Lostapressin

Not used during pregnancy, as it may cause injury or death of the developing fetus.

Lostapressin 25mg, 50mg and 100 mg F. C. tablets:
Active ingredients:
LOSARTAN POTASSIUM 25, 50 and 100mg.
Inactive ingredients for Lostapressin 25mg, 50mg F.C. tablets:
•Microcrystalline cellulose
•Lactose monohydrate.
•Hydroxy propyl methyl cellulose
•Magnesium stearate
•Starch1500
•Polyethylene glycol 6000
•Titanium dioxide
Inactive ingredients for 100 mg tablets:
•Croscarmellose sodium
•Lactose
•Magnesium stearate
•Microcrystalline cellulose
•Aerosil 200
•Hydroxy propyl methyl cellulose
•Titanium dioxide
•Polyethylene glycol
Clinical Pharmacology:
Mechanism of action:
Angiotensin II [formed from angiotensin I in a reaction catalyzed by angiotensin converting enzyme (ACE, kininase II)], is a potent vasoconstrictor, the primary vasoactive hormone of the rennin angiotensin system and an important component in the pathophysiology of hypertension. It also stimulates aldosterone secretion by the adrenal cortex. Losartan and its principal active metabolite block the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor found in many tissues, (e.g., vascular smooth muscle, adrenal gland).
There is also an AT2 receptor found in many tissues but it is not known to be associated with cardiovascular homeostasis. Both losartan and its principal active metabolite do not exhibit any partial agonist activity at the AT1 receptor and have much greater affinity (about 1000-fold) for the AT1 receptor than for the AT2 receptor. In vitro binding studies indicate that losartan is a reversible, competitive inhibitor of the AT2 receptor. The active metabolite is 10 to 40 times more potent by weight than losartan and appears to be a reversible, non-competitive inhibitor of the AT1 receptor.
Neither losartan nor its active metabolite inhibits ACE (kininase II, the enzyme that converts angiotensin I to angiotensin II and degrades bradykinin); nor do they bind to or block other hormone receptors or ion channels known to be important in cardiovascular regulation.
PHARMACOKINETICS:
General:
Losartan is an orally active agent that undergoes substantial first-pass metabolism by cytochrome P450 enzymes. It is converted, in part, to an active carboxylic acid metabolite that is responsible for most of the angiotensin II receptor antagonism that follows losartan treatment.
Losartan metabolites have been identified in human plasma and urine. In addition to the active carboxylic acid metabolite, several inactive metabolites are formed. Following oral and intravenous administration of ^{14}C-labeled losartan potassium, circulating plasma radioactivity is primarily attributed to losartan and its active metabolite.
The terminal half-life of losartan is about 2 hours and of the metabolite is about 6-9 hours. The pharmacokinetics of losartan and its active metabolite are linear with oral losartan doses up to 200 mg and do not change over time. Neither losartan nor its metabolite accumulates in plasma upon repeated once-daily dosing.
Following administration, losartan is well absorbed (based on absorption of radio labeled losartan) and undergoes substantial first-pass metabolism; the systemic bioavailability of losartan is approximately 33%. About 14% of an orally-administered dose of losartan is converted to the active metabolite. Mean peak concentrations of losartan and its active metabolite are reached in 1 hour and in 3-4 hours, respectively. While maximum plasma concentrations of losartan and its active metabolite are approximately equal, the AUC of the metabolite is about 4 times as great as that of losartan. A meal slows absorption of losartan and decreases its C max but has only minor effects on losartan AUC or on the AUC of the metabolite (about 10% decreased).
The volume of distribution of losartan and the active metabolite is about 34 liters and 12 liters, respectively. Total plasma clearance of losartan and the active metabolite is about 600 mL/min and 50 mL/min, respectively, with renal clearance of about 75 mL/min and 25 mL/min, respectively. After single doses of losartan administered orally, about 4% of the dose is excreted unchanged in the urine and about 6% is excreted in urine as active metabolite. Biliary excretion contributes to the elimination of losartan and its metabolites.
Following oral ^{14}C-labeled losartan, about 35% of radioactivity is recovered in the urine and about 60% in the feces.
Both losartan and its active metabolite are highly bound to plasma proteins, primarily albumin, with plasma free fractions of 1.3% and 0.2% respectively.
Plasma protein binding is constant over the concentration range achieved with recommended doses.
