Film Coated Tablets

COZAAR®

(losartan potassium)

THERAPEUTIC CLASS

COZAAR® (losartan potassium), the first of a new class of antihypertensives, is an angiotensin II receptor (type AT1) antagonist.

INDICATIONS

COZAAR is indicated for the treatment of hypertension.

DOSAGE AND ADMINISTRATION

The usual starting and maintenance dose is 50 mg once daily for most patients. The maximal antihypertensive effect is attained 3-6 weeks after initiation of therapy. Some patients may receive an additional benefit by increasing the dose to 100 mg once daily.
For patients with intravascular volume-depletion (e.g., those treated with high-dose diuretics), a starting dose of 25 mg once daily should be considered (see PRECAUTIONS).

No initial dosage adjustment is necessary for elderly patients or for patients with mild renal impairment (i.e. creatinine clearance 20-50 mL/min). For patients with moderate to severe renal impairment (i.e. creatinine clearance <20 mL/min) or patients on dialysis, a lower starting dose of 25 mg once daily is recommended.

A lower dose should be considered for patients with a history of hepatic impairment (see PRECAUTIONS).

COZAAR may be administered with other antihypertensive agents.

COZAAR may be administered with or without food.

CONTRAINDICATIONS

COZAAR is contraindicated in patients who are hypersensitive to any component of this product.

COZAAR should not be administered with aliskiren in patients with diabetes (see DRUG INTERACTIONS).

PRECAUTIONS

General: Although Cozaar is antihypertensive in all races; as with other drugs that affect the renin-angiotensin-aldosterone system, black hypertensive patients have a smaller average response to losartan monotherapy. If Cozaar is given together with thiazide-type diuretics, the blood-pressure-lowering effects are approximately additive. Losartan potassium administered in doses of up to 150 mg once daily did not cause clinically important changes in fasting triglyserides, total cholesterol or HDL cholesterol, in patients with hypertension. The same dose of losartan had no effect on fasting glucose levels. Cozaar should not be used with potassium-sparing diuretics.

Fetal Toxicity
Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. Resulting oligohydramnios can be associated with fetal lung hypoplasia and skeletal deformations. Potential neonatal adverse effects include skull hypoplasia, anuria, hypotension, renal failure, and death. When

pregnancy is detected, discontinue COZAAR as soon as possible. See PREGNANCY.

Hypersensitivity: Angioedema. See SIDE EFFECTS.

Hypotension and Electrolyte/Fluid Imbalance
In patients who are intravascularly volume-depleted (e.g., those treated with high-dose diuretics), symptomatic hypotension may occur. These conditions should be corrected prior to administration of COZAAR, or a lower starting dose should be used (see DOSAGE AND ADMINISTRATION).

Electrolyte imbalances are common in patients with renal impairment, with or without diabetes, and should be addressed. In a clinical study conducted in type 2 diabetic patients with proteinuria, the incidence of hyperkalemia was higher in the group treated with COZAAR as compared to the placebo group; however, few patients discontinued therapy due to hyperkalemia (see SIDE EFFECTS and LABORATORY TEST FINDINGS).

Concomitant use of other drugs that may increase serum potassium may lead to hyperkalemia (see DRUG INTERACTIONS).

Liver Function Impairment
Based on pharmacokinetic data which demonstrate significantly increased plasma concentrations of losartan in cirrhotic patients, a lower dose should be considered for patients with a history of hepatic impairment (see DOSAGE AND ADMINISTRATION).

Renal Function Impairment
As a consequence of inhibiting the renin-angiotensin system, changes in renal function including renal failure have been reported in susceptible individuals; these changes in renal function may be reversible upon discontinuation of therapy.

Other drugs that affect the renin-angiotensin system may increase blood urea and serum creatinine in patients with bilateral renal artery stenosis or stenosis of the artery to a solitary kidney. While not confirmed, this potentially may occur with angiotensin II receptor antagonists.

PREGNANCY

Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.

When pregnancy is detected, discontinue COZAAR as soon as possible.

Although there is no experience with the use of COZAAR in pregnant women, animal studies with losartan potassium have demonstrated fetal and neonatal injury and death, the mechanism of which is believed to be pharmacologically mediated through effects on the renin-angiotensin system. In humans, fetal renal perfusion, which is dependent upon the development of the renin-angiotensin system, begins in the second trimester; thus, risk to the fetus increases if COZAAR is administered during the second or third trimesters of pregnancy.

