xxxxxxxx-5343

NIFEDIPINE

HARTIGARD SR

20 mg Sustained Release Tablet
Calcium Channel Blocker

FORMULATION:
Each sustained release tablet contains:
Nifedipine ..... 20 mg

PHARMACOKINETICS:
Nifedipine is completely absorbed after oral administration. Plasma drug concentrations rise at a gradual, controlled rate after Nifedipine Sustained Release Tablet dose and plateau is maintained with minimal fluctuations over the 12 hour dosing interval. Nifedipine is extensively metabolized 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 unchanged form can be detected in the urine. The remainder is excreted in the feaces in metabolized 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:
Nifedipine is used in the managment of hypertension; in the prophylaxis of angina pectoris, particularly when a vasospastic element is present, as in Prinzmetal's angina, and in the treatment of Raynaud's disease.

CONTRAINDICATIONS:
Should not be administered to patients with known hypersensitivity to Nifedipine and in patients with cardiogenic shock.

USE IN PREGNANCY AND LACTATION:
Nifedipine is contraindicated throughout pregnancy as administration in animals was associated with embryotoxic, fetotoxic and teratogenic effects.
Nifedipine passes into milk. As there is no experience of possible effects on infants, breastfeeding should be stopped if nifedipine treatment is needed during lactation.

PRECAUTIONS:
Nifedipine should be used with caution in patients with hypotension, in patients whose cardiac reserve is poor, and in those with heart failure since deterioration of heart failure has been noted. Nifedipine should not be used in carcinogenic shock, in patients who have recently suffered a myocardial infarction, or in acute stable angina. Nifedipine should not be used to treat an anginal attack/in chronic stable angina. In patients with severe aortic stenosis nifedipine may increase risk of developing heart failure. Sudden withdrawal of nifedipine might be associated with an exacerbation of angina.

ADVERSE REACTIONS:
The most common adverse effects of nifedipine are associated with its vasodilatory action and often diminish on continued therapy. They include dizziness, flushing, headache, hypotension, peripheral oedema, tachycardia, and palpitations. Nausea and other gastrointestinal disturbances, increased micturation frequency, lethargy, eye pain and mental depression have also occurred. A paradoxical increase in ischaemic chest pain may occur at the start of treatment and in few patients excessivefall in blood pressure has led to cerebral or myocardial ischaemia or transient blindness. There have been reports of rashes (including erthema multiforme), fever, and abnormalities in liver function due to hypersensitivity reactions. Gingival hyperplasia has been reported which may regress on withdrawal of therapy.
Overdosage may be associated with bradycardia and hypotension. Nifedipine has been reported teratogenic in animals.

DOSAGE AND ADMINISTRATION:
The recommended daily dose is one tablet (20 mg) twice daily. The dosage may be adjusted within in the range of 20 mg once daily up to 40 mg twice daily, to achieve the desired effect.
The tablets must be swallowed whole and not to be broken or chewed.

DRUG INTERACTIONS:
The blood pressure-lowering effect of Nifedipine may be potentiated by other antihypertensives and by tricyclic antidepressants. The effects on blood pressure and heart rate are potentiated on combination with nitrates. When nifedipine is administered simultaneously with beta-receptor blockers, the patient should be carefully monitored, since fairly severe hypotension may occur. Nifedipine can causes a drop in the plasma quinidine level, or there is a clear rise in the plasma quinidine level after withdrawal of nifedipine, so that checks of the plasma quinidine are recommended in patients on combined therapy.
Nifedipine may produce an increase in the plasma levels of digoxin and theophylline, so that monitoring of their levels is recommended. Cimetidine can increase the plasma level of nifedipine and thus intensify the action of Nifedipine. Rifampicin accelerates the degradation of Nifedipine. Rifampicin must not be administered simultaneously with nifedipine, since active amounts of Nifedipine will not be reached in the blood.

STORAGE:
Store at temperatures not exceeding 30^{o}C.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

AVAILABILITY:
Nifedipine (Hartigard SR) 20mg Sustained Release Tablet - In box of 100's (Blister Pack of 10's)

torrent PHARMA

Manufactured by :
TORRENT PHARMACEUTICALS LTD.
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Imported and Distributed by :
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