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

# NIPINE-SR 20

NIFEDIPINE EXTENDED RELEASE  
TABLETS USP 20 mg

## (Antihypertensive)

### COMPOSITION :

Each extended release tablet contains :  
Nifedipine USP 20 mg  
Excipients q.s.

### DESCRIPTION :

Nifedipine the active ingredient of **Nipine-SR 20** 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.

Each tablet of **Nipine-SR 20** contains : Nifedipine USP 20 mg **Nipine-SR 20** tablet is a specially designed to produce sustained blood levels for 12 hours.

### PROPERTIES :

Nifedipine, the active ingredient of **Nipine-SR 20**, is a powerful and specific blocker of slow calcium channels of smooth muscle cells. It inhibits the influx of calcium-ions into the cells of smooth muscle of coronary arteries, peripheral resistance vessels and also the myocardium. This action brings about uncoupling of excitation-contraction resulting in a decrease in the mechanical contraction of myocardium, coronary arteries and peripheral resistance vessels. In fact Nifedipine exerts a selective action on the smooth muscle of coronary and peripheral blood vessels resulting in the relief of coronary spasm, coronary vasodilation and peripheral vasodilation. The peripheral vasodilating action of Nifedipine leads to a decrease in peripheral vascular resistance and thereby a fall in blood pressure. The fall in blood pressure produced by Nifedipine is proportionate to the pre-treatment level of blood pressure. Unlike other calcium channel blocking agents, Nifedipine does not inhibit calcium influx into cells of atrioventricular node, therefore, it does not affect intracardiac impulse conduction.

The use of **Nipine-SR 20** is not associated with disturbances of atrioventricular 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 Nifedipine does not produce development of tolerance to its therapeutic actions and its abrupt discontinuation does not lead to occurrence of any withdrawal reaction.

**Nipine-SR 20** is compatible with beta-blockers, digitalis, antithrombotics, anticoagulants and antidiabetics.

**Nipine-SR 20** tablet is specially designed to provide sustained levels of Nifedipine in blood for 12 hours so that twice a day administration of the drug is sufficient to provide adequate and sustained control over raised blood pressure.

### INDICATIONS :

**Nipine-SR 20** tablet is indicated in the treatment of all grades of essential hypertension.

### CONTRAINDICATIONS :

**Nipine-SR 20** tablet is contraindicated in :

1. Pregnancy
2. Cardiogenic shock
3. Hypersensitivity of Nifedipine.

### PRECAUTIONS :

**Nipine-SR 20** tablets should be used with caution in patients having poor cardiac reserve and impaired hepatic function.

Although, in most patients **Nipine-SR 20** does not produce excessive hypotension, but in occasional patients, particularly in those receiving other antihypertensives, it may lead to excessive hypotension, therefore blood pressure should be closely monitored specially during the initial phase of therapy.

Rarely, patients having severe obstructive coronary disease may develop increased frequency during and or severity of angina on starting treatment with **Nipine-SR 20** tablet. Similarly, patients abruptly withdrawn from beta blockers and put on **Nipine-SR 20** therapy may experience angina pectoris. Therefore, it is important to taper beta-blockers before starting treatment with **Nipine-SR 20**

Concomitant administration of **Nipine-SR 20** with beta-blockers may lead to heart failure, particularly in patients having tight aortic stenosis.

### ADVERSE EFFECTS :

**Nipine-SR 20** is generally well tolerated by majority of patients. The reported side effects are mild and transient in nature which tends to disappear on continuation of therapy. These side effects are mostly extension of its pharmacological effects and include headache, sensation of warmth, flushing, dizziness, light headedness, giddiness, weakness, nausea and heart burn. Sometimes it may lead to palpitation, tremor and nervousness. On very rare occasions, it may lead to angina pectoris and excessive hypotension. Ankle edema has also been reported with the use of **Nipine-SR 20**

### DOSAGE :

**Nipine-SR 20** is recommended to be administered in a dose of one tablet twice a day (12 hourly). If the blood pressure is not adequately controlled, its dose may be increased to 2 tablets twice a day.

**Nipine-SR 20** is not recommended for use in children.

Discontinuation of **Nipine-SR 20** therapy has not been reported to cause withdrawal syndrome, however, it is recommended to taper the dosage of **Nipine-SR 20** when discontinuation of treatment is necessary.

Prescription only medicine.

### AVAILABILITY :

**Nipine-SR 20** in Blister of 10 tablets and Jar of 1000 tablets.

### STORAGE :

Store in a cool (below 30°C), dry place. Protect from light.  
Keep out of reach of children.

Medicines you can trust

Mfg. by: Centurion Laboratories Private Limited  
At : Plot No. P-2, Savji Bio-Tech Park, Manjusar,  
Ta: Savli, Dist: Vadodara - 391 775, India.

**asence**

Manufactured for :

**Asence Pharma Private Limited**

Sarabhai Campus, Dr. Vikram Sarabhai Marg,  
Wadi Wadi, Vadodara 390 023, India.



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Actual Size : 80 x 145 mm

■ Black