Lisinopril And Hydrochlorothiazide Tablets

Lisinopril And Hydrochlorothiazide 10 Tablets
Lisinopril And Hydrochlorothiazide 20 Tablets

• Active Ingredients:
Each tablet contains 10 mg lisinopril (as the dihydrate) and 12,5 mg hydrochlorothiazide.

Each tablet contains 20 mg lisinopril (as the dihydrate) and 12,5 mg hydrochlorothiazide.

• COMPOSITION
Each tablet contains 10 mg lisinopril and 12,5 mg hydrochlorothiazide.

Each tablet contains 20 mg lisinopril and 12,5 mg hydrochlorothiazide.

PHARMACOLOGICAL CLASSIFICATION
A 7.1.3 Other hypotensives.

PHARMACOLOGICAL ACTION
Lisinopril/HCT is a combination of an angiotensin converting enzyme inhibitor, lisinopril and a diuretic, hydrochlorothiazide. Both these components have been widely used alone and in combination for the treatment of hypertension due to additive effects. Lisinopril is a peptidyl dipeptidase inhibitor and inhibits the angiotensin converting enzyme (ACE) that catalyses the conversion of angiotensin I to angiotensin II. Angiotensin II is a vasoconstrictor peptide which also stimulates aldosterone secretion by the adrenal cortex.
Inhibition of ACE results in decreased concentrations of angiotensin II which results in decreased vasopressor activity and reduced aldosterone secretion. Reduced aldosterone secretion may result in an increase in serum potassium concentration.
The mechanism of action through which lisinopril lowers blood pressure is mainly via suppression of the renin-angiotensin-aldosterone system; however lisinopril also has antihypertensive effects in patients with low-renin hypertension.
ACE is identical to kininase II, an enzyme that degrades bradykinin. It could be possible that increased levels of bradykinin, a potent vasodilatory peptide, play a role in the therapeutic effects of lisinopril. However, this remains to be elucidated.
Hydrochlorothiazide is a thiazide diuretic and an antihypertensive agent. It affects the distal renal tubular mechanism of electrolyte re-absorption and increases excretion of sodium and chloride in approximately equivalent amounts. Natriuresis may be accompanied by some loss of potassium and bicarbonate. The mechanism of the antihypertensive effects of the thiazides is unknown. Thiazides do not usually affect normal blood pressure.
Pharmacokinetics
The concomitant administration of lisinopril and hydrochlorothiazide has no clinical significant effect on the pharmacokinetics of either drug.
Lisinopril
Approximately 60% of lisinopril is absorbed after oral administration. The absorption varies between individuals (6 to 60%).
Following oral administration of lisinopril, peak serum concentrations occur within about 7 hours. Lisinopril has an effective half-life of 12 hours.
Lisinopril does not bind to other serum proteins.
The absorption of lisinopril is not affected by the presence of food in the gastrointestinal tract.
Lisinopril does not undergo metabolism and absorbed drug is excreted unchanged entirely in the urine. Impaired renal function decreases elimination of lisinopril. This decrease only becomes clinically important when the glomerular filtration rate is below 30 mL/min. Lisinopril can be removed by dialysis.
Older patients have higher blood levels and higher values for the area under the plasma concentration time curve than younger patients.
Hydrochlorothiazide
The plasma half-life of hydrochlorothiazide can vary between 5 and 15 hours. Approximately 60% of the dose is eliminated unchanged within 24 hours.
After oral administration of hydrochlorothiazide, diuresis begins within 2 hours, peaks in about 4 hours and lasts 6 to 12 hours.

• INDICATIONS
Mild to moderate hypertension in patients who have been stabilized on their individual components given in the same proportions.

CONTRA INDICATIONS
Anuria.
Hypersensitivity to any component of this product.
Patients with a history of angioedema relating to previous treatment with an angiotensin-converting enzyme inhibitor.
Patients with hereditary or idiopathic angioedema (see Special Precautions). Hypersensitivity to other sulphonamide-derived medicines.
Pregnancy and Breast feeding Mothers - see Pregnancy and Lactation. Patients with aortic stenosis or hypertrophic cardiomyopathy.
Bilateral renal artery stenosis or unilateral renal artery stenosis in the presence of a single kidney.

• WARNINGS
Should a woman become pregnant while receiving Lisinopril And Hydrochlorothiazide, the treatment must be stopped immediately and switched to an alternative medicine. Should a woman contemplate pregnancy, an alternative antihypertensive medication should be used.

