30^{o}C, Protect from light.

PRESENTATION
Esamlo® 2.5 Tablet : Box, 3 strips @ 10 tablets, Reg. No. DKLxxxxxxxxxxx
Esamlo® 5 Tablet : Box, 3 strips @ 10 tablets, Reg. No. DKLxxxxxxxxxxx

DRUG CLASSIFICATION
Prescription Drug

ON MEDICAL PRESCRIPTION ONLY
HARUS DENGAN RESEP DOKTER

Manufactured by :
PT. PRATAPA NIRMALA
Tangerang – Indonesia

FAHRENHEIT

INFORMASI PRODUK UNTUK PASIEN

Esamlo®

Levamlodipine Maleate

TABLET

Apa itu Esamlo® Tablet?

Esamlo® tablet adalah obat yang diresepkan oleh dokter untuk mengobati tekanan darah tinggi (hipertensi) pada pasien dewasa. **Esamlo®** tablet dapat dikonsumsi secara tunggal atau dengan dikombinasi dengan obat darah tinggi lainnya.

Siapa yang tidak boleh menggunakan Esamlo® Tablet?

Jangan menggunakan **Esamlo®**

- jika Anda alergi terhadap amlodipine atau terhadap bahan lain yang terkandung dalam obat ini.
- jika anda alergi terhadap obat antagonis kalsium –dihydropyridines lainnya.
- konsultasikan kepada dokter atau apoteker bila anda merasa tidak yakin.

Apa yang harus pasien beritahukan pada dokter sebelum menggunakan Esamlo® Tablet?

Anda harus memberi tahu dokter jika Anda mempunyai atau pernah mengalami kondisi berikut:

- Gagal jantung
- Penyakit hati

Harap beritahu dokter atau apoteker Anda jika Anda sedang atau belum lama ini meminum obat lain, termasuk obat-obatan yang diperoleh tanpa resep.

Esamlo® dapat berpengaruh atau dipengaruhi oleh obat-obatan lain seperti:

- ketokonazol, itrakonazol (obat anti jamur)
- ritonavir (disebut juga inhibitor protease digunakan untuk pengobatan HIV)
- rifampisin, eritromisin, klaritromisin (antibiotik)
- Hypericum perforatum (St. John's Wort)
- diltiazem (obat jantung)
- takrolimus, sirolimus, temsirolimus, dan everolimus (obat-obatan yang digunakan untuk mengubah cara kerja sistem imun)
- simvastatin (obat penurun kolesterol))
- siklosporin (suatu imunosupresan)

Esamlo® dengan makanan dan minuman

Jus dan buah grapefruit tidak boleh dikonsumsi oleh orang yang meminum **Esamlo®**. Ini karena buah dan jus grapefruit dapat meningkatkan kadar bahan aktif obat di dalam darah, yang dapat menyebabkan peningkatan efek penurun tekanan darah yang tak terduga dari **Esamlo®**.

Apakah Esamlo® aman bagi ibu hamil dan menyusui?

Kehamilan

Keamanan amlodipine pada ibu hamil maupun ibu menyusui belum diketahui. Jika ada dugaan Anda sedang hamil, atau berencana untuk hamil, Anda harus memberitahu dokter Anda sebelum meminum **Esamlo®**.

Menyusui
Amlodipine telah terbukti dapat dialirkan ke dalam ASI dalam jumlah kecil. Jika Anda sedang menyusui atau hendak mulai menyusui, Anda harus memberi tahu dokter Anda sebelum meminum **Esamlo®**.

Apakah pasien diizinkan mengemudi dan mengoperasikan mesin saat menggunakan Esamlo®.?
Penggunaan **Esamlo®** kemungkinan tidak akan memengaruhi kemampuan pasien untuk mengemudi atau mengoperasikan mesin.

Bagaimana cara menggunakan Esamlo® Tablet?
Selalu gunakan obat ini dengan tepat sesuai anjuran dokter atau apoteker Anda. Tanyakan kepada dokter atau apoteker jika Anda merasa tidak yakin.

Dosis awal yang dianjurkan adalah 2,5 mg sekali sehari. Dosis ini dapat ditingkatkan menjadi maksimum 5 mg sekali sehari.

Obat Anda dapat diminum sebelum atau sesudah makan. Anda harus meminum obat Anda pada waktu yang sama setiap hari dengan meminum air. Jangan meminum **Esamlo®** dengan jus grapefruit.

Jika Anda lupa meminum Esamlo®
Jika Anda melewatkan satu dosis, minumlah segera setelah Anda ingat. Jangan minum **Esamlo®** jika sudah lebih dari 12 jam sejak Anda melewatkan dosis terakhir Anda. Tunggu dan ambil dosis berikutnya pada waktu yang sesuai. Jangan meminum dosis ganda untuk mengganti dosis yang terlewatkan.

