

MICRO LABS LIMITED, BANGALORE, INDIA								
1	Product Name	Nipartan-H			Colours Used ■ BLACK			
2	Strength	50 mg and 12.5 mg						
3	Component	Leaflet						
4	Category	Export - Philippines						
5	Dimension	120 x 170 mm						
6	Artwork Code	EXG-ML01I-1244/A						
7	Pharma Code	N/A						
8	Reason for Change	Size and New Regulation						
	Prepared by (DTP)	Checked by (PD)	Approved by					
Sign	Kanthalaju L.		Head CQA	Head Production/Packing (Site)	Head QC (Site)	Head QA (Site)		
Date	19-11-2021							

Size: 120 (L) x 170 (H) mm

Folding size: 30 x 120 mm

Back Carton size: 53 x 25 x 130 mm

Front



LOSARTAN POTASSIUM + HYDROCHLOROTHIAZIDE

NIPARTAN™ - H

50 mg / 12.5 mg Tablet

Angiotensin II Antagonist/Diuretic

PRODUCT NAME:
NIPARTAN-H

DOSAGE FORM AND STRENGTH:
Losartan Potassium 50 mg & Hydrochlorothiazide 12.5 mg

PHARMACOLOGIC CATEGORY:
Angiotensin II Antagonist/Diuretic

PRODUCT DESCRIPTION:
Orange coloured, circular, biconvex film coated tablets with a breakline on one surface

FORMULATION/COMPOSITION:
Each film-coated tablet contains:

Losartan Potassium 50 mg
Hydrochlorothiazide 12.5 mg

PHARMACOLOGY:
Angiotensin converting enzyme is a non-specific enzyme and plays a crucial role in the conversion of Angiotensin I to Angiotensin II. Angiotensin II is a potent vasoconstrictor and an important component incriminated in the pathophysiology of hypertension. It elicits its actions through two known membrane receptors, AT₁ and AT₂. The effects mediated through AT receptors includes vasoconstriction, aldosterone stimulation and salt and water retention. The role of AT₂ receptors in cardiovascular homeostasis is not yet established. Losartan potassium selectively antagonises binding of Ang II to AT₁ receptors. Consequently, 1 further effect of Ang II is blocked. As a supporting role, Losartan potassium's carboxylic acid metabolite also selectively blocks AT₁ receptors. One of the strategies in the management of hypertension is to alter body sodium levels by restriction of salt in the diet. Pharmacologically also sodium levels can be altered with the help of diuretics. Hydrochlorothiazide affects electrolyte reabsorption at the level of distal convoluted tubule and increase the excretion of sodium and chloride in approximately amounts by its inhibitory effects on Na Cl symport located in luminal membrane.

INDICATIONS:
Losartan Potassium + Hydrochlorothiazide (Nipartan-H) is indicated for the treatment of hypertension.

DOSAGE AND MODEL ROUTE OF ADMINISTRATION:
The usual dosage recommended is one tablet daily in the morning. The usual daily dosage recommended for the treatment of hypertension is 25-100 mg and 25-50 mg for Losartan and Hydrochlorothiazide respectively. Use lower starting doses in patients having impaired renal or hepatic function. Adjust the doses to a minimum effective strength in elderly patients on Hydrochlorothiazide. Losartan potassium can be given with or without food. Or as prescribed by the physician

CONTRAINDICATIONS & PRECAUTION(S), WARNING(S)
Losartan Potassium + Hydrochlorothiazide is contraindicated in patients who are Hypersensitivity to either drug & to other sulfonamide derived drugs, Anuria, Pregnancy & Breastfeeding mothers.

PRECAUTIONS AND WARNINGS:

In patients having intravascular volume depletion, either lower dose of Losartan potassium should be used, or salt and volume depletion should be corrected prior to Losartan potassium therapy.

ADVERSE EFFECTS:

The adverse effects reported frequently include headache, dizziness, asthenia / fatigue. Other effects include first dose hypotension, skin rash, oedema, transient elevation of liver enzymes, hyperkalaemia and taste disturbances. According to clinical trials, albeit cough has not been reported as a specific drug-related event with Losartan Potassium, the incidence of cough experienced is comparable to that placebo. The adverse effects frequently experienced with hydrochlorothiazide include electrolyte imbalances, glycosuria, hyperglycaemia, hyperuricaemia and weakness. Other side effects include gastrointestinal disturbances, headache, dizziness, photosensitivity reactions, postural hypotension, paraesthesia, impotence, xanthopsia, hypersensitivity reactions, cholestatic jaundice, pancreatitis and blood dyscrasias. The hyperkalaemia produced by hydrochlorothiazide.

STORAGE CONDITION:

Store at temperatures not exceeding 30°C.

DOSAGE FORMS AND PACKAGING AVAILABLE:

Losartan Potassium 50 mg & Hydrochlorothiazide 12.5 mg Alu/Alu blister pack of 10's (Box of 30'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 Sts., Legaspi Village, Makati City, Philippines

NAME AND ADDRESS OF MANUFACTURER:

MICRO LABS LIMITED
92, SIPCOT INDUSTRIAL COMPLEX,
HOSUR-635 126 (T.N), 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-872

DATE OF FIRST AUTHORIZATION:
09 January 2018

DATE OF REVISION OF PACKAGE INSERT:
Sep. 2019

EXG-ML01I-1244/A

170 mm

120 mm

120 mm