Use of drugs that act on the renin-angiotensin system during the second and third trimesters of pregnancy reduces fetal renal function and increases fetal and neonatal morbidity and death. Resulting oligohydramnios can be associated with fetal lung hypoplasia and skeletal deformations. Potential neonatal adverse effects include skull hypoplasia, anuria, hypotension, renal failure, and death. When pregnancy is detected, discontinue COZAAR as soon as possible.

These adverse outcomes are usually associated with the use of these drugs in the second and third trimesters of pregnancy. Most epidemiologic studies examining fetal abnormalities after exposure to antihypertensive use in the first trimester have not distinguished drugs affecting the renin-angiotensin

system from other antihypertensive agents. Appropriate management of maternal hypertension during pregnancy is important to optimize outcomes for both mother and fetus.

In the unusual case that there is no appropriate alternative to therapy with drugs affecting the renin-angiotensin system for a particular patient, apprise the mother of the potential risk to the fetus. Perform serial ultrasound examinations to assess the intra-amniotic environment. If oligohydramnios is observed, discontinue COZAAR, unless it is considered life-saving for the mother. Fetal testing may be appropriate, based on the week of pregnancy. Patients and physicians should be aware, however, that oligohydramnios may not appear until after the fetus has sustained irreversible injury. Closely observe infants with histories of in utero explosure to COZAAR for hypotension, oliguria, and hyperkalemia.

NURSING MOTHERS

It is not known whether losartan is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

PEDIATRIC USE

Neonates with a history of in utero exposure to COZAAR:
If oliguria or hypotension occur, direct attention toward support of blood pressure and renal perfusion. Exchange transfusions or dialysis may be required as a means of reversing hypotension and/or substituting for disordered renal function.

USE IN THE ELDERLY

In clinical studies there was no age-related difference in the efficacy or safety profile of losartan.

DRUG INTERACTIONS

In clinical pharmacokinetic trials, no drug interactions of clinical significance have been identified with hydrochlorothiazide, digoxin, warfarin, cimetidine phenobarbital, ketoconazole and erythromycin. Rifampin and fluconazole have been reported to reduce levels of active metabolite. The clinical consequences of these interactions have not been evaluated.

As with other drugs that block angiotensin II or its effects, concomitant use of potassium-sparing diuretics (e.g., spironolactone, triamterene, amiloride), potassium supplements, salt substitutes containing potassium, or other drugs that may increase serum potassium (e.g., trimethoprim-containing products) may lead to increases in serum potassium.

As with other drugs which affect the excretion of sodium, lithium excretion may be reduced. Therefore, serum lithium levels should be monitored carefully if lithium salts are to be co-administered with angiotensin II receptor antagonists.

Non-steroidal anti-inflammatory drugs (NSAIDs) including selective cyclooxygenase-2 inhibitors (COX-2 inhibitors) may reduce the effect of diuretics and other antihypertensive drugs. Therefore, the antihypertensive effect of angiotensin II receptor antagonists or ACE inhibitors may be attenuated by NSAIDs including selective COX-2 inhibitors.

In some patients with compromised renal function (e.g., elderly patients or patients who are volume-depleted, including those on diuretic therapy) who are being treated with non-steroidal anti-inflammatory drugs, including selective cyclooxygenase-2 inhibitors, the co-administration of angiotensin II receptor antagonists or ACE inhibitors may result in a further deterioration of renal function, including possible acute renal failure. These effects are usually reversible. Therefore, the combination should be

administered with caution in patients with compromised renal function.

Dual blockade of the renin-angiotensin-aldosterone system (RAAS) with angiotensin receptor blockers, ACE inhibitors, or aliskiren is associated with increased risks of hypotension, syncope, hyperkalemia, and changes in renal function (including acute renal failure) compared to monotherapy. Closely monitor blood pressure, renal function, and electrolytes in patients on COZAAR and other agents that affect the RAAS. Do not co-administer aliskiren with COZAAR in patients with diabetes. Avoid use of aliskiren with COZAAR in patients with renal impairment (GFR <60 mL/min).

Grapefruit juice contains components that inhibit CYP 450 enzymes and may lower the concentration of the active metabolite of COZAAR which may reduce the therapeutic effect. Consumption of grapefruit juice should be avoided while taking COZAAR.

SIDE EFFECTS

COZAAR has been found to be generally well tolerated in controlled clinical trials for hypertension; side effects have usually been mild and transient in nature and have not required discontinuation of therapy. The overall incidence of side effects reported with COZAAR was comparable to placebo.

In controlled clinical trials for essential hypertension, dizziness was the only side effect reported as drug related that occurred with an incidence greater than placebo in one percent or more of patients treated with COZAAR. In addition, dose-related orthostatic effects were seen in less than one percent of patients. Rarely, rash was reported, although the incidence in controlled clinical trials was less than placebo.

