SUMMARY OF PRODUCT CHARACTERISTICS

A. Brand Name
NIPINE-10

B. International Non-Proprietary Names (INNs)
Nifedipine tablets

C. Pharmaceutical Form, Dosage and Route of Administration
Pharmaceutical Form: Tablet, Yellow coloured, round shaped, biconvex, uncoated tablet with a break line on one side.

Dosage: The dosage should be adjusted, depending on the severity of the disease and the response to the patient.
a) Hypertension-5 mg to 20 mg three times a day. For the treatment of hypertensive growth, 10 mg to 20 mg sublingually are usually recommended. Rarement, some cases may require up to 30mg.
b) Coronary artery disease - The recommended dosage is 10 mg to 20 mg three times daily for Prinzmetal's angina (resting angina). Effective treatment in individual cases may be possible by transiently increasing the daily dose of 20 mg 4 to 6 times daily at intervals of at least 2 hours

Route of Administration: In general, the tablets should be swallowed with a glass of water, except for meals.
In case of angina attack and / or hypertensive crisis, the tablet can be chewed and allowed to dissolve and remain in the mouth for a short period. Owing to contract with the buccal mucosa the active ingredient is rapidly absorbed.

D. Qualitative and Quantitative Composition of active ingredients and excipients

Sr. No.	Raw Material	Specification	QTY. / TABLET MGS. / Tablet		QTY. / BATCH (KGS. / Batch.)		Category
1	Nifedipine	BP	10.000	mg	1.000	Kg	Active Pharmaceutical Ingredient
2	Purified Talc	BP	1.000	mg	0.100	Kg	Lubricant & glidant
3	Magnesium Stearate	BP	1.000	mg	0.100	Kg	Lubricant
4	Yellow Base Granules	IH	90.00	mg	9.000	Kg	Diluent & Binding agent
5	Croscarmellose Sodium	BP	8.000	mg	0.800	Kg	Superdisintegrant
	Total		110.00	mg	11.000	Kg	---

BP : British Pharmacopoeia
IH: In house specifications

NOTES:
1. Active material issue quantity calculated on actual assay & L.O.D to compensate the 100 % assay.
2. If issue qty. is less than standard qty. in this case active material qty. compensate by adding excipients & if issue qty. is more than standard qty. in this case active material qty. compensate by reducing excipients.

E. Therapeutic Indications

a) Hypertension- All grades of Primary Essential and Secondary Hypertension.

b) 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 the angina of Prinzmetal (spontaneous angina).

F. Dosage and Method of Administration

Refer section C above in the SPC

G. Contra-indications

Absolute:

i) Hypersensitivity to nifedipine

ii) Pregnancy

H. Precautions and Warnings

Nifedipine should be used with caution in hypotensive patients, patients with poor cardiac reserve, and those with heart failure because of a deterioration of heart failure. Nifedipine should not be used in cardiogenic shock, in patients who have had a myocardial infarction within 2 to 4 weeks, in acute unstable angina. Nifedipine should not be used to treat a seizure in chronic stable angina pectoris. In patients with severe aortic stenosis nifedipine may increase the risk of developing heart failure abrupt discontinuation of nifedipine therapy to be associated with an aggravation of the angina pulp. Reduced doses of nifedipine are needed in patients presenting hepatic insufficiency. Nifedipine should be discontinued in patients who experience ischemic pain.

In pediatric

The safety and efficacy of nifedipine in children under the age of 18 have not been established.

In hepatic insufficiency

Nifedipine 10 and 20 should be used with caution in patients with hepatic impairment. Dose reduction, especially in severe cases, may be necessary. Close monitoring of the response and the metabolic effect should be applied.

In the elderly

The Pharmacokinetics of nifedipine is impaired in the elderly, who may require lower maintenance doses than younger patients.

In diabetics

A possible interaction with glucose induced by insulin release should be taken into account when treating diabetic patients with nifedipine, but based on a long experience; nifedipine has no real diabetic potential.

I. Drug Interactions

Nifedipine may increase the antihypertensive effects of other antihypertensive drugs such as betabloquan, which is generally well tolerated. Its combination with drugs such as antipsychotics increases the antihypertensive effects causing hypotension.
Nifedipine can alter the insulin, glucose responses. Therefore, diabetic patients should adjust their antidiabetic treatment when taking nifedipine.
Nifedipine is metabolized in the liver by cytochrome CYP3A4 isoenzyme P450. Interactions may occur with other drugs, such as quinidine, by sharing the same metabolic pathway and with enzyme inducers, such as carbamazepine, phenytoin, and rifampicin, and enzyme inhibitors such as iminidine, and the like erythromycin and inhibitors of HIV protease.

J. Use during Pregnancy and Lactation

Pregnancy:

Nifedipine has potentials for hypoxiefootal, child birth caesarean section, laprematuritis and intrauterine growth retardation may be associated with maternal hypotension. Therefore, she is against indicated during pregnancy.

