GIS Pharma Part. Ltd.
ห้างหุ้นส่วนจำกัด จีไอเอส ฟาร์มา

MYOPRIL-5

ENALAPRIL MALEATE TABLETS U.S.P. 5 mg

0.65 cm.

โปรดอ่านรายละเอียดเพิ่มเติมในเอกสารกำกับยา

ฆศ.842/2561

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Each uncoated tablet contains :

Enalaril Maleate U.S.P.....5 mg.

CLINICAL PHARMACOLOGY

MECHANISM OF ACTION :

The beneficial effects of MYOPRIL in hypertension & heart failure appear to result primarily from suppression of the renin-angiotensin-aldosterone system. Inhibition of ACE results in decreased plasma angiotensin II, which leads to decreased vasopresser activity & to decreased aldosterone secretion.

PHARMACOKINETICS & METABOLISM :

Following oral administration of MYOPRIL, peak serum concentrations of enalapril occur within about one hour. Enalapril is hydrolized to enalaprilat, which is a more potent angiotensin converting enzyme inhibitor than enalapril. Peak serum concentrations of enalaprilat occur 3-4 hours after and oral dose of MYOPRIL is primarily renal.

PHARMACODYNAMICS & CLINICAL EFFECTS :

In some patients achievement of optimal blood pressure reduction may require several weeks of therapy. The antihypertensive effect of MYOPRIL have continued during long term therapy. Abrupt withdrawal of MYOPRIL has not been associated with a rapid increase in blood pressure. In haemodynamic studies in patients with essential hypertension, blood pressure reduction was accompanies by reduction in peripheral arterial resistance with an increase in cardiac output & a little or no change in heart rate.

When given together with thiazide-type diuretics, the blood pressure lowering effects of MYOPRIL are approximately additive.

INDICATION & USAGE :

HYPERTENSION :

MYOPRIL is indicated for the treatment of hypertension. The blood pressure lowering effects of MYOPRIL & thiazides are approximately additive.

HEART FAILURE : MYOPRIL is indicated as adjunctive therapy in the management of heart failure, in patients who are not responding adequately to diuretics & digitalis. MYOPRIL is to be used with diuretics & digitalis. Captopril, has caused agranulocytosis, particularly in patients with renal impairment or collagen vascular disease & that available data are insufficient to show that MYOPRIL does not have similar risk.

CONTRAINDICATIONS :

MYOPRIL is contraindicated in patients who are hypertensive to this product & in patients with a history of angioedema related to previous treatment with an angiotensin converting enzyme inhibitor.

WARNING :

ANGIOEDEMA : Angioedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported in patients treated with angiotensin converting enzyme inhibitor, including MYOPRIL.

HYPOTENSION : Excessive hypotension is rare in uncomplicated hypertensive patients treated with MYOPRIL alone.

FETAL / NEONATAL MORBIDITY & MORTALITY :

ACE Inhibitor can cause fetal & neonatal morbidity & death when administered to pregnant women.

Prematurity Intrauterine growth retardation & patent ductus arteriosus have also been reported, although it is not clear whether these occurrences were due to the ACE-Inhibitor exposure.

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PRECAUTIONS :

GENERAL : In patients with severe heart failure whose renal function may depend on the activity of the renin-angioten sin-aldosterone system, treatment with angiotensin converting enzyme inhibitors, including MYOPRIL, may be associated with oliguria and/or progressive azotemia & rarely with acute renal failure and/or death.

INFORMATION FOR PATIENTS :

ANGIOEDEMA : Angioedema including laryngeal edema, may occur especially following the first dose of MYOPRIL.

HYPOTENSION : Patients should be cautioned to report lightheadness especially during the first few days of therapy.

HYPERKALEMIA : Patients should be told not to use salt substitutes containing potassium without consulting their physician.

DRUG INTERACTIONS :

HYPOTENSION-PATIENS ON DIURETIC THERAPY :

Patients on diuretics & especially those in whom diuretic therapy was recently instituted, may occasionally experience an excessive reduction of blood pressure after initiation of therapy with MYOPRIL.

NERVOUS/PSYCHIATRIC : Depression, confusion, ataxia, somnolence, insomnia, nervousness, peripheral neuropathy (e.g : paresthesia, dysethesia)

RESPIRATORY : Bronchospasm, rhinorrhea, sore throat & hoarseness, asthma.

SKIN : Exfoliative dermatitis, toxic epidermal necrolysis.

SPECIAL SENSES : Blurred vision, taste alteration, anosmia, tinnutis.

OVERDOSAGE :

Limited data are available in regard to overdosage in humans. The most likely manifestation of overdosage would be hypo-tension, for which the usual treatment would be intravenous infusion of normal saline solution. Enalaprilat may be removed from gerteral circulation by hemodialysis & has been removed from neonatal circulation by peritoneal dialysis.

DOSAGE & ADMINISTRATION :

The recommended staring dose is 2.5 mg administered once or twice daily. The usual therapeutic dosing range is 5-20 mg daily. Given as a single dose or two divided doses; the majority of patient experience in clinical studies has been with twice daily dosing. Dosage may be adjusted depending upon clinical response.

STARAGE :

Store in a cool (below 25°C) dry place. Protect from light.

PRESENTATION :

Strip of 10 tablets (10 X 10's).

Manufactured by :

UNIQUE PHARMACEUTICAL LABS.

(A Division of J.B. Chemicals & Pharmaceuticals Ltd.)

128/1, GIDC, Ankleshwar-393002, Gujarat State, India.

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