PRESCRIBING INFORMATION

LACE Tablets لیس ٹیبلیٹس

(Lisinopril Tablets USP)

COMPOSITION:
Lace 5 Tablets :
Each Tablet Contains:
Lisinopril Dihydrate USP equivalent to Lisinopril Anhydrous ..... 5 mg

Lace 10 Tablets :
Each Tablet Contains:
Lisinopril Dihydrate USP equivalent to Lisinopril Anhydrous ..... 10 mg

DESCRIPTION:
Lace (Lisinopril Tablets USP) a synthetic peptide derivative, is an oral long-acting angiotensin converting enzyme (ACE) inhibitor, inhibits ACE, resulting in decreased plasma angiotensin II and decreased aldosterone excretion, the consequence of which is a reduction of blood pressure in hypertensive patients and improvement in the signs and symptoms of congestive heart failure.

INDICATIONS:
Lace (Lisinopril Tablets USP) is indicated in the treatment of essential hypertension and in renovascular hypertension. Lace (Lisinopril Tablets USP) is indicated in the management of heart failure as adjunctive treatment with diuretics and where appropriate, digitalis. Lace (Lisinopril Tablets USP) is indicated for the treatment of hemodynamically stable patients within 24 hours of acute myocardial infarction, to prevent the subsequent development of left ventricular dysfunction or heart failure and improve survival.

DOSAGE AND ADMINISTRATION:
Since absorption of tablet Lace (Lisinopril Tablets USP) is not affected by food, the tablets may be administered before, during or after meals. Lace (Lisinopril Tablets USP) should be administered in a single daily dose. As with all single daily dose medications, Lace (Lisinopril Tablets USP) should be taken at approximately the same time each day.
Essential Hypertension: In patients with essential hypertension the usual recommended starting dose is 10 mg. The usual effective maintenance dosage is 20 mg administered in a single daily dose.
Diuretic Treated Patients: Symptomatic hypotension may occur following initiation of therapy with Lace (Lisinopril Tablets USP),this is more likely in patients who are being treated currently with diuretics. Caution is recommended, therefore, these patients may be volume and / or salt depleted.
Renovascular Hypertension: Some patients with renovascular hypertension, especially those with bilateral renal artery stenosis or stenosis of the artery to a solitary kidney, may develop an exaggerated response to the first dose of Lace (Lisinopril Tablets USP). Therefore, a lower starting dose of 2.5 or 5mg is recommended. Therefore, the dosage may be adjusted according to the blood pressure response.
Congestive Heart Failure: The initial dose of Lace (Lisinopril Tablets USP) in patients with heart failure is 2.5 mg given once a day. The usual effective dosage range is 5 to 20 mg per day administered in a single daily dose.
Acute Myocardial Infarction: Treatment with Lace (Lisinopril Tablets USP) may be started within 24 hours of the onset of symptoms. The first dose of Lace (Lisinopril Tablets USP) is 5mg given orally, followed by 5mg after 24 hours, 10mg after 48 hours and then 10mg once daily thereafter.

SIDE EFFECTS:
Lace (Lisinopril Tablets USP) has been found in controlled clinical trials to be generally well tolerated. The most frequent clinical side effects of Lace (Lisinopril Tablets USP) in controlled trials were dizziness, headache, diarrhoae, fatigue, cough and nausea. Other side effects occurring less frequently were orthostatic effects (including hypotension), rash, and asthenia.
Hypersensitivity/Angioneurotic Edema: Angioneurotic edema of the face, extremities, lips, ,tongue, glottis, and larynx has been reported rarely.
Respiratory: Bronchospasm
Cardiovascular: Hypotension, palpitation, tachycardia.
Neurological: Mood alterations, mental confusion, paresthesia.
Digestive: Abdominal pain, dry mouth, pancreatitis, hepatitis.
Urogenital: Uremia, oliguria, impotence.
Dermatological: urticaria, pruritus, alopecia.
Haemopoietic: Bone marrow depression, manifest as anemia and thrombocytopenia and leukopenia, has been reported. Hyperkalemia and hyponatremia have occurred.

CONTRAINDICATIONS:
Lace (Lisinopril Tablets USP) is contraindicated in patients who are hypersensitive to any component of this product and in patients with a history of angioneurotic oedema relating to previous treatment with an angiotensin-converting enzyme inhibitor and in patients with hereditary or idiopathic angioedema.

CAUTIONS:
Symptomatic hypotension: Symptomatic hypotension was seen rarely in uncomplicated hypertensive patients. In hypertensive patients receiving Lace (Lisinopril Tablets USP), hypotension is more likely to occur if the patient has been volume-depleted, e.g. by diuretic therapy, dietary salt restriction, dialysis, diarrhoea or vomiting. In patients with congestive heart failure, with or without associated renal insufficiency symptomatic hypotension has been observed.
Hypotension in Acute Myocardial infarction: Treatment with Lace (Lisinopril Tablets USP) must not be initiated in acute myocardial infarction patients who are at risk of further serious hemodynamic deterioration after treatment with a vasodilator.
Aortic Stenosis/Hypertrophic Cardiomyopathy: As with all vasodilators, ACE inhibitors should be given with caution to patients with obstruction in the outflow tract of the left ventricle.

