

## COMPOSITION

**Nidipine<sup>®</sup>** tablet: Each tablet contains Nifedipine BP 10 mg.

**Nidipine<sup>®</sup> SR** tablet: Each tablet contains Nifedipine BP 20 mg in sustained release formulation.

## PHARMACOLOGY

**Nidipine<sup>®</sup>** (Nifedipine) is an inhibitor of Calcium Channel Blocker that blocks the transmembrane influx of Calcium ions into muscle cells.

**Nidipine<sup>®</sup>** has selective effects as a dilator of arterial vessels. Nifedipine dilates main coronary and systemic arteries. As a result blood pressure falls and this elicits a sympathetic reflex response causing tachycardia and an increased cardiac output. Pulmonary arterial pressure also falls. **Nidipine<sup>®</sup>** has direct negative inotropic effects on cardiac muscles and these effects are seen at higher doses than dose which causes arterial vasodilatation.

Absorption of **Nidipine<sup>®</sup>** appears to be over 90% but the measured mean systolic bioavailability is between 45 and 70%.

Substantial presystemic metabolism may take place though no evidence of saturation is observed with the doses between 5 and 60 mg. The peak plasma levels occurs between 120 and 240 min. **Nidipine<sup>®</sup>** is widely distributed in the tissue and appears to undergo hepatic oxidation to three inactive metabolites which are excreted in the urine (80%) and faeces (20%). The elimination half life is apparently 6-11 hrs and plasma half life is 2-6 hours.

## INDICATION

**Nidipine<sup>®</sup>** (Nifedipine) is indicated in the management of all types of essential & renal hypertension. Also indicated in the management of hypertension during pregnancy & during coronary by pass surgery.

**Nidipine<sup>®</sup>** is also used for prophylaxis and the treatment of unstable & variant angina, myocardial infarction, and silent myocardial ischaemia. Moreover Nidipine<sup>®</sup> is also used in Raynaud's phenomenon & heart failure.

## DOSAGE AND ADMINISTRATION

**Nidipine<sup>®</sup>** tablet:

*Angina:* Initially 10 mg 3 times daily with food increased to 20 mg 3 times daily if necessary, in elderly patients, initially 5 mg 3 times daily.

*Raynaud's Phenomenon:* 10 mg 3 times daily; maximum 60 mg daily. In urgent cases, the tablet should be dissolved under the tongue like a sublingual tablet. The effect occurs within some minutes.

**Nidipine<sup>®</sup> SR** tablet:

The starting dose for patients, not previously prescribed Nifedipine products is one tablet once daily.

The recommended dose in hypertension and angina prophylaxis is 20 mg twice daily during or after food. Dosage may be adjusted within the range 10 mg twice daily to 40 mg twice daily.

Patients with liver dysfunction should commence therapy with 10 mg twice daily with careful monitoring. Patients with renal impairment do not require adjustment of dosage.

### **CONTRAINDICATION AND PRECAUTION**

Cardiogenic shock, advanced aortic stenosis, nursing mothers, GI obstruction, inflammatory bowel disease, hypotension.

Tablets should be swallowed whole and should not be bitten, chewed or broken up. It should be used with caution in patient whose cardiac reserve is poor. Should be withdrawn if ischaemic pain occurs or existing pain worsens shortly after initiating treatment. Use in diabetic patients requires adjustment of their control. Since the absorption of the drug could be modified by renal disease, caution should be exercised in treating such patients.

### **SIDE EFFECTS**

Headache, flushing, lethargy, gravitational oedema rash, nausea, increased frequency of micturation, eye pain, gum hyperplasia, depression, tremor, photosensitivity and few cases of jaundice have been reported. These reactions may regress on discontinuation of therapy. Its introduction may induce attacks of ischaemic pain in some patients with angina pectoris.

### **DRUG INTERACTION**

ACE inhibitors : Enhanced hypotensive effect.  
Anti-arrythmics : Plasma concentration of quinidine is reduced.  
Anti-bacterials : Rifampicin possibly increases metabolism of Nifedipine.  
Anti-epileptics : Plasma concentration of phenytoin increases.  
Antipsychotics : Enhanced hypotensive effect.  
 $\beta$ -blockers : Occasionally severe hypotension and heart failure may occur.  
Cyclosporin : Plasma concentration of Nifedipine possibly increases.  
Muscle relaxants : Effect of muscle relaxants e.g. tubocurarine increases.  
Ulcer healing drugs : Metabolism of Nifedipine increases.

### **USE IN PREGNANCY**

There are no adequate and well controlled studies in pregnant women. It should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

### **STORAGE CONDITION**

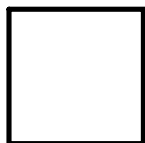
Protect from strong light, store in a cool place in the original pack.

### **HOW SUPPLIED**

**Nidipine**<sup>®</sup> tablet: Box containing 20 x 10 tablets in Aluminium strip pack.

**Nidipine**<sup>®</sup> **SR** tablet: Box containing 10 x 10 tablets in Aluminium strip pack.

® Registered Trade Mark





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