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For the use only of registered medical practitioners or a hospital or a laboratory

TM **NIPINE-10**

(Antihypertensive)

DESCRIPTION :

Nifedipine, the active ingredient of **NIPINE** tablets is chemically designated as 1,4-di-hydro-2,6-dimethyl-4-(o-nitrophenyl)-Pyridine-3,5-dicarboxylic acid dimethyl ester. It is a yellow coloured substance, practically insoluble in water but soluble in ethanol.

COMPOSITION :

Each uncoated tablet contains :
Nifedipine BP 10 mg
Excipients q.s.

PROPERTIES :

NIPINE is the most potent and specific calcium antagonist. It inhibits the influx of calcium-ions into the cells of myocardium and smooth muscle of coronary arteries and peripheral blood vessels. This action brings about uncoupling of excitation - contraction resulting in a decrease in the mechanical contraction of heart, coronary arteries and peripheral resistance of the vessels. In contrast to other calcium antagonist, **NIPINE** exerts a selective action on the cardiac muscle and contractile cells of the vessels. It does not inhibit calcium influx into the cells of atrioventricular node, therefore, intracardiac impulse conduction is not affected.

NIPINE exerts these major pharmacological actions which are responsible for improving the energy balance of heart in cases of ischaemic heart disease.

- 1) Direct reduction of myocardial oxygen requirement by decreasing the utilization of energy-rich phosphate.
- 2) Reduction of cardiac after-load due to decrease in peripheral vascular resistance.
- 3) Coronary vasodilation, coronary spasmolysis and improvement of post-stenotic blood flow in coronary circulation.

As result of the above actions, **NIPINE** abolishes the anginal attacks, improves exercise-tolerance and corrects the E.C.G. changes in Ischaemic Heart Disease.

Administration of **NIPINE**, even at low dosage, produces objectively demonstrable anti-hypertensive effect due to dilatation of blood vessels resulting in reduction of peripheral vascular resistance.

The use of **NIPINE** is not associated with disturbances of atrio-ventricular conduction, deterioration of pulmonary functions due to bronchoconstriction in cases of chronic obstructive pulmonary disease (COPD), and impairment of haemodynamic adjustments. Long-term administration of **NIPINE** does not produce development of tolerance to its therapeutic actions and its abrupt discontinuation does not lead to occurrence of any withdrawal reaction.

NIPINE is compatible with beta-blockers, digitalis, anti-thrombotics, anti-coagulants and anti-diabetics.

Following oral administration, **NIPINE** is rapidly absorbed producing effective serum concentration within 20 minutes. For termination of acute attacks of angina, the tablet of **NIPINE** can be kept under the tongue from where it is very quickly absorbed within 3 minutes. With both the routes of administration the peak serum level is achieved. It undergoes complete metabolism and is excreted via kidneys.

INDICATIONS :

- a) Coronary Heart Disease - For the termination of acute and long term therapy of Chronic Stable Angina Pectoris and Post-infarction Syndrome. **NIPINE** is proved to be particularly effective in Prinzmetal's Angina.
- b) Hypertension - All grades of Primary Essential and Secondary Hypertension.

CONTRAINDICATIONS :

- i) Hypersensitivity to Nifedipine
- ii) Pregnancy.

ADVERSE EFFECTS :

NIPINE is generally well tolerated by majority of patients. The occasionally reported side effects occur in the early stage of therapy and they are mild and transient in nature. These side effects represents the extension of its pharmacological action on blood vessels and include headache, sensation of warmth, facial flush, nausea and dizziness. On very rare occasions, chest pain may develop 15-30 minutes after the administration, such a side effects is seen with most other vasoactive drugs.

DOSEAGE :

The dosage should be individualized, depending upon the severity of the disease and responsiveness of the patient.

- a) Coronary Heart Disease - The recommended dosage is 10 mg to 20 mg three times a day in Prinzmetal's angina (angina at rest) a successful treatment may in individual cases only be possible by a further transitory increase in the daily dose to 20 mg given 4 to 6 times a day at intervals of not less than 2 hours.
- b) Hypertension - 5 mg to 20 mg three times a day. For the treatment of hypertensive crisis, 10 mg to 20 mg are usually recommended sublingually rarely some cases may require upto 30 mg.

Prescription only medicine.

ADMINISTRATION :

Generally the tablets should be swallowed with a glass of water, independent of meals.

For termination of anginal attack and/or hypertensive crisis the tablet may be chewed and allowed to dissolve and remain in the mouth for a short time. Owing to contact with the buccal mucosa the active ingredient is rapidly absorbed.

STORAGE :

Store in a cool (below 30°C), dry place. Protect from light.

AVAILABILITY :

NIPINE 10 : Blister of 10 tablets.



SARABHAI[®]

Medicines you can trust

Manufactured by :
Ambalal Sarabhai Enterprises Limited
Division :

SARABHAI CHEMICALS
Dr. Vikram Sarabhai Marg, Wadi Wadi,
Vadodara 390 023, India.

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