The following additional adverse reactions have been reported in post-marketing experience:

Hypersensitivity: Anaphylactic reactions, angioedema including swelling of the larynx and glottis causing airway obstruction and/or swelling of the face, lips, pharynx and/or tongue has been reported rarely in patients treated with losartan; some of these patients previously experienced angioedema with other drugs including ACE inhibitors. Vasculitis, including Henoch-Schoenlein purpura, has been reported rarely.
Gastrointestinal: Hepatitis (reported rarely), liver function abnormalities, vomiting.
General disorders and administration site conditions: Malaise.
Hematologic: Anemia, thrombocytopenia (reported rarely).
Musculoskeletal: Myalgia, arthralgia.
Nervous System/Psychiatric: Migraine, dysgeusia.
Reproductive system and breast disorders: Erectile dysfunction/impotence.
Respiratory: Cough.
Skin: Urticaria, pruritus, erythroderma, photosensitivity.

LABORATORY TEST FINDINGS

In controlled clinical trials, clinically important changes in standard laboratory parameters were rarely associated with administration of COZAAR. Hyperkalemia (serum potassium >5.5 mEq/L) occurred in 1.5% of patients, but in these trials, discontinuation of losartan therapy due to hyperkalemia was not necessary. Elevations of ALT occurred rarely and usually resolved upon discontinuation of therapy.

Serum potassium should be monitored, particularly in the elderly and patients with renal impairment.

OVERDOSAGE

Limited data are available in regard to overdosage in humans. The most likely manifestation of overdosage would be hypotension and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation. If symptomatic hypotension should occur, supportive treatment should be instituted.

Neither losartan nor the active metabolite can be removed by hemodialysis.

AVAILABILITY

Box of 2 blisters of 15 film coated tablets each. Each tablet contains 50 mg losartan potassium.

STORAGE AND HANDLING

Store below 30°C. (86°F.) and protect from light. Shelf life: 36 months

Manufactured by
Organon Pharma (UK) Limited, Cramlington, England

HARUS DENGAN RESEP DOKTER

Registered and packed by
PT Organon Pharma Indonesia Tbk
Pasuruan, Jawa Timur

Reg. No.: DKL2006609617A1

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PI Version 4.0

ORGANON

INFORMASI MENGENAI COZAAR UNTUK PASIEN

Harap baca leaflet ini dengan seksama sebelum anda mulai minum obat ini, walau anda telah menggunakan obat ini sebelumnya. Beberapa informasi dalam leaflet sebelumnya dapat berubah.
Ingatlah bahwa dokter anda meresepkan obat ini hanya untuk anak anda. Jangan berikan kepada orang lain.

Apakah COZAAR

COZAAR (losartan potassium) adalah tablet salut selaput berwarna putih, berbentuk oval mengandung 50 mg losartan potasium sebagai bahan aktif.

Selain itu, COZAAR mengandung zat tambahan sebagai berikut: *Microcrystalline Cellulose, Lactose Hydrous, Pregelatinized Starch, Magnesium Stearate, Hydroxypropyl Cellulose, Hypromellose, Titanium Dioxide, Purified Water, Carnauba Wax*

Meskipun COZAAR mengandung jumlah kalium yang sangat kecil, namun tidak dapat menggantikan suplemen kalium. Jika dokter Anda telah meresepkan suplemen kalium, terus ikuti sarannya.

COZAAR tersedia sebagai tablet 50 mg.

Didaftarkan oleh:

PT Organon Pharma Indonesia Tbk

Pasuruan, Jawa Timur

Produsen Pembuat Produk:

Organon Pharma (UK) Limited, Cramlington, England

Mengapa dokter saya meresepkan COZAAR?

Dokter Anda telah meresepkan COZAAR karena Anda memiliki kondisi yang dikenal sebagai hipertensi (tekanan darah tinggi).

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Bagaimana cara kerja Cozaar?

COZAAR bekerja dengan memperlebar pembuluh darah Anda untuk memudahkan jantung memompa darah ke seluruh bagian tubuh Anda. Ini membantu mengurangi tekanan darah tinggi.

Informasi untuk Pasien dengan Tekanan Darah Tinggi

Apa itu tekanan darah?
Tekanan yang disebabkan oleh jantung yang memompa darah ke seluruh bagian tubuh Anda disebut tekanan darah. Tanpa tekanan darah tidak akan ada sirkulasi darah di tubuh Anda. Tekanan darah normal adalah bagian dari kesehatan yang baik. Tekanan darah Anda berubah sepanjang hari tergantung pada aktivitas, stres, dan kegembiraan.

