For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

Nusar® - H

Losartan Potassium & Hydrochlorothiazide Tablets

Therapeutic Segment :
It is a fixed dose combination tablet of Losartan Pottassium and Hydrochlorothiazide for better control of hypertension.

Composition :
Each film coated tablet contains :
Losartan Potassium USP 50 mg
Hydrochlorothiazide BP 12.5 mg
Excipients q.s.

Description :
Losartan Potassium is an orally active non-peptide angiotensin II receptor antagonist. It is the first of a new class of drugs to be introduced for clinical use in hypertension. chemically it is 2-butyll-4-chloro-1-[P-(O-1)-H-tetrazol-5 yl(phenyl)-benzyl]-imidazole-5, menthol monopotassium salt. Its molecular weight is 461.01 and emperical formula is $C_{12}H_{22}ClKN_6O$.
Hydrochlorothiazide is a thiazide diuretic. Chemically it is 6-chloro-3, 4-dihydro-2H-1,2,4-benzothiadiazine - 7-sulphonemide 1,1-dioxide. Its molecular weight is 297.7 emperical formula is $C_7H_8ClN_3O_4S_2$.

Pharmacokinetics :
Losartan Potassium is coverted in the liver, to its active metabolite E-3174, which is a more potent antagonist of the AT1 receptor. E-3174 is responsible for most of the pharmacological effects of Losartan Potassium. Its half-life contributes to the extended duration of action of the drug. Bioavailability of Losartan Potassium is about 33% and is not altered by presence of food. About 14% of administered drug is metabolized into E-3174 in most cases. Tmax for the drug is 1 hour and 3-4 hours to 6 hours depending upon the population type, terminal half life of the metabolite is larger by 2 hours than the parent drug. 30% of patients with severe hypertension get their conditions managed with Losartan Potassium plus Hydrochlorothiazide 12.5 mg in 12 weeks period. Clinical studies show that compared to Losartan Potassium monotherapy, the combination therapy is found to reduce diastolic BP additionally by 4 to 6 mm of Hg in patients.

Indications :
For the treatment of Hypertension, and hypertension not controlled by monotherapy.

Side Effects :
The adverse affect profile of the Losartan Potassium-Hydrochlorothiazide combination resembles those for Losartan Potassium monotherapy, Dissiness has been reported as the only drug related side effect. Hydrochlorothiazide is known to cause dose dependent primary hypokalemia. It is also reported to produce pancreatitis.

Precautions :
Since Hydrochlorothiazide is a diuretic patients should be observed for evidence of fluid or electrolyte imbalance.

Drug Interactions :
This drug may be administered with other anti hypertensive agents.

The drug can be given with or without food. Alcohol, barbiturates or narcotic potentiates orthostatic hypotension when used with hydrochlorothiazide Dose adjustment of Oral anti-diabetics or insulin may be required when used with this drug.

Overdosage and Treatment :
Electrolyte depletion and dehydration occurs with overdose of Hydrochlorothiazide. In the event of over dosage, symptonatic and supportive measures should be employed. Neither Losartan nor its derivatives can be removed through hemodialysis.

Warnings :
Should be used with caution in patients with impaired hepatic function or progressive liver diseases.
Since drugs acting directly on Angiotension II receptors are known to cause mortality of fetus, this therapy should be discontinued as soon as possible, when ever pregnancy is reported in patients on this therapy.

KEEP AWAY FROM THE REACH OF CHILDREN.

Contraindications :
Hypersensitivity to Losartan Potassium and or Hydrochlorothiazide or other Sulphonamide derived drugs.

Dosage and Administration :
For patients whose blood pressure not adequately controlled with Losartan Monotherapy, Initial dose is
One tablet once daily
If Blood pressure remains uncontrolled after about 3 weeks of therapy, the dose may be increased to:
Two tablets once daily.

Storage :
Store in a dry place, below 25°C.

Presentation :
Strip of 10 tablets.

Manufactured by :
Emcure®
PHARMACEUTICALS LTD.
Lane No. 3, Phase-II, SIDCO,
Bari-Brahmana, Jammu-181 133, INDIA.

514441328NG01

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Product	Nusar - h	**New / Revised A/W**	New A/W	**FDA Lic. Availability**	Avail.
Dosage form	Tablet	**Reason for change**	New for Nigeria	**Proof 1**	15-11-2011
Therapeutic Category	Antihypertensive	**Colour Scheme**	Black	**Corrections of Proof 1**	
Item	Nigeria Export Carton A/W	**Pantone Shades**	N.A.	**Proof 2**	16-11-2011
Dimension	L. 80 x H. 210 mm. (Folded : 80 x 27)	**Total No. of Colours**	1	**Corrections of Proof 2**	
Substrate	Super white maplitho paper (J.K. Mill)	**Special Effect (if any)**	N.A.	**Proof 3**	17-11-2011
Specification	60 GSM	**Item Code**	514441328NG01	**Corrections of Proof 3**	
Printing Area	B/B	**Marketing Division**	Emcure Export	**Final**	7-1-2012
Item Style	N.A.	**Design / Colour Approved on**	N.A.	**A/W Checked by**	PMD Cell
A/W Proportion	Same Size	**Vendor**	Dayal	**A/W Verified by**	Production / QC
Product Status	Emcure Own Jammu Unit	**Country**	Nigeria Exp.	**A/W Approved by**	Unit Head
Remark (If any) : New for Nigeria Export					