Special populations:
Pediatric:
Pharmacokinetics of losartan and its active metabolite were generally similar across the studied age groups and similar to historical pharmacokinetic data in adults.
Pharmacodynamics and clinical effects:
Adult hypertension:
Losartan inhibits the pressor effect of angiotensin II (as well as angiotensin I) infusions. A dose of 100 mg inhibits the pressor effect by about 85% at peak with 25-40% inhibition persisting for 24 hours.
Removal of the negative feedback of angiotensin II causes a 2 to 3 fold rise in plasma rennin activity and consequent rise in angiotensin II plasma concentration in hypertensive patients. Losartan does not affect the response to bradykinin, whereas ACE inhibitors increase the response to bradykinin. Aldosterone plasma concentrations fall following losartan administration. In spite of the effect of losartan on aldosterone secretion, very little effect on serum potassium was observed.
LOSTAPRESSIN was effective in reducing blood pressure regardless of race, although the effect was somewhat less in black patients (usually allow-rennin population).
The effect of losartan is substantially present within one week but in some studies the maximal effect occurred in 3-6 weeks.There is no apparent rebound effect after abrupt withdrawal of losartan. There was essentially no change in average heart rate in losartan treated patients in controlled trials.
INDICATIONS AND USAGE
Hypertension
LOSTAPRESSIN is indicated for the treatment of hypertension.
It may be used alone or in combination with other antihypertensive agents, including diuretics.
Hypertensive Patients with Left Ventricular Hypertrophy
Lostapressin is indicated to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy, but there is evidence that this benefit does not apply to black patients.
Nephropathy in Type 2 Diabetic Patients
Lostapressin is indicated for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (urinary albumin to creatinine ratio ≥300 mg/g) in patients with type 2 diabetes and a history of hypertension. In this population, lostapressin reduces the rate of progression of nephropathy as measured by the occurrence of doubling of serum creatinine or end stage renal disease (need for dialysis or renal transplantation).
CONTRAINDICATIONS:
•LOSTAPRESSIN is contraindicated in patients who are hypersensitive to any component of this product.
•Pregnancy.
·The concomitant use of (lostapressin) with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60ml/min/1.73m2).
WARNINGS:
Fetal/Neonatal Morbidity and Mortality
Drugs that act directly on the rennin- 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, LOSTAPRESSIN should be discontinued as soon as possible. The use of drugs that act directly on the rennin-angiotensin system during the 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 function; 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 occurrences were due to exposure to the drug.
These adverse effects do not appear to have resulted from intrauterine drug exposure that has been limited to the first trimester.
Mothers whose embryos and fetuses are exposed to an angiotensin II receptor antagonist only during the first trimester should be so informed. Nonetheless, when patients become pregnant, physicians should have the patient discontinue the use of LOSTAPRESSIN as soon as possible.
Rarely (probably less often than once in every thousand pregnancies), no alternative to an angiotensin II receptor antagonist will be found.
In these rare cases, the mothers should be apprised of the potential hazards to their fetuses, and serial ultrasound examinations should be performed to assess the intra-amniotic environment.
If oligohydramnios is observed, lostapressin should be discontinued unless it is considered life-saving for the mother. Contraction stress testing (CST), a non-stress test (NST), or biophysical profiling (BPP) may be appropriate, depending upon the week of pregnancy. Patients aged physicians should be aware, however, that oligohydramnios may not appear until after the fetus has sustained irreversible injury.
Infants with histories of in utero exposure to an angiotensin II receptor antagonist should be closely observed for hypotension, oliguria, and hyperkalemia. If oliguria occurs, attention should be directed toward support of blood pressure and renal perfusion. Exchange transfusion or dialysis may be required as means of reversing hypotension and/or substituting for disordered renal function.
Losartan potassium has been shown to produce adverse effects in rat fetuses and neonates, including decreased body weight, delayed physical and behavioral development, mortality and renal toxicity.
