CALCIGARD- 10 RETARD / CALCIGARD RETARD

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

Abbreviated Prescribing information for CALCIGARD - 10 RETARD, CALCIGARD RETARD
[Nifedipine 10 mg and 20 mg sustained release Tablets I.P]
[Please refer to the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Nifedipine is a 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 as specific and potent calcium antagonist. Nifedipine has a spasmolytic effect on the cells of the myocardium, vascular wall of mainly coronary arteries and the peripheral resistance vessels. The main action of nifedipine is to relax the smooth arterial muscle, both in the coronary and peripheral circulation.

INDICATIONS: For the treatment of mild to moderate hypertension. For the prophylaxis of chronic stable angina pectoris either as monotherapy or in combination with a beta-blocker.

DOSAGE AND ADMINISTRATION: Oral use. As a rule, tablets are swallowed whole with a little liquid, either with or without food. Calcigard Retard should not be taken with grapefruit juice.

CONTRAINDICATION: Nifedipine sustained release should 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. • It should not be used in cases of cardiogenic shock, clinically significant aortic stenosis, unstable angina, or during or within one month of a myocardial infarction. • It should not be used for the treatment of acute attacks of angina. • The safety of It in malignant hypertension has not been established. It should not be used for secondary prevention of myocardial infarction. • Owing to the duration of the formulation, it should not be administered to patients with hepatic impairment. • It should not be administered to patients with a history of gastrointestinal obstruction, oesophageal obstruction, or any degree of decreased lumen diameter of the gastro-intestinal tract. • It must not be used in patients with a Kock pouch (ileostomy after proctocolectomy). • It is contra-indicated in patients with inflammatory bowel disease or Crohn's disease. • It should not be administered concomitantly with rifampicin since effective plasma levels of nifedipine may not be achieved owing to enzyme induction.

WARNINGS & PRECAUTIONS: Caution should be exercised in patients with hypotension as there is a risk of further reduction in blood pressure and care must be exercised in patients with very low blood pressure. It 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 sulfate, owing to the possibility of an excessive fall in blood pressure, which could harm both mother and fetus. It is not recommended for use during breast-feeding. In patients with impaired liver function careful monitoring and, in severe cases, a dose reduction may be necessary. It should be used with caution in patients whose cardiac reserve is poor. Diabetic patients taking Nifedipine sustained release may require adjustment of their control. In dialysis patients with malignant hypertension and hypovolemia, a marked decrease in blood pressure can occur. Care should be exercised when administering Nifedipine sustained release to patients, as obstructive symptoms may occur. Bezoars can occur in very rare cases and may require surgical intervention. A false positive effect may be experienced when performing a barium contrast x-ray.

DRUG INTERACTIONS: Upon co-administration of known inhibitors of the cytochrome P450 3A4 system, the blood pressure should be monitored and, if necessary, a reduction in the nifedipine dose considered. 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. When nifedipine is administered simultaneously with ß-receptor blockers, the patient should be carefully monitored. The simultaneous administration of nifedipine and digoxin may lead to reduced digoxin clearance and, hence, an increase in the plasma digoxin level. 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. Nifedipine may increase the spectrophotometric values of urinary vanillylmandelic acid falsely. However, HPLC measurements are unaffected.

ADVERSE REACTIONS: Agranulocytosis, leucopenia, allergic reaction, allergic oedema/angioedema (including larynx oedema), pruritus, urticaria, rash, anaphylactic/anaphylactoid reaction, anxiety reactions, sleep disorders, depression, hyperglycemia, headache, dizziness, vertigo, migraine, tremor, paraesthesia/dysaesthesia, hypoesthesia, somnolence, visual disturbances, eye pain, tachycardia, palpitations, chest pain (angina pectoris), oedema (including peripheral oedema), vasodilatation, hypotension, syncope, joint swelling, muscle cramps, arthralgia, myalgia, nosebleed, nasal congestion, dyspnoea, pulmonary oedema, constipation, gastrointestinal and abdominal pain, nausea, dyspepsia, flatulence, dry mouth, gingival hyperplasia, bezoar, dysphagia, intestinal obstruction, intestinal ulcer, vomiting, gastroesophageal sphincter insufficiency, transient increase in liver enzymes, jaundice, erythema, toxic epidermal necrolysis, palpable purpura, photosensitivity allergic reaction, polyuria, dysuria, erectile dysfunction, feeling unwell, unspecific pain, and chills.

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

IN/CALCIGARD- 10 RETARD, CALCIGARD RETARD 20 mg/MAY-2025/03/ABPI

(Additional information is available on request)