• DOSAGE AND DIRECTIONS FOR USE

The usual dosage is one tablet daily, taken at approximately the same time each day. It is recommended that if the desired clinical effect cannot be achieved within 2 to 4 weeks with this dosage, the dosage may be increased to a maximum of two tablets, administered once daily.

Prior Treatment with Diuretics

Symptomatic hypotension may occur after the initial dose of Lisinopril And Hydrochlorothiazide; this phenomenon occurs more likely in patients who are volume and/or salt depleted as a result of prior diuretic therapy. If possible, the diuretic therapy should be discontinued for 2-3 days prior to initiation of therapy with Lisinopril And Hydrochlorothiazide; or if this is not possible, lisinopril should be given alone at a low initial dose of 5 mg.

Renal Impairment

Thiazides may not be suitable diuretics for use in patients with renal impairment and are ineffective in moderate or severe renal impairment (creatinine clearance values of 30 mL/min or below).

Lisinopril And Hydrochlorothiazide should not be used as initial therapy in any patient with renal insufficiency.

In patients with creatinine clearance of >30 and <80 mL/min, Lisinopril And Hydrochlorothiazide may be used, but only after titration of the individual components.

Use in children

Safety and efficacy in children have not been established.

Use in the Elderly

There are no significant differences in the efficacy and tolerability to lisinopril and hydrochlorothiazide, administered concomitantly,

INTERACTIONS

Serum Potassium

The decrease in potassium caused by thiazide diuretics is usually attenuated by the effect of lisinopril. The use of potassium supplements, potassium-sparing agents or potassium-containing salt substitutes, especially in patients with impaired renal function, may result in a significant increase in serum potassium. Should it be required to administer Lisinopril And Hydrochlorothiazide concomitantly with any of these agents, caution should be exercised and serum potassium should be monitored on a regular basis.

Lithium

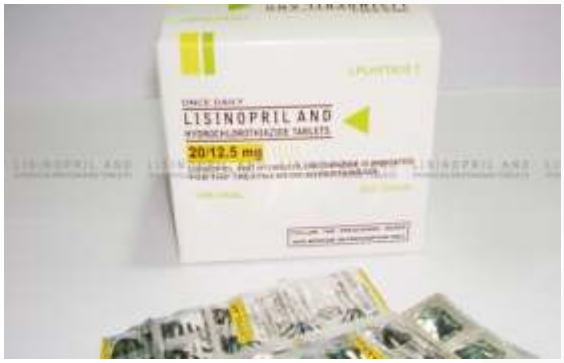
The concomitant use of lithium with diuretics or ACE-inhibitors is not indicated. The renal clearance of lithium is reduced by ACE-inhibitors and diuretic agents and a high risk of lithium toxicity exists. The prescribing information for lithium preparation should be reviewed before use of these preparations.

Non-steroidal anti-inflammatory drugs (NSAIDs)

Indomethacin may decrease the antihypertensive efficacy of Lisinopril And Hydrochlorothiazide. In some patients with compromised renal function who are being treated with non-steroidal anti-inflammatory drugs (NSAIDs), the co-administration of lisinopril may result in a further deterioration in renal function.

The administration of a non-steroidal anti-inflammatory agent can reduce the diuretic, natriuretic and antihypertensive effects of diuretics in some patients.

Tubocurarine



PREGNANCY AND LACTATION

Safety in pregnancy and lactation has not been established. Refer to WARNINGS. Lisinopril And Hydrochlorothiazide can cause foetal and neonatal morbidity and mortality when administered to pregnant women during the 2nd and 3rd trimesters. Lisinopril And Hydrochlorothiazide passes through the placenta and can be presumed to cause disturbance in foetal blood regulatory mechanisms.

Use of Lisinopril And Hydrochlorothiazide during the second and third trimester has been associated with foetal and neonatal injury including hypotension, renal failure, hyperkalaemia, oliguria, anuria and skull hypoplasia in the newborn. Maternal oligohydramnios, presumably representing decreased foetal renal function, has occurred and may result in limb contractures, craniofacial deformations and hypoplastic lung development. Prematurity and low birth mass can occur. These adverse effects to the embryo and foetus do not appear to have resulted from intrauterine ACE-inhibitor exposure limited to the first trimester.

Infants whose mothers have taken Lisinopril And Hydrochlorothiazide should be closely observed for hypotension, oliguria and hyperkalaemia. Lisinopril, which crosses the placenta, has been removed from the neonatal circulation by peritoneal dialysis with some clinical benefit. There is no experience with the removal of hydrochlorothiazide, which also crosses the placenta, from the neonatal circulation.