Jika Anda berhenti meminum Esamlo®
Dokter Anda akan menentukan berapa lama Anda harus meminum obat. Kondisi sakit Anda dapat kembali jika Anda berhenti meminum obat sebelum waktu yang disarankan.
Jika Anda memiliki pertanyaan lebih lanjut seputar penggunaan obat ini, tanyakan kepada dokter atau apoteker Anda

Apa efek samping yang mungkin ditemukan pada penggunaan Esamlo® Tablet?
Seperti semua obat-obatan yang ada, obat ini bisa menimbulkan efek samping, meskipun tidak semua orang mengalaminya.
Efek samping yang **paling sering** teramati adalah:
- Sakit kepala, pusing, mengantuk
- Palpitasi (jantung berdebar), kulit panas dan memerah
- Sakit perut, merasa ingin muntah (mual)
- Edema (retensi cairan), kelelahan

Efek samping yang **tidak terlalu sering** teramati adalah:
- Penurunan jumlah sel darah putih, penurunan trombosit dalam darah yang dapat mengakibatkan memar yang tidak biasa atau mudah mengalami perdarahan
- Kadar gula dalam darah berlebih (hiperglikemia)
- Perubahan suasana hati, sulit tidur
- Peningkatan ketegangan otot
- Sensasi kebas atau kesemutan pada anggota gerak Anda, hilangnya sensasi nyeri

- Kelainan pada saraf yang dapat menyebabkan otot melemah, kesemutan, atau kebas
- Abnormalitas indra perasa, pingsan
- Gemetar, postur kaku, wajah seperti topeng, gerakan melambat, dan jalan menyeret dan tidak seimbang
- Gangguan penglihatan, penglihatan ganda
- Telinga berdenging
- Tekanan darah rendah
- Peradangan pembuluh darah, sering kali disertai ruam kulit
- Batuk
- Kesulitan bernapas
- Bersin/pilek yang disebabkan oleh peradangan dinding rongga hidung (rinitis)
- Perubahan kebiasaan buang air besar, mulut kering, muntah (rasa ingin muntah)
- Gangguan saluran cerna, perut kembung yang tidak normal (gastritis)
- Pembengkakan gusi
- Peradangan pankreas yang dapat menyebabkan nyeri punggung dan abdominal yang parah disertai dengan perasaan sangat tidak sehat
- Rambut rontok, produksi keringat meningkat, gatal-gatal pada kulit, bercak kemerahan pada kulit, perubahan warna kulit
- Nyeri, merasa tidak enak badan
- Nyeri pada sendi atau otot, sakit punggung
- Kelainan saat buang air kecil, meningkatnya kebutuhan untuk buang air kecil di malam hari, meningkatnya intensitas buang air kecil
- Disfungsi ereksi, rasa tidak nyaman atau terjadi pembesaran payudara pada laki-laki
- Peningkatan atau penurunan berat badan

Kejadian yang **jarang** dilaporkan adalah:

- Reaksi alergi di antaranya gatal-gatal pada kulit, ruam, pembengkakan, dan bercak kemerahan pada kulit
- Fungsi hati yang tidak normal, peradangan hati (hepatitis), kulit menguning (penyakit kuning), peningkatan enzim hati yang dapat memengaruhi hasil beberapa tes kesehatan.

Pelaporan Efek Samping

Jika mengalami efek samping apa pun, sampaikan kepada dokter atau apoteker termasuk jika mengalami efek samping yang mungkin terjadi yang tidak tercantum pada leaflet ini. Dengan melaporkan efek samping yang terjadi, anda dapat membantu memberikan informasi lebih lanjut mengenai keamanan obat ini. Laporkan setiap efek samping yang dicurigai merugikan melalui Pusat Farmakovigilans kami di :

Email : pharmacovigilance@fahrenheit.co.id, pv@omegaresearch.id; Telepon : +62-21-3905831

Tanda-tanda dan gejala-gejala overdosis

Meminum tablet terlalu banyak dapat menurunkan tekanan darah Anda hingga menjadi terlalu rendah atau bahkan berbahaya. Jika tekanan darah Anda turun terlalu rendah dapat menyebabkan terjadinya renjatan.

Apa yang harus dilakukan jika Anda menggunakan lebih dari dosis yang dianjurkan?

Jika Anda tanpa sengaja meminum terlalu banyak tablet **Esamlo®**, segera hubungi dokter Anda atau datangi unit gawat darurat di rumah sakit terdekat.

Bawa selalu kemasan obat berlabel, baik yang masih ada tablet **Esamlo®** yang tersisa di dalamnya atau tidak.
Jangan meminum tablet lagi hingga dokter Anda memerintahkan Anda.

Bagaimana cara menyimpan Esamlo® Tablet?
Simpan **Esamlo®** tablet pada suhu di bawah 30°C, terlindung dari cahaya.
Jauhkan Esamlo® tablet dan semua obat dari jangkauan anak-anak

Informasi umum tentang penggunaan Esamlo® Tablet yang aman dan efektif
Jangan gunakan **Esamlo®** tablet untuk mengobati penyakit selain yang memang diresepkan oleh dokter.
Jangan berikan **Esamlo®** tablet kepada orang lain, meskipun mereka mempunyai gejala yang sama dengan yang anda alami, karena dapat membahayakan mereka.
Anda dapat menanyakan pada apoteker atau dokter mengenai informasi terkait **Esamlo®** tablet yang ditunjukan untuk petugas kesehatan.

Apa komposisi Esamlo® Tablet?
Zat aktif : Levamlodipine Maleate
Zat tambahan : Sodium Starch Glycolate, Microcrystalline Cellulose, Beta Cyclodextrin, Colloidal Silicon Dioxide, Magnesium Stearate

Kemasan
Esamlo® 2,5 mg Tablet : Dus, 3 Strip @ 10 Tablet, No. Reg. DKLXXXXXXXXXX
Esamlo® 5 mg Tablet : Dus, 3 Strip @ 10 Tablet, No. Reg. DKLXXXXXXXXXX

HARUS DENGAN RESEP DOKTER

Diproduksi oleh :
PT. PRATAPA NIRMALA
Tangerang - Indonesia

FAHRENHEIT

Telah Diperiksa & Disetujui Oleh			
Packdev	Formulasi	RnD Manager	Registrasi