MICRO LABS LIMITED, BANGALORE, INDIA			
1	Product Name	Nipartan	Colours Used
2	Strength	50 mg	BLACK
3	Component	Leaflet	
4	Category	Export - Philippines	
5	Dimension	120 x 170 mm	
6	Artwork Code	EXG-ML01I-1277/C	
7	Pharma Code	N/A	
8	Reason for Change	Size and New Regulation	

	Prepared by (DTP)	Checked by (PD)	Approved by			
			Head CQA	Head Production/ Packing (Site)	Head QC (Site)	Head QA (Site)
Sign	Kantharaju L.					
Date	13-11-2021					

Size: 120 (L) x 170 (H) mm
Folding size: 30 x 120 mm
Carton size: 46 x 22 x 106 mm

Front

Back

170 mm

LOSARTAN POTASSIUM

NIPARTAN™

50 mg Tablet
Angiotensin II Receptor Blocker

PRODUCT NAME:
NIPARTAN

DOSAGE FORM AND STRENGTH:
Losartan Potassium 50 mg

PHARMACOLOGIC CATEGORY: Angiotensin II Receptor Blocker

PRODUCT DESCRIPTION:
Bluish green coloured, circular, biconvex film coated tablets

FORMULATION/COMPOSITION:
Each film-coated tablet contains:
Losartan Potassium ..... 50 mg

Pharmacokinetics:
Losartan is readily absorbed from the gastro-intestinal tract following oral administration, with an oral bioavailability of about 33%. It undergoes first-pass metabolism to form an active carboxylic acid metabolite E-3174 (EXP-3174), which has greater pharmacological activity than losartan, and some inactive metabolites. Peak plasma concentrations of losartan and E-9174 occur 1 hour and 3 to 4 hours respectively after an oral dose. Both losartan and E-317 4 are more the 98% bound to plasma proteins. Losartan is excreted in the urine; end in the faeces via bile, as unchanged drug metabolites. Following oral dosing about 35% of the dose is excreted in the urine and about 60% in the faces. The E-3174 is about 1.5 to 2.5 hours and 3 to 9 hours, respectively.

INDICATIONS:
Used In the management of hypertension; diabetic nephropathy in type 2 diabetes mellitus

DOSAGE AND MODEL ROUTE OF ADMINISTRATION:
In hypertension the usual dose is 50 mg once daily. The maximum effect is achieved in about 3 lo 6 weeks after Initiating treatment. The dose may be increased, if necessary, lo 100 mg daily in one or two divided dose or as directed by the physician.
Use in elderly:
Patients over 75 years and for patients with moderate and severe renal impairment (creatinine clearance less than 20mL per minute), or intravascular fluid depletion. A reduced dose should be considered for patients with hepatic impairment.

CONTRAINDICATIONS &PRECAUTION(S), WARNING(S)
Losartan is contraindicated in patients who are hypersensitive to any component of this product. Losartan is also contraindicated in pregnancy and if pregnancy is detected, Losartan should be discontinued immediately.

PRECAUTIONS AND WARNINGS:
Losartan is contraindicated in pregnancy and breastfeeding. It should also be used with caution in patients with renal artery stenosis. Reduced doses may be required in patients with hepatic impairment. Patients with volume depletion (for example those who have received high-dose diuretic therapy) may experience hypotension, which may be minimized by initiating treatment with a low dose of losartan. Since hyperkalaemia may occur, serum-potassium concentrations should be monitored, especially in the elderly and patients with renal Impairment, and the concomitant use of potassium-sparing diuretics should be avoided.

ADVERSE EFFECTS:
Adverse effects of losartan have been reported to be usually mild and transient, and include dizziness and dose related orthostatic hypotension. Hypotension may occur particularly in patient with volume depletion (for example those who have received high-dose diuretics).
Impaired renal function and rarely, rash, angioedema, and raised alanine aminotransferase may occur. Hyperkalaemia and myalgia have been reported. Losartan appears less likely than ACE inhibitors to cause cough.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

DOSAGE FORMS AND PACKAGING AVAILABLE:
Losartan Tablets 50mg, Alu/Alu blister pack of 10's (Box of 30's and 100's)

INSTRUCTIONS AND SPECIAL PRECAUTIONS FOR HANDLING AND DISPOSAL (IF APPLICABLE):
Not Applicable

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:
Marketing Authorization Holder
Brown & Burk Philippines Inc.
U-501, 5/F SEDCCO 1 Bldg., 120 Rada cor.
Legaspi St., Legaspi Village, Makati City

NAME AND ADDRESS OF MANUFACTURER:
MICRO LABS LIMITED
92, Sipcot, Hosur – 635 126,
Tamil Nadu, India.

CAUTION STATEMENT:
FOODS, DRUGS, DEVICES, AND COSMETICS ACT PROHIBITS DISPENSING WITHOUT PRESCRIPTION.

ADR REPORTING STATEMENT:
FOR SUSPECTED ADVERSE DRUG REACTION, REPORT TO THE FDA: www.fda.gov.ph
Seek medical attention immediately at the first sign of Adverse Drug Reaction.

REGISTRATION NUMBER:
DRP-897

DATE OF FIRST AUTHORIZATION:
-

DATE OF REVISION OF PACKAGE INSERT:
Sep. 2019

EXG-ML01I-1277/C

120 mm

120 mm