The routine use of diuretics in otherwise healthy pregnant woman is not recommended and exposes mother and foetus to unnecessary hazard. Diuretics do not prevent development of toxaemia of pregnancy and there is no satisfactory evidence that they are useful in the treatment of toxaemia. Thiazides cross the placental barrier and appear in cord blood. Hazards include foetal or neonatal jaundice, thrombocytopenia and possibly other adverse reactions which occur in the adult.

Breast-feeding

It is not known whether lisinopril is distributed into human breast milk; however the thiazides do appear in human milk. If the drug is deemed essential, the patient should stop nursing.

• SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects
The following side effects are listed according to the organ class system for Lisinopril And Hydrochlorothiazide as well as the individual components, lisinopril and hydrochlorothiazide:

• Gastrointestinal

Lisinopril And Hydrochlorothiazide:
Less frequent:diarrhoea, nausea, vomiting
Hydrochlorothiazide

Psychiatric

Lisinopril:mood alterations, mental confusion

• Nervous system

Lisinopril And Hydrochlorothiazide
Frequent:headache, dry mouth
Less frequent:paraesthesia, dizziness and fatigue, which generally diminished when the dosages are reduced asthenia
Hydrochlorothiazide:vertigo, fever
Frequent:restlessness
Lisinopril: vertigo, sleep disturbance, hypoaesthesia
Less frequent: paraesthesia

• Musculoskeletal
Lisinopril And Hydrochlorothiazide
Frequent:muscle cramps
Less Frequent: weakness
Hydrochlorothiazide
Frequent:muscle spasm

• Hepato-biliary
Hydrochlorothiazide:hyperglycaemia, glycosuria
Less frequent:jaundice (intrahepatic cholestatic jaundice), pancreatitis, hyperuricaemia
Lisinopril:hepatitis (hepatocellular or cholestatic)

• Respiratory
Lisinopril And Hydrochlorothiazide
Frequent:dry cough
Hydrochlorothiazide:respiratory distress including pneumonitis and pulmonary oedema, anaphylactic reactions
Lisinopril:bronchospasm, rhinitis, sinusitis, pulmonary infiltrates

• Cardiac
Lisinopril And Hydrochlorothiazide:
Less frequent:palpitation, chest discomfort
Lisinopril
Less frequent:myocardial infarction or cerebrovascular accident possibly secondary to excessive hypotension in high risk patients (see Special Precautions), tachycardia

• Vascular
Lisinopril And Hydrochlorothiazide:
Less frequent:hypotension including orthostatic hypotension
Hydrochlorothiazide:necrotizing angiitis (vasculitis) (cutaneous vasculitis)

• Renal and urinary
Hydrochlorothiazide
Less frequent:renal failure, renal dysfunction and interstitial nephritis
Lisinopril:diaphoresis, uraemia, oliguria/anuria, renal dysfunction, acute renal failure

• Skin and appendages
Lisinopril And Hydrochlorothiazide
Less frequent:rash and photosensitivity
Hydrochlorothiazide: purpura
Less frequent:photosensitivity, urticaria
Lisinopril:psoriasis and severe skin disorders, including pemphigus, toxic epidermal necrolysis, erythema multiforme, alopecia
Less frequent:pruritus, urticaria

