CALCIGARD

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for CALCIGARD [Nifedipine 5 mg and 10 mg capsules I.P.]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Nifedipine is a specific and potent calcium antagonist of the 1, 4- dihydropyridine type. Calcium antagonists reduce the transmembranal influx of calcium ions through the slow calcium channel into the cell. Nifedipine acts particularly on the cells of the myocardium and the smooth muscle cells of the coronary arteries and the peripheral resistance vessels.

INDICATIONS: It is indicated for the management of vasospastic angina. It is indicated for the management of chronic stable angina (effort-associated angina) without evidence of vasospasm in patients who remain symptomatic despite adequate doses of beta blockers and/or organic nitrates or who cannot tolerate those agents.

DOSAGE AND ADMINISTRATION: For Oral use. Nifedipine capsules should not be taken with grapefruit juice. The recommended starting dose is 5mg, every 8 hours, swallowed with water, with subsequent titration of dosage according to response. The dosage may be adjusted to 20mg, every 8 hours.

CONTRAINDICATION: •Nifedipine capsules must not be administered to patients with known hypersensitivity to the active substance, or to other dihydropyridines because of the theoretical risk of cross reactivity, or to any of the excipients. •They should not be used in women who are or who may become pregnant. •Nifedipine capsules must not be used in cases of cardiogenic shock, clinically significant aortic stenosis, unstable angina, or during or within 4 weeks of an acute myocardial infarction. •Nifedipine should not be used for the treatment of acute attacks of angina, or in patients who have had ischaemic pain following its administration previously. •Nifedipine capsules should not be used for secondary prevention of myocardial infarction. •Nifedipine capsules are contra-indicated in patients with acute porphyria. •Nifedipine capsules should not be used in patients with Kock pouch (ileosetomy after proctocolectomy). •Nifedipine capsules should not be administered concomitantly with rifampicin since effective plasma levels of nifedipine may not be achieved owing to enzyme induction.

WARNINGS & PRECAUTIONS: Nifedipine capsules should not be used during pregnancy unless the clinical condition of the woman requires treatment with nifedipine. Careful monitoring of blood pressure must be exercised when administering nifedipine with I.V. magnesium sulphate, owing to the possibility of an excessive fall in blood pressure, which could harm both mother and foetus. Nifedipine capsules are not recommended for use during breast-feeding because nifedipine has been reported to be excreted in human milk and the effects of nifedipine exposure to the infant are not known. In patients with mild, moderate or severe impaired liver function, careful monitoring, and a dose reduction may be necessary. Nifedipine capsules should be used with caution in patients whose cardiac reserve is poor; in patients with heart failure or significantly impaired left ventricular function. Excessive falls in blood pressure may result in transient blindness. If affected the patient should not attempt to drive or use machinery. Upon co-administration with drugs that are known inhibitors of the cytochrome P450 3A4 system, the blood pressure should be monitored and, if necessary, a reduction of the nifedipine dose should be considered.

DRUG INTERACTIONS: The use of nifedipine in combination with rifampicin is therefore contraindicated. Upon co-administration of inducers of the cytochrome P450 3A4 system, the clinical response to nifedipine should be monitored and, if necessary, an increase in the nifedipine dose considered. Increased plasma levels of nifedipine have been reported during concomitant use of alcohol, cyclosporin, gingko biloba and ginseng. Enhanced hypotensive effect of nifedipine may occur with: aldesleukin, alprostadil, anaesthetics, antipsychotics, diuretics, phenothiazides, prazosin and intravenous ionic X-ray contrast medium. Decreased plasma levels of nifedipine have also been reported during concomitant use of St John's Wort. The simultaneous administration of nifedipine and digoxin may lead to reduced digoxin clearance and, hence, an increase in the plasma digoxin level. Consequently, when nifedipine is either additionally administered or discontinued, monitoring of the quinidine plasma concentration, and if necessary, adjustment of the quinidine dose are recommended. There is an increased risk of excessive hypotension, bradycardia and heart failure with β-blockers. Grapefruit juice inhibits the cytochrome P450 3A4 system. Administration of nifedipine together with grapefruit juice thus results in elevated plasma concentrations and prolonged action of nifedipine due to a decreased first pass metabolism or reduced clearance.

ADVERSE REACTIONS: Agranulocytosis, allergic reaction, angioedema, pruritus, anaphylactic/ anaphylactoid reaction, anxiety reactions, mood changes, depression, hyperglycaemia, headache, vertigo, migraine, par-/dysaesthesia, somnolence, lethargy, cerebral ischemia, visual disturbances, transient blindness, tachycardia, chest pain, myocardial infarction, oedema, hypotension, flushing, nasal congestion, dyspnoea, pulmonary oedema, constipation, gastrointestinal and abdominal pain, gingival hyperplasia, gastroesophageal sphincter insufficiency, transient increase in liver enzymes, intra-hepatic cholestasis, erythema, toxic epidermal necrolysis, photosensitivity, muscle cramps, arthralgia, worsening of myasthenia gravis, polyuria, dysuria, erectile dysfunction, feeling unwell, unspecific pain, chills.

MARKETED BY:

Torrent Pharmaceuticals Limited.

IN/CALCIGARD 5, 10mg/MAY-2025/03/ABPI

(Additional information is available on request)