With the exception of neonatal weight gain (which was affected at doses as low as 10 mg/kg/day), doses associated with these effects exceeded 25 mg/kg/day (approximately three times the maximum recommended human dose of 100 mg on a mg/mbasis). These findings are attributed to drug exposure in late gestation and during lactation.
Hypotension – volume depleted patients
In patients who are intravascularly volume-depleted (e.g. those treated with diuretics), symptomatic hypotension may occur after initiation of therapy with LOSTAPRESSIN. These conditions should be corrected prior to administration of LOSTAPRESSIN or a lower starting dose should be used.
Dual blockade of the renin-angiotensin-aldosterone system (RAAS)
There is evidence that the concomitant use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren increases the risk of hypotension, hyperkalaemia and decreased renal function (including acute renal failure). Dual blockade of RAAS through the combined use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren is therefore not recommended.
If dual blockade therapy is considered absolutely necessary, this should only occur under specialist supervision and subject to frequent close monitoring of renal function, electrolytes and blood pressure. ACE-inhibitors and angiotensin II receptor blockers should not be used concomitantly in patients with diabetic nephropathy.
PRECAUTIONS:
General
Hypersensitivity: angioedema.
Impaired hepatic function
Based on pharmacokinetic data which demonstrate significantly increased plasma concentrations of losartan in cirrhotic patients, a lower dose should be considered for patients with impaired liver function.
Impaired renal function
As a consequence of inhibiting the rennin – angiotensin-aldosterone system, changes in renal function have been reported in susceptible individuals treated with LOSTAPRESSIN in some patients these changes in renal function were reversible upon discontinuation of therapy.
In patients whose renal function may depend on the activity of the rennin-angiotensin – aldosterone system (e.g. patients with severe congestive heart failure), treatment with angiotensin converting enzyme inhibitors has been associated with oliguria and/or progressive azotemia and (rarely) with acute renal failure and/or death, in studies of ACE inhibitors in patients with unilateral or bilateral renal artery stenosis, increases in serum creatinine or blood urea nitrogen (BUN) have been reported, these effects were reversible upon discontinuation of therapy.
Electrolyte Imbalance
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 losartan as compared for the placebo group however few patients discontinued therapy due to hyperkalemia.
Information for patients:
Pregnancy: not used during pregnancy as it may cause injury or death of the developing fetus.
Potassium supplements: a patient receiving LOSTAPRESSIN should be told not to use potassium supplements or salt substitutes containing potassium without consulting the prescribing physician.
DRUG INTERACTIONS
No significant drug-drug pharmacokinetic interactions have been found in interaction studies with hydrochlorothiazide, digoxin, warfarin, and cimetidine and phenobarbital.
Rifampin an inducer of drug metabolism decreased the concentrations of LOSTAPRESSIN and its active metabolite. In humans two inhibitors of P450 3A4 have been studied.
Ketoconazole did not affect the conversion of losartan to the active metabolite after intravenous administration of losartan and erythromycin had no clinically significant effect after oral administration.
Fluconazole an inhibitor of P450 2C9 decreased active metabolite concentration and increased LOSTAPRESSIN interaction.
The pharmacodynamic consequences of concomitant use of losartan and inhibitors of P450 2C9 have not been examined. Subjects who do not metabolize losartan to active metabolite have been shown to have a specific, rare defect in cytochrome P450 2C9. These data suggest that the conversion of losartan to its active metabolite is mediated primarily by P450 2C9 and not P450 3A4.
As with other drugs that block angiotensin II or its effects, concomitant use of potassium-sparing diuretics (e.g., spironolactone, triamterene, amiloride), potassium supplements, or salt substitutes containing potassium may lead to increases in serum potassium.