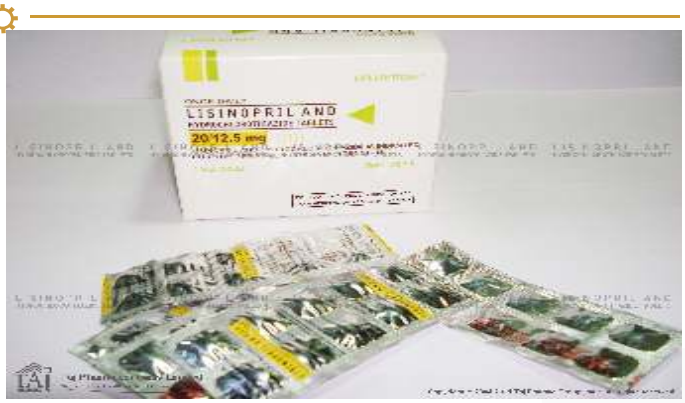
• Blood and lymphatic system

- **Metabolism and nutrition**

Lisinopril And Hydrochlorothiazide
Less frequent: gout

- **Hydrochlorothiazide**

Frequent:electrolyte imbalance including hyponatraemia
Less frequent: anorexia



- **Endocrine**

Hydrochlorothiazide: sialoadenitis

- **Reproductive system**

Lisinopril And Hydrochlorothiazide:
Less frequent: impotence

Hypersensitivity Reactions

Lisinopril And Hydrochlorothiazide
Less frequent: Angioedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported (see Contra-Indications and Special Precautions). A symptom complex has been reported which may include fever, vasculitis, myalgia, arthralgia/arthritis, a positive Antinuclear antibody (ANA), elevated erythrocyte sedimentation rate, eosinophilia and leukocytosis.
Lisinopril: Stevens-Johnson Syndrome

Laboratory Test Findings

Hyperkalaemia, hyperglycaemia and hyperuricaemia and have been noted. Increases in serum creatinine and in blood urea nitrogen have been reported in patients without renal impairment. These are usually reversible if medication is discontinued.
Bone marrow depression manifesting as anaemia and/or thrombocytopenia and/or leucopenia have also occurred. Agranulocytosis has been reported.
Small decreases in haemoglobin and haematocrit have been reported frequently in hypertensive patients treated with Lisinopril And Hydrochlorothiazide but were rarely of clinical significance unless another cause of anaemia was also present.
Elevations of liver enzymes (AST and ALT) and/or serum bilirubin have been reported.

Special Precautions

Hypotension and Electrolyte/Fluid Imbalance
Symptomatic hypotension may occur in the patients with the following: fluid or electrolyte imbalance, e.g. volume depletion, hyponatraemia, hypochloraemic alkalosis, hypomagnesaemia or hypokalaemia which may occur from prior treatment with diuretics, a salt restricted diet, dialysis, or after severe diarrhoea and repeated vomiting.
Determination of serum electrolytes should be performed at appropriate intervals in such patients.
Initiation of treatment and dose adjustment should be monitored under close medical supervision in patients with an increased risk of symptomatic hypotension. Special consideration should be given when this medication is administered to patients with ischemic heart or cerebrovascular disease as an excessive decrease in blood pressure could result in a myocardial infarction or cerebrovascular accident.
If hypotension occurs, the patient should be placed in the supine position and, if necessary, should receive an intravenous infusion of 0,9% saline. A transient hypotensive response does not warrant discontinuation of further doses.
Once effective blood volume and pressure have been stabilised, therapy at a reduced dosage may be reinstituted; or alternatively either of the components may be used appropriately as monotherapy.
Renal Insufficiency
Thiazides may not be suitable diuretics for use inpatients with renal impairment and are ineffective at creatinine clearance values of 30 mL/min or below (i.e. moderate or severe renal insufficiency.)
Lisinopril And Hydrochlorothiazide should not be administered to patients with a creatinine clearance < 80 mL/min until titration of the individual components has shown the need for the doses present in Lisinopril And Hydrochlorothiazide.
In some patients with bilateral renal artery stenosis or stenosis of the artery to a solitary kidney, who have received ACE inhibitor treatment, increases in blood urea and serum creatinine, usually reversible upon discontinuation of therapy, have been seen. This is especially likely to occur in patients with renal insufficiency.
Some hypertensive patients with no apparent pre-existing renal disease have developed increases in blood urea and serum creatinine when lisinopril has been given concomitantly with a diuretic. If this occurs during therapy with, it should be discontinued. Reinstitution of therapy at a reduced dosage may be possible: or either of the components may be used alone as appropriate.
Haemodialysis
The use of Lisinopril And Hydrochlorothiazide is not indicated in patients requiring dialysis for renal failure.
Anaphylactoid reactions have been reported in patients undergoing haemodialysis procedures with certain dialysis membranes (e.g. with the high-flux membranes) and concurrent treatment with Lisinopril And Hydrochlorothiazide Consideration to the use of a different type of dialysis membrane or a different class of anti hypertensive agent should be given in these patients.
Hepatic Disease
Caution should be exercised when thiazides are used in patients with hepatic impairment or progressive liver disease, as minor alterations of fluid and electrolyte balance may precipitate hepatic coma in these patients.
Surgery/Anaesthesia
In patients undergoing major surgery or during anaesthesia with agents that produce hypotension, lisinopril may block angiotensin II formation secondary to compensatory renin release. Should hypotension occur, and is considered to be due to this mechanism, it can be corrected by volume expansion.
Metabolic and Endocrine Effects
Thiazide diuretics may impair glucose tolerance. Dosage adjustment of antidiabetic agents, including insulin, may be required.