Tekanan darah Anda terdiri dari dua angka, misalnya 120/80. Angka teratas mengukur gaya saat jantung Anda memompa. Angka bawah mengukur gaya saat istirahat, di antara detak jantung.

Apa itu tekanan darah tinggi (atau hipertensi)?
Anda memiliki tekanan darah tinggi atau hipertensi jika tekanan darah Anda tetap tinggi bahkan ketika Anda tenang dan rileks. Tekanan darah tinggi berkembang ketika pembuluh darah mengencang, sehingga lebih sulit bagi darah untuk lewat.

Bagaimana saya tahu jika saya memiliki tekanan darah tinggi?
Biasanya tidak ada gejala tekanan darah tinggi. Satu-satunya cara mengetahui bahwa Anda memiliki hipertensi adalah mengetahui tekanan darah Anda. Oleh karena itu, Anda harus memeriksakan tekanan darah Anda secara teratur.

Mengapa tekanan darah tinggi harus dirawat?
Tekanan darah tinggi jika tidak ditangani dapat merusak organ vital seperti jantung dan ginjal. Anda mungkin merasa baik-baik saja dan tidak memiliki gejala, tetapi akhirnya hipertensi dapat menyebabkan stroke, serangan jantung, gagal jantung, gagal ginjal atau kebutaan.

Bagaimana seharusnya tekanan darah tinggi dirawat?

Setelah tekanan darah tinggi didiagnosis, beberapa perawatan selain obat mungkin direkomendasikan. Dokter Anda dapat merekomendasikan beberapa perubahan dalam gaya hidup. Dokter Anda mungkin memutuskan bahwa Anda juga memerlukan obat untuk mengontrol tekanan darah Anda. Tekanan darah tinggi dapat diobati dan dikendalikan dengan mengambil obat-obatan seperti COZAAR.

Dokter Anda dapat memberi tahu Anda apa target tekanan darah individu Anda seharusnya. Ingatlah nomor ini dan ikuti saran dokter Anda tentang cara mencapai target ini.

Bagaimana COZAAR mengobati tekanan darah tinggi?
COZAAR menurunkan tekanan darah dengan secara khusus memblokir zat yang disebut angiotensin II. Angiotensin II biasanya mengencangkan pembuluh darah Anda. Perawatan dengan COZAAR memungkinkan mereka untuk bersantai. Meskipun dokter Anda akan dapat memberi tahu Anda bahwa obat tersebut bekerja dengan mengukur tekanan darah Anda, Anda mungkin akan merasa tidak berbeda ketika Anda meminum COZAAR.

Apa yang menyebabkan penebalan bilik kiri jantung?

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Tekanan darah tinggi menyebabkan jantung bekerja lebih keras. Seiring waktu, ini dapat menyebabkan jantung menebal

Apa yang harus saya ketahui sebelum mengambil COZAAR?

Siapa yang tidak boleh mengambil COZAAR?

Jangan mengambil COZAAR jika Anda alergi terhadap bahan-bahannya.
Jangan minum COZAAR jika Anda menderita diabetes dan minum obat yang disebut aliskiren untuk mengurangi tekanan darah.

Gunakan dalam kehamilan dan menyusui

Penggunaan COZAAR saat Anda hamil atau menyusui tidak dianjurkan. COZAAR dapat menyebabkan bahaya atau kematian pada bayi yang belum lahir. Bicarakan dengan dokter Anda tentang cara lain untuk menurunkan tekanan darah Anda jika Anda berencana untuk hamil. Jika Anda hamil saat meminum COZAAR, segera hubungi dokter.

Apa yang harus saya sampaikan kepada dokter atau apoteker saya sebelum menggunakan COZAAR?

Katakan kepada dokter atau apoteker Anda tentang masalah medis yang Anda miliki atau alami, dan tentang alergi apa pun. Katakan kepada dokter Anda jika Anda baru saja mengalami muntah atau diare yang berlebihan. Sangat penting untuk memberi tahu dokter Anda jika Anda memiliki penyakit hati atau ginjal.

Katakan kepada dokter Anda jika Anda mengonsumsi obat lain yang dapat meningkatkan serum kalium (lihat **Dapatkah saya mengkonsumsi COZAAR dengan obat-obatan lain atau zat lain?**).

Penggunaan pada orang tua

COZAAR bekerja sama baiknya dan sama-sama ditolerir dengan baik oleh kebanyakan pasien dewasa yang lebih tua dan lebih muda. Kebanyakan pasien yang lebih tua memerlukan dosis yang sama dengan pasien yang lebih muda.

Dapatkah saya mengonsumsi COZAAR dengan obat-obatan lain atau zat lain?