Lithium: 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 agents including selective cyclo-oxygenase- 2 inhibitors: In patients who are elderly, volume-depleted (including those on diuretic therapy), or with compromised renal function, co-administration of NSAIDs, including selective COX-2 inhibitors, with angiotensin II receptor antagonists (including losartan) may result in deterioration of renal function, including possible acute renal failure. These effects are usually reversible. Monitor renal function periodically in patients receiving losartan and NSAID therapy.
The antihypertensive effect of angiotensin II receptor antagonists, including losartan, may be attenuated by NSAIDs, including selective COX-2 inhibitors. Reports suggest that NSAIDs including selective COX-2 inhibitors may diminish the antihypertensive effect of angiotensin II receptor antagonists, including LOSTAPRESSIN. This interaction should be given consideration in patients taking NSAIDs including selective COX-2 inhibitors concomitantly with angiotensin II receptor antagonists.
Nursing mothers:
It is not known whether losartan potassium is excreted in human milk, but significant levels of losartan potassium and its active metabolite were shown to be present in rat milk. 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:
Antihypertensive effects of LOSTAPRESSIN have been established in hypertensive pediatric patients aged 6 to 16 years.There are no data on the effect of LOSTAPRESSIN on blood pressure in pediatric patients under the age of 6 in hypertensive pediatric patients with glomerular filtration rate <30 ml/min/1.73 m^2.
Geriatric use:
No overall differences in effectiveness or safety were observed between these patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out.
ADVERSE REACTIONS:
Hypertension
LOSARTAN has been evaluated for safety in more than 3300 adult patients treated for essential hypertension and 4058 patients/subjects overall.
Over 1200 patients were treated for over 6 months and more than for over one year.
In general, treatment with LOSARTAN was well-tolerated.
The adverse experiences reported in ≥1% patients treated with losartan and more commonly than placebo are shown below:
Musculoskeletal: cramp/ muscle, pain/ back, pain/ leg.
***Nervous system*/psychiatric:** dizziness.
Respiratory: congestion, nasal infection, upper respiratory sinusitis.The following adverse events were also reported at a rate of 1% or greater in patients treated with losartan but were as or more frequent, in the placebo group: asthenia/fatigue, edema/swelling, abdominal pain, chest pain, nausea, headache, pharyngitis, diarrhea, dyspepsia, myalgia, insomnia, cough, sinus disorder.
Adverse events occurred at about the same rates in men and women older and younger patients and black and non-black patients.
It cannot be determined whether these events were causally related to losartan:
Body as a whole: facial edema, fever, orthostatic effects, syncope.
Cardiovascular: angina pectoris, second degree AV black CVA hypotension, myocardial infarction, arrhythmias including atrial fibrillation palpitation, sinus bradycardia, tachycardia, ventricular tachycardia, ventricular fibrillation.
Digestive: anorexia, constipation, dental pain, dry mouth, flatulence, gastritis, vomiting.
Hematologic: anemia.
Metabolic: gout.
Musculoskeletal: arm pain, hip pain, joint swelling, knee pain, musculoskeletal pain shoulder pain stiffness, arthralgia, arthritis, fibromyalgia, muscle weakness.
Nervous system /psychiatric: anxiety, anxiety disorder, ataxia, confusion, depression, dream abnormality, hypoesthesia decreased libido memory impairment migraine, nervousness, paresthesia, peripheral neuropathy, panic disorder, sleep disorder, somnolence, tremor, vertigo.
Respiratory: dyspnea, bronchitis, pharyngeal discomfort epistaxis, rhinitis, respiratory congestion.
Skin: alopecia, dermatitis, dry skin, eechymosis, erythema, flushing, photosensitivity, pruritus, rash, sweating, urticaria.
Special senses: blurred vision, burning/stinging in the eye, conjunctivitis, taste perversion, tinnitus, and decrease in visual acuity.
Urogenital: impotence, nutria, urinary frequency, urinary tract infection.
Persistent dry cough with an incidence of a few percent has been associated with ACE inhibitor use and in practice can be a cause of discontinuation of ACE inhibitor therapy. Cases of cough including positive re-challenges have been reported with the use of LOSARTAN in post-marketing experience.
The adverse experiences, regardless of drug relationship reported with an incidence of >/=4% of patients treated with losartan and occurring more commonly than placebo, on a background of conventional antihypertensive therapy, are shown below:
Body as a Whole: asthenia/fatigue, fever, infection, influenza-like disease, trauma.
Cardiovascular: hypotension, orthostatic hypotension.
Digestive: diarrhea, dyspepsia, gastritis.