Decreased urinary calcium excretion caused by thiazides may result in intermittent and a slightly raised serum calcium concentration. Should marked hypercalcaemia occur, it may be evidence of underlying hyperparathyroidism. Lisinopril And Hydrochlorothiazide therapy should be discontinued before carrying out tests for parathyroid function (see Interactions). Increased cholesterol and triglyceride levels may be a result of thiazide diuretic therapy.
Thiazide diuretics may precipitate hyperuricaemia and/or gout in certain patients. Due to the increase in urinary uric acid caused by lisinopril, hyperuricaemia may be attenuated by Lisinopril And Hydrochlorothiazide which contains both components.
Sensitivity/Angioedema
Angioedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported in patients with angiotensin-converting enzyme inhibitors, including lisinopril. In such cases Lisinopril And Hydrochlorothiazide should be discontinued immediately and appropriate measures should be instituted to ensure complete resolution of symptoms prior to dismissing the patient. In instances where swelling has been confined only to the face and lips, the condition usually resolves without treatment, although antihistamines have been useful in relieving symptoms.
Angioedema associated with laryngeal oedema may be fatal. Where there is involvement of the tongue, glottis or larynx, likely to cause airway obstruction, appropriate emergency therapy should be administered promptly. This may include the administration of adrenaline and/or maintenance of a patients airway. The patient should be under close medical supervision until complete and sustained resolution of symptoms has occurred. These patients should never receive any Lisinopril And Hydrochlorothiazide again.
Patients with a history of angioedema unrelated to Lisinopril And Hydrochlorothiazide therapy may be at increased risk of angioedema while receiving Lisinopril And Hydrochlorothiazide (see also Contra-indications).
In patients receiving thiazides, sensitivity reactions may occur with or without a history of allergy or bronchial asthma. Exacerbation or activation of systemic lupus erythematosus has been reported with the use of thiazides.
Race
Lisinopril And Hydrochlorothiazide causes a higher rate of angioedema in black patients than in non-black patients.
Desensitisation
Patients receiving ACE-inhibitors during desensitisation treatment (e.g. hymenoptera venom) have sustained anaphylactoid reactions. These reactions have been avoided when ACE-inhibitors were temporarily withheld but they reappeared upon inadvertant rechallenge.
Cough
A non-productive, persistent cough has been reported with the use of ACE-inhibitors. The cough resolves after discontinuation of therapy. ACE-inhibitor-induced cough should be considered as part of the differential diagnosis of cough.

• KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Treatment is symptomatic and supportive. No specific information is available on the treatment of overdosage with Lisinopril And Hydrochlorothiazide. Therapy with Lisinopril And Hydrochlorothiazide should be discontinued and the patient should be kept under very close supervision. Suggested measures include induction of emesis and/or gastric lavage, if ingestion is recent, and correction of dehydration, electrolyte imbalance and hypotension by established procedures.
Lisinopril:The most likely features of overdosage may include hypotension, electrolyte disturbance and renal failure. Treatment is symptomatic and supportive.
Hydrochlorothiazide:The most common signs and symptoms observed are those caused by electrolyte depletion (hypokalaemia, hypochloraemia, hyponatraemia) and dehydration resulting from excessive diuresis. If digitalis has been used concomitantly, hypokalaemia

• IDENTIFICATION:

Lisinopril And Hydrochlorothiazide 10 Tablets	Round, biconvex. The tablets are uniformly pink coloured, the surface is smooth and free from fractures and scratches. Diameter: 6,9 –7,3 mm; Height: 2,8 –3,2 mm
	Round, biconvex. The tablets are uniformly pink coloured, the surface is smooth and free from fractures and scratches. Diameter: 8.9 mm –9.3 mm; Height: 3,6 - 4,2 mm

• PRESENTATION:
The tablets are packed into white, opaque PVC/aluminium blister strips containing 10 tablets each.
3 (10) blister strips packed into a carton i.e. 30 tablets per carton

• STORAGE INSTRUCTIONS:
Store in a well-closed container, in a dry place, below 25°C. Protect from light.
KEEP OUT OF REACH OF CHILDREN.

DISLAIMER

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According to the Indian Trade Mark the company owns about 450 brands and 4600 generic manufacturing permissions in India. According to the export data analysis the company was the largest exporter of generic medicines to the Europe and Middle East countries.
www.tajpharma.com

The company medicines are present in France, Georgia, Egypt and CIF countries.

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