Secara umum, COZAAR tidak berinteraksi dengan makanan atau obat-obatan lain yang mungkin Anda konsumsi. Bagaimanapun anda harus memberi tahu dokter Anda tentang semua obat yang Anda konsumsi atau berencana untuk konsumsi, termasuk yang diperoleh tanpa resep. Penting untuk memberi tahu dokter Anda jika Anda mengonsumsi:

- suplemen kalium
- agen pengimbang kalium
- pengganti garam yang mengandung kalium atau obat lain yang dapat meningkatkan serum potasium (misalnya, produk yang mengandung trimethoprim)
- obat pereda nyeri dan arthritis tertentu
- obat tekanan darah lainnya, atau lithium (obat yang digunakan untuk mengobati depresi tertentu)
- *grapefruit juice* (harus dihindari saat mengonsumsi COZAAR)

Dapatkah saya mengemudi atau mengoperasikan mesin saat menggunakan COZAAR?

Hampir semua pasien dapat, tetapi Anda tidak boleh melakukan tugas yang mungkin memerlukan perhatian khusus (misalnya, mengendarai mobil atau mengoperasikan mesin berbahaya) sampai Anda tahu bagaimana Anda mentoleransi obat Anda.

Bagaimana saya harus mengonsumsi COZAAR?

Minum COZAAR setiap hari, persis seperti yang diinstruksikan dokter Anda. Dokter Anda akan memutuskan dosis COZAAR yang tepat, tergantung pada kondisi Anda dan apakah Anda mengonsumsi obat lain. Penting untuk terus menggunakan COZAAR selama dokter meresepkannya untuk menjaga tekanan darah Anda tetap terkontrol.

Tekanan darah tinggi

Dosis umum COZAAR untuk sebagian besar pasien dengan tekanan darah tinggi adalah 50 mg sekali sehari untuk mengontrol tekanan darah selama 24 jam.

COZAAR dapat dikonsumsi dengan atau tanpa makanan. Demi kenyamanan dan untuk membantu Anda mengingat, cobalah untuk mengambil COZAAR pada waktu yang sama setiap hari.

Apa yang harus saya lakukan jika terjadi overdosis?

Dalam kasus overdosis, hubungi dokter Anda segera sehingga perhatian medis dapat diberikan segera.

Apa yang harus saya lakukan jika saya melewatkan dosis?

Cobalah untuk mengambil COZAAR setiap hari seperti yang ditentukan. Namun, jika Anda melewatkan dosis, jangan mengambil dosis ekstra. Lanjutkan saja jadwal biasa Anda.

Apa efek yang mungkin tidak diinginkan COZAAR miliki?

Obat apapun dapat memiliki efek yang tidak diinginkan yang disebut efek samping. Beberapa pasien mungkin mengalami pusing, kelelahan, kepala terasa ringan, ruam, gatal-gatal, perubahan rasa, muntah atau peningkatan kepekaan kulit terhadap matahari. Dokter atau apoteker Anda memiliki daftar yang lebih lengkap. Beritahukan kepada dokter atau apoteker Anda segera tentang ini atau gejala tidak biasa lainnya.

Beberapa pasien, terutama mereka yang menderita diabetes tipe 2 dengan protein dalam urin, mungkin juga mengalami peningkatan kadar kalium dalam darah mereka. Jika Anda memiliki penyakit ginjal dan diabetes tipe 2 dengan protein dalam urin, dan / atau mengonsumsi suplemen kalium, agen pengimbang kalium atau pengganti garam yang mengandung kalium, bicarakan dengan dokter Anda.

Jika Anda mengembangkan reaksi alergi yang melibatkan pembengkakan wajah, bibir, tenggorokan dan / atau lidah yang dapat menyebabkan kesulitan bernapas atau menelan, berhenti minum COZAAR dan segera hubungi dokter Anda.

Bagaimana saya bisa belajar lebih banyak tentang COZAAR dan kondisi saya?

Anda dapat memperoleh informasi lebih lanjut dari dokter atau apoteker Anda, yang memiliki informasi lebih rinci tentang kondisi Anda dan COZAAR.

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Berapa lama saya harus menyimpan obat saya?

Jangan gunakan obat ini setelah tanggal pada keterangan setelah kata Exp. Date pada kemasan.

Bagaimana saya harus menyimpan COZAAR?
Simpan pada suhu di bawah 30ºC (86ºF) dan lindungi dari cahaya.

Jauhkan obat dari jangkauan anak-anak.

HARUS DENGAN RESEP DOKTER

Cozaar, Dus, 2 blister @ 15 tablet salut selaput

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