Endocrine: diabetic neuropathy, diabetic vascular disease.
Eyes, ears, nose and throat: cataract, sinusitis.
Hemic: anemia.
Metabolic and Nutrition: hyperkalemia, hypoglycemia, weight gain.
Musculoskeletal: back pain, leg pain, knee pain, muscular weakness.
Nervous System: hypesthesia.
Respiratory: bronchitis, cough.
Skin: cellulitis.
Urogenital: urinary tract infection
Post-marketing experience:
The following additional adverse reactions have been reported in post-marketing experiences:
Digestive: Hepatitis (reported rarely).
General disorders and administration site conditions: Malaise.
Hemic: thrombocytopenia (reported rarely).
Hypersensitivity: 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-Schönlein purpura, has been reported. Anaphylactic reactions have been reported.
Metabolic and nutrition: hyperkalemia, hyponatremia have been reported with losartan.
Musculoskeletal: rare cases of rhabdomyolysis have been reported in patients receiving angiotensin II receptor blockers.
Nervous system disorders: Dysgeusia
Respiratory: Dry cough. (See above)
Skin: Erythroderma
Laboratory parameters:
Test findings
Creatinine, blood urea nitrogen: minor increases in blood urea nitrogen (BUN) or serum creatinine were observed in less than 0.1 percent of patients with essential hypertension treated with LOSTAPRESSIN alone.
Hemoglobin and Hematocrit: small decreases in hemoglobin and hematocrit (mean decreases of approximately 0.11 grams percent and 0.09 volume percent, respectively), occurred frequently in patients treated with losartan alone, but were rare of clinical importance.
No patients were discontinued due to anemia.
Liver function tests: occasional elevations of liver enzymes and/or serum bilirubin have occurred. In patients with essential hypertension treated with losartan alone one patient (<0.1%) was discontinued due to these laboratory adverse experiences.
Overdose:
Limited data are available in regard to over dosage in humans.
The most likely manifestation of over dosage 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 its active metabolite can be removed by hemodialysis.
Dosage and Administration:
Adult hypertensive patients
LOSTAPRESSIN may be administered with other antihypertensive agents, and with or without food. Dosing must be individualized.
The usual starting dose of LOSTAPRESSIN is 50 mg once daily, with 25 mg used in patients with possible depletion of intravascular volume (e.g. patients treated with diuretics) and patients with a history of hepatic impairment.
LOSTAPRESSIN can be administered once or twice daily with total daily doses ranging from 25 mg to 100 mg.
If the antihypertensive effect measured at trough using once a day dosing is inadequate, a twice a day regimen at the same total daily dose or an increase in dose may give a more satisfactory response.
The effect of LOSTAPRESSIN is substantially present within one week but in some studies the maximal effect occurred in 3-6 weeks.
If blood pressure is not controlled by LOSTAPRESSIN alone a one dose of a diuretic may be added. Hydrochlorothiazide has been shown to have an additive effect.
No initial dosage adjustment is necessary for elderly patients or for patients with renal impairment, including patients on dialysis.
Pediatric Hypertensive Patients ≥6 years of age
The usual recommended starting dose is 0.7 mg/kg once daily (up to 50 mg total) administered as a tablet or suspension.
Dosage should be adjusted according to blood pressure response.
Doses above 1.4 mg/kg (or in excess of 100 mg) daily have not been studied in pediatric patients.
LOSTAPRESSIN is not recommended in pediatric patients <6 years of age or in pediatric patients with glomerular filtration rate <30 ml/min/1.73 m^2.
Hypertensive patients with left ventricular hypertrophy
The usual starting dose is 50 mg of LOSTAPRESSIN once daily hydrochlorothiazide 12.5 mg daily should be added and/or the dose of LOSTAPRESSIN should be increased to 100 mg once daily recellowed by an increase in hydrochlorothiazide to 25 mg once daily based on blood pressure response.
Nephropathy in type 2 diabetic patients
The usual starting dose is 50 mg once daily.
The dose should be increased to 100 mg once daily based on blood pressure response.
LOSTAPRESSIN may be administered with insulin and other commonly used hypoglycemic agents (e.g. sulfonylureas, glitazones and glucosidase inhibitors).
How supplied:
LOSTAPRESSIN is available as 25mg, 50mg and100 mg film coated tablets.
Carton box containing one or two (AL/P.V.C.) strips each of 7 film coated tablets & an insert leaflet.
STORAGE:
Store at temperature not exceeding 30°C in a dry place.

