For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

CALCIGARD RETARD

(nifedipine 20mg sustained release tablets)

Calcigard (nifedipine) Retard, a dihydropyridine derivative is a specific and potent calcium channel blocker.

DESCRIPTION
Brown coloured, round, biconvex, film coated tablets with bisecting line on one side.

COMPOSITION
Each film coated substained release tablet contains Nifedepine USP 20 mg.

CLINICAL PHARMACOLOGY
Calcigard Retard inhibits influx of calcium through cardiac muscle and vascular smooth muscle cell membrane.
As a specific and potent calcium channel blocker, the main action of Calcigard is to relax arterial smooth muscle both in the coronary and peripheral circulation. In hypertension, the main action of Calcigard Retard is to cause peripheral vasodilation and thus reduce peripheral resistance. Calcigard Retard administered twice daily provides 24 hour control of raised blood pressure. Calcigard Retard causes reduction in blood pressure such that the percentage lowering is directly related to its initial height, In normotensive individuals, Calcigard Retard has little or no effect on blood pressure.

PHARMACOKINETICS
NifedipIne is completely absorbed after oral administration. Plasma drug concentrations rise at a gradual, controlled rate after Calcigard Retard tablet dose and plateau is maintained with minimal fluctuations over the 12 hour dosing interval. Nifedipine is extensively metabolised to highly water soluble, inactive metabolites accounting for 60 to 80% of the dose excreted in the urine. The elimination half-life of nifedipine is approximately 2 hours. Less than 0.1 % of the dose of unchanged form can be detected in the urine. The remainder is excreted in the faeces in metabolised form, most likely as a result of biliary excretion. Thus, the pharmacokinetics of nifedipine are not significantly influenced by the degree of renal impairment. Pharmacokinetics of nifedipine may be altered in patients with chronic liver disease.

INDICATIONS
For the prophylaxis of chronic stable angina pectoris and the treatment of hypertension.

DOSAGE & ADMINISTRATION :
Long-term Treatment: The retard tablets are generally swallowed whole with a little liquid, independently of mealtimes.
The recommended dose is 1 tablet (20mg) twice daily, dose may be adjusted to 40 mg every 12 hours.
The recommended interval between individual doses is about 12 hrs and should not be less than 4 hrs.

CONTRAINDICATIONS
Calcigard Retard should not be administered to patients with known hypersensitivity to nifedipine. Calcigard should not be used in patients with cardiogenic shock.

WARNING & PRECAUTIONS
Calcigard Retard tablets must be swallowed whole; under no circumstances should they be bitten, chewed or broken up.

Caution should be exercised in patients with hypotension as there is a risk of further reduction in blood pressure.

Calcigard Retard may be used in combination with beta-blocking drugs and other anti-hypertensive agents but the possibility of an additive effect resulting in postural hypotension should be borne in mind. Calcigard Retard will not prevent possible rebound effects after cessation of other antihypertensive therapy.

Calcigard Retard should be used with caution in patients whose cardiac reserve is poor. Deterioration of heart failure has occasionally been observed with nifedipine.

Ischaemic pain has been reported in a small proportion of patients following the introduction of nifedipine therapy. Although a 'steal' effect has not been demonstrated, patients experiencing this effect should discontinue nifedipine therapy.

Diabetic patients taking Calcigard Retard may require adjustment of their control.

In dialysis patients with malignant hypertension and hypovolaemia, a marked decrease in blood pressure can occur.

Whilst nifedipine is contra-indicated in pregnancy, particular care must be exercised when administering nifedipine in combination with i.v. magnesium sulphate to pregnant women.

DRUG INTERACTIONS:
The blood pressure-lowering effect of Calcigard Retard may be potentiated by other antihypertensive drugs.
When Calcigard Retard is administered simultaneously with ß-receptor blockers the patient should be carefully monitored in view of the possibility of severe hypotension; heart failure has also been known to develop.
The antihypertensive effect may be potentiated when nifedipine and cimetidine are administered simultaneously.

PREGNANCY & LACTATION
Nifedipine may not be used at any time during pregnancy.
Nifedipine passes into breast milk. It is not yet known whether a drug-induced (pharmacological) effect can occur in infants, but as a precaution it is recommended to stop breast feeding.

ADVERSE REACTION
Most adverse reactions are consequences of the vasodilator effects of nifedipine and include headache, dizziness and flushing. Gravitational oedema, not associated with heart failure or weight gain, has also been reported. Other less commonly reported side-effects include rash, nausea, lethargy and increased frequency of micturition. There are

reports of gingival hyperplasia which may regress on withdrawal of therapy.

OVERDOSAGE:
Reports of overdosage are limited and symptoms are not necessarily dose-related. Severe hypotension, bradycardia and unconsciousness have been observed. Gastric lavage and charcoal instillation have been employed. Intravenous calcium gluconate or calcium chloride appear most helpful, with intravenous atropine for bradycardia. Metaraminol has been beneficially combined with calcium in the experimental situation.

PRESENTATION
Calcigard Retard tablets are available in strips of 10, each tablet contains nifedipine 20 mg in sustained release form.

STORAGE CONDITION
Store below 30° C, protected from light and moisture.

SHELF LIFE
3 years from date of manufacture.

Manufactured by
TORRENT PHARMACEUTICALS LTD.
Indrad-382 721, Dist. Mehsana, INDIA.