Lactation:

Nifedipine passes into breast milk. The available evidence is insufficient to determine the effects of nifedipine in infants. It is recommended to stop breastfeeding if nifedipine is used.

K. Side Effects

NIPINE is generally well tolerated by the majority of patients. Occasional side effects occur early in therapy and are mild and transient. These side effects represent the extension of its pharmacological action on the blood vessels and give headaches, sensation of warmth, facial flush, nausea and dizziness. On rare occasions, chest pain may develop 15-30 minutes after administration, and such side effects occur with most other vasoactive drugs.

L. Over dosage

Redness, headache, low blood pressure, tachycardia, bradycardia, hyperglycemia, metabolic acidosis, hypoxia, cardiogenic shock with pulmonary disease, disturbances of the consciousness of coma, If these symptoms are observed in time, the first therapeutic measure to consider is gastric lavage in combination with coal, if necessary with irrigation of the small intestine. Hemodialysene serves nothing, since nifedipine is not dialysable. However, plasmapherese is advisable. There is no specific antidote. The treatment is symptomatic and supportive. Bradycardia can be treated symptomatically by beta-sympathetic metabolism. Hypotension following cardiogenic shock and vasodilation arterial can be treated with calcium (10-20 ml of a 10% solution of gluconate decalcium administered in slow IV and repeater sinecessaire.)

M. Pharmacodynamic Data

Nifedipine, the active ingredient in NIPINE tablets, is chemically designated as 1, 4-di-hydro-2, 6-dimethyl-14- (O-nitrophenyl) -pyridine-3,5-dicarboxylic acid dimethyl ester. It is a yellow substance, practically insoluble in water but soluble in ethanol. NIPINE is a calcium antagonist. It inhibits the influx of calcium ions into myocardial cells, smooth muscles of the coronary arteries and peripheral blood vessels. This action results in the separation of excitation - contraction resulting in a decrease in the mechanical contraction of the coronary artery, coronary arteries and peripheral resistance vessels. Unlike other calcium antagonists, NIPINE has a selective action on the heart muscle and contractile cells of vessels. It does not inhibit the influx of calcium into atrioventricular node cells; therefore the conduction of intracardiac impulses is unaffected.

NIPINE carries out these pharmacological actions which are responsible for improving the energy balance of the heart in cases of ischemic heart disease:
1) direct reduction of myocardial oxygen requirement by decreasing the use of energy-rich phosphate.
2) Reduction of post cardiac load due to a decrease in peripheral vascular resistance.
3) Coronary vasodilatation, coronary spasmolysis and improvement of post-stenotic blood flow in the coronary circulation.

As a result of these actions, NIPINE suppresses anginal attacks, improves exercise tolerance and corrects ECG changes in ischemic heart disease.

The administration of NIPINE even at a low dose objectively produces a demonstrable antihypertensive effect due to the dilation of the blood vessels resulting from the reduction of peripheral vascular resistance.
The use of NIPINE is not associated with atrioventricular conduction disorders, deterioration of pulmonary function due to bronchoconstriction in chronic obstructive pulmonary disease (COPD), and impaired hemodynamic adjustments.
The long-term administration of NIPINE does not produce the development of solubility for its therapeutic effects and its abrupt arrest does not lead to the appearance of a withdrawal action.
NIPINE is compatible with betablockers, digitalis, anti-thromobotics, anticoagulants and antidiabetic agents.

N. Pharmacokinetic Data

After oral administration, NIPINE is rapidly absorbed into producing the effective seric concentration in 20 minutes. In case of acute angina pectoris, the NIPINE tablet can be kept under the tongue where it is very quickly absorbed within 3 minutes. With both routes of administration, the magpie is reached. It is completely transformed into inactive metabolites in the liver and is excreted by the kidneys.

O. Incompatibilities

Not applicable

P. Storage Conditions

Store in a cool (below 30^0C), dark place. Protect from light. Keep out of the reach of children.

Q. Instructions For Use /handling

Use as directed by a physician.

R. Effect on Ability to Drive and Use Machines

Reactions to the drug, which vary in intensity from individual to individual, may impair the ability to drive or to operate machinery (see Section K. side effects). This applies particularly at the start of treatment, on changing the medication and in combination with alcohol.

S. Shelf Life

36 months

T. Inscription in the List of Poisonous Substance

Not applicable

U. Packaging

Available in Blister pack of 10 x 10 tablets placed in carton along with insert.

V. Name and Address of the Manufacturer

Ambalal Sarabhai Enterprises Limited
Division: Sarabhai Chemicals
Dr.Vikram Sarabhai Marg, Wadi Wadi,
Vadodara – 390 023, India
Contract Manufactured at:
Centurion Remedies Pvt. Ltd.
Plot No: G/5 & G/6, B.I.D.C, Gorwa,

Dist. Vadodara – 390016.
Country: India

W. Name and Address of the MA Holder
Asence Pharma Pvt. Ltd.
Sarabhai Campus,
Dr. Vikram Sarabhai Marg, Wadi Wadi,
Vadodara – 390 023, India