DELTA PHARMA S.A.E
Tenth of Ramadan City , A.R.E

لوستابرسين

لا يستخدم أثناء الحمل حيث أنه قد يسبب إصابة أو وفاة الجنين.

معلومات للمريض

لوستابرسين أقراص مغلفة (لوسارتان البوتاسيم ٢٥ مجم ،٥٠مجم، ١٠٠مجم).

يوصف بمعرفة الطبيب فقط.

يجب قراءة معلومات المريض قبل البدء فى تناول الدواء، قد يكون هناك معلومات جديدة

هذه النشرة لا تغنى عن التحدث مع طبيبك حول حالتك والعلاج.

ما هى أهم المعلومات التى يجب أن أعرفها عن لوستابرسين؟

ما هو لوستابرسين ؟

لوستابرسين هو دواء ووصفة طبية تسمى غالق مستقبلات أنجيوتنسين فهو يستخدم:

•وحده أو مع أدوية أخرى لخفض ضغط الدم المرتفع.

•لتقليل فرصة حدوث السكتة الدماغية فى المرضى الذين يعانون من إرتفاع ضغط الدم ومشاكل فى القلب يسمى تضخم البطين الأيسر.

• لوستابرسين قد لا يساعد المرضى ذوى البشرة السوداء الذين يعانون من هذه المشكلة.

•للحد من تفاقم الإصابة بأمراض الكلى فى المرضى الذين يعانون من السكرى من النوع الثانى أو الذين لديهم إرتفاع فى ضغط الدم.

لوستابرسين لم تتم دراسته فى الأطفال أقل من ٦ سنوات من العمر أو فى الأطفال الذين يعانون من مشاكل معينة فى الكلى.

إرتفاع ضغط الدم: ضغط الدم هو القوة الضاغطة على الأوعية الدموية عندما يدق القلب وعندما ينبسط.

و يكون لديك إرتفاع فى ضغط الدم عندما تكون القوة الضاغطة كبيرة جداً .

لوستابرسين يمكن أن يساعد على إسترخاء الأوعية الدموية حتى ينخفض ضغط الدم.

تضخم البطين الأيسر(LVH): هو تضخم جدران الغرفة اليسرى من القلب (غرفة الضخ الرئيسية فى القلب) ويمكن أن يحدث من عدة أشياء وإرتفاع ضغط الدم هو السبب الأكثر شيوعاً لتضخم البطين الأيسر .