Renal Function Impairment: In patients with congestive heart failure, hypotension following the initiation of therapy with ACE inhibitors may lead to some further impairment in renal function. Acute renal failure, usually reversible, has been reported in this situation.Increase of blood urea and serum creatinine, usually reversible upon discontinuation of therapy, have been reported.
Hypersensitivity/Angioneurotic Oedema: Angioneurotic oedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported rarely in patients treated with angiotensin converting enzyme inhibitors including Lace (Lisinopril Tablets USP). Angioneurotic oedema associated with laryngeal oedema may be fatal.
Hemodialysis Patients: Anaphylactoid reactions have been reported in patients dialyzed with high-flux membranes and treated concomitantly with an ACE inhibitor. In these patients consideration should be given to use a different type of dialysis membrane or a different class of antihypertensive agent.
Cough: Cough has been reported with the use of ACE inhibitors. Characteristically, the cough is non-productive, persistent and resolves after discontinuation of therapy.
Surgery / Anesthesia: In patients undergoing major surgery or during anesthesia with agents that produce hypotension, Lace (Lisinopril Tablets USP) may block angiotensin II formation secondary to compensatory renin release. If hypotension occurs and is considered to be due to this mechanism, it can be corrected by volume expansion.

USE IN PREGNANCY AND LACTATION:
The use of Lace (Lisinopril Tablets USP) during pregnancy is not recommended. Caution should be exercised if Lace (Lisinopril Tablets USP) is given to a nursing mother.

DRUG INTERACTIONS:
Diuretics: When a diuretic is added to the therapy of a patient receiving Lace (Lisinopril Tablets USP), the antihypertensive effect is usually additive.
Other Agents: Indomethacin may diminish the antihypertensive efficacy of concomitantly administered Lace (Lisinopril Tablets USP). In some patients with compromised renal function who are being treated with non-steroidal anti-inflammatory drugs, the co-administration of ACE inhibitors may result in a further deterioration of renal function.
Serum Potassium: Although in clinical trials, serum potassium usually remained within normal limits, hyperkalemia did occur in some cases. Risk factors for the development of hyperkalemia include renal insufficiency, diabetes mellitus and concomitant use of potassium sparing diuretics (e.g. spironolactone triamterene or amiloride), potassium supplements, or potassium containing salt substitutes.

OVERDOSAGE:
The most likely manifestation of overdosage would be hypotension, for which the usual treatment would be intravenous infusion of normal saline solution, if available, angiotensin II may be beneficial. Lisinopril may be removed from the general circulation by hemodialysis.

STORAGE: Store at temperature 15 to 30 °C away from light & moisture.

PRESENTATION:
Lace (Lisinopril Tablets USP) 5 Tablets : Pack of 20 Tablets.
Lace (Lisinopril Tablets USP) 10 Tablets : Pack of 20 Tablets.

خوراک اور طریقہ استعمال

غذا کے استعمال سے لیس ٹیبلیٹ کی سرایت متاثر نہیں ہوتی لہذا یہ ٹیبلیٹ کھانے سے پہلے، درمیان یا بعد میں دی جا سکتی ہے لیس ٹیبلیٹ کو روزانہ یکساں اوقات میں دینا چاہیئے

بنیادی ہائپر ٹینشن (بلند فشار خون)

ان مریضوں میں تجویز کردہ دوا کی مقدار 10 ملی گرام ہے اور 20 ملی گرام واحد استعمال کے طور پر ہے۔

ڈائی یوریٹکس استعمال کرنے والے مریض

لیس کے استعمال سے علامتی ہائپوٹینشن ہو سکتی ہے یہ ان مریضوں کے ساتھ زیادہ ممکن ہے جو ڈائی یوریٹکس کا استعمال بھی کرتے ہیں ایسے مریضوں میں احتیاط لازم ہے چونکہ ان میں نمکیات اور پانی کی کمی ہو سکتی ہے۔

Renovascular Hypertension

ایسے مریضوں میں جنکے دونوں گردوں کی شریانوں میں اسٹینوسس ہو۔ان میں دوا کی پہلی خوراک سے شدید علامات ظاہر ہو سکتی ہیں لہذا ان مریضوں میں ابتداء میں خوراک کم رکھنی چاہیے جیسا کہ 2.5 تا 5 ملی گرام کا استعمال موثر ہے۔

کنجیسٹیو ہارٹ فیلیور

لیس کی ابتدائی خوراک ہارٹ فیلیور کے مریضوں کے لیئے 2.5 ملی گرام روزانہ دن میں ایک مرتبہ ہے اور عمومی خوراک 5 تا 20 ملی گرام روزانہ ایک مرتبہ ہے

ایکیوٹ مایوکارڈیئل انفارکشن

علامات کے ظاہر ہونے کے 24 گھنٹوں کے اندر علاج ضروری ہے لیس کی پہلی خوراک 5 ملی گرام بذریعہ منہ ہے 24 گھنٹوں کے بعد 5 ملی گرام، 48 گھنٹوں کے بعد 10 ملی گرام اور پھر 10 ملی گرام کا روزانہ استعمال ایک موثر طریقہ علاج ہے۔

اسٹوریج:

15 سے 30 ڈگری سینٹی گریڈ درجہ حرارت پر روشنی اور نمی سے بچا کر رکھیئے۔

brookes

Manufactured by:

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ISO 9001
ISO14001
OHSAS 18001
BUREAU VERITAS
Certification