السكرى من النوع الثانى وأمراض الكلى: السكرى من النوع الثانى هو نوع من داء السكرى الذى يحدث بشكل رئيسى عند البالغين.

و إذا كان لديك إعتلال الكلية السكرى فهذا يعنى أن الكليتين لا تعملان بشكل صحيح بسبب الأضرار الناجمة عن مرض السكرى.

المرضى الذين يجب عليهم عدم تناول لوستابرسين؟

لا تأخذ لوستابرسين إذا كانت لديك حساسية لأى من المكونات فى لوستابرسين، أنظر نهاية هذه النشرة للحصول على قائمة كاملة من المكونات غير الفعالة فى لوستابرسين أقراص.

لا تتناول لوستابرسين إذا كنت:

مصاباً بداء البول السكري وإختلال فى وظائف الكلى وتتناول دواء لخفض ضغط الدم يحتوي على أليسكيرين.

ماذا يجب أن أخبر به طبيبى قبل تناول لوستابرسين؟

أخبر طبيبك عن كافة الظروف الطبية بما فى ذلك إذا كنت:

- حاملاً أو تخططين لتصبحين حاملاً.
- هل أنت فى مرحلة الرضاعة الطبيعية ؟

من غير المَعروف إذا ما كان لوستابرسين يمر فى حليب الثدى، لذا يجب عليكى أن تختارى إما أن تتناولين لوستابرسين أقراص أو الإرضاع ولكن ليس كليهما معاً.

- القيء الكثير أوحدوث الكثير من الإسهال.
- لديك مشاكل فى الكبد.
- لديك مشاكل فى الكلى.

أخبر طبيبك عن كل الأدوية التى تأخذها، بما فى ذلك الأدوية التى تصرف من دون وصفة طبية والفيتامينات والمكملات العشبية فقد يتفاعل لوستابرسين والأدوية الأخرى مع بعضها البعض كما يجب خصوصاً إخبار الطبيب إذا كنت تتناول:

- مكملات البوتاسيوم.
- بدائل الملح التى تحتوى على البوتاسيوم.
- أقراص الماء (مدرات البول).
- الأدوية المستخدمة لعلاج آلام والتهاب المفاصل ،(الأدوية غير الإستيرويدية المضادة للإلتهاب) بما فى ذلك مثبطات كوكس ٢ .

تناول لوستابرسين مع أدوية أخري:

قد يحتاج طبيبك إلى تغيير الجرعة و / أو اتخاذ الإحتياطات الأخرى:

إذا كنت تتناول غالقات مستقبلات الأنجيوتنسين ٢؛ (ARB) أو مثبطات الإنزيم المحول للإنجيوتنسين (ACEIs).

كيف يمكن أن أتناول لوستابرسين؟

يجب تناول لوستابرسين تماماً على النحو الذى يحدده الطبيب، فالطبيب قد يغير الجرعة إذا لزم الأمر.

عادة ما تبدا الجرعة اليومية بتناول ٥٠ مجم مرة واحدة يومياً، كما يمكن أن يؤخذ لوستابرسين مرة أو مرتين يومياً على أن تتراوح الجرعة اليومية الكلية من ٢٥ إلى ١٠٠ مجم.

لوستابرسين يمكن أن يؤخذ مع أو بدون الطعام.

إذا نسيت الجرعة فعليك تناولها فور تذكرها وإذا كانت قريبة من الجرعة التالية لا تأخذ الجرعة الفائتة، فقط تناول الجرعة المقبلة فى وقتها المعتاد.

إذا تناولت جرعة زائدة من لوستابرسين، اتصل فوراً بالطبيب أو مركز مراقبة السموم أو الذهاب إلى أقرب غرفة للطوارىء فى المستشفى على الفور.

ما هى الأعراض الجانبية المحتملة للوستابرسين؟

لوستابرسين قد يسبب ما يلى من الأعراض الجانبية التى قد تكون خطيرة:

إصابة أو وفاة المولود.

رد الفعل التحسسى: و أعراض الحساسية هى تورم فى الوجه والشفتين واللسان أوالحلق، يجب الحصول على المساعدة الطبية فى حالات الطوارىء على الفور والتوقف عن تناول لوستابرسين.

إنخفاض ضغط الدم (هبوط ضغط الدم): قد يؤدى الإنخفاض فى ضغط الدم إلى الشعور بالدوار أو الإغماء، لذا يجب الإستلقاء إذا كنت تشعر بالدوار أو الإغماء وإستدعاء الطبيب فوراً.

بالنسبة للأشخاص الذين يعانون أصلاً من مشاكل فى الكلى: قد ترى تدهوراً فى مدى عمل الكليتين، لذا يجب إستدعاء الطبيب إذا كان لديك تورم فى القدمين والكاحلين أو اليدين أو إكتساب الوزن غير المبرر.

من الأعراض الجانبية الأكثر شيوعاً للوستابرسين فى الناس مع إرتفاع ضغط الدم هى:

- نزلات البرد (عدوى الجهاز التنفسى العلوى).
- دوخة.
- إنسداد الأنف.
- آلام الظهر.

من الأعراض الجانبية الأكثر شيوعاً فى مرضى السكرى من النوع الثانى (السكرى الكلوى):

- الإسهال.
- التعب.
- إنخفاض السكر فى الدم.
- ألم فى الصدر.
- إرتفاع البوتاسيوم فى الدم.
- إنخفاض ضغط الدم.

أخبر طبيبك على الفور إذا حدث أى من الأعراض الطبية المزعجة.

هذه ليست قائمة كاملة من الأعراض الجانبية و للحصول على قائمة كاملة، اسأل طبيبك أو الصيدلى.

كيفية تخزين لوستابرسين؟

لوستابرسين أقراص يجب أن تخزن فى درجة حرارة لا تتعدى ٣٠° درجة مئوية.

حافظ على لوستابرسين فى علبة مغلقة بإحكام ويجب أن يحفظ الدواء بعيداً عن الضوء.

حافظ على لوستابرسين وجميع الأدوية بعيداً عن متناول الأطفال.

معلومات عامة عن لوستابرسين:

أحياناً توصف الأدوية فى حالات لم يرد ذكرها فى نشرة المعلومات للمريض .

لا تستخدم لوستابرسين لغير ما وصف له و لاتعطى لوستابرسين لمرضى آخرين، حتى لو كانت لديهم نفس الأعراض التى لديك لأنها قد تضر بهم.

وتلخص هذه النشرة أهم المعلومات عن لوستابرسين، و إذا كنت تود الحصول على مزيد من المعلومات عليك التحدث مع طبيبك، كما يمكنك أن تسأل الصيدلى أو الطبيب للحصول على معلومات حول لوستابرسين مما هو مكتوب للمتخصصين.

المواد غير الفعالة:

لوستابرسين ٢٥مجم، و ٥٠مجم أقراص مغلفة: ميكروكريستالين سيليلوز، لاكتوز مونو هيدرات، نشا ١٥٠٠، هيدروكسى بروبيل ميثيل سيليلوز، ماغنيسيوم ستيارات، تيتانيوم داى أوكسيد، بولى إيثيلين جليكول ٦٠٠٠.

لوستابرسين ١٠٠ مجم أقراص مغلفة: كروس كارميلوز صوديوم، لاكتوز، ماغنيسيوم ستيارات، ميكروكريستالين سيليلوز، إيروسيل، هيدروكسى بروبيل ميثيل سيليلوز، تيتانيوم داى أوكسيد، بولى إيثيلين جليكول.

العبوة:

علبة كرتون تحتوى على شريط أو شريطين (AL/PVC) به ٧ أقراص مغلفة + نشرة داخلية.

شركة الدلتا للصناعات الدوائية ش.م.م

مدينة العاشر من رمضان - ج.م.ع

DELTA PHARMA