SHELCAL CM

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

Abbreviated Prescribing information for SHELCAL CM [Calcium and Vitamin D3 Tablet I.P]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: ***Calcium Citrate Maleate*** - Calcium Citrate Maleate dissociates in the gastrointestinal tract to release free calcium ions, which are readily absorbed through both active, vitamin D–dependent transport in the duodenum and passive diffusion throughout the small intestine. The citrate and maleate components enhance calcium solubility and absorption, even in individuals with low stomach acid. Once absorbed, calcium enters the bloodstream and contributes to various physiological functions. ***Vitamin D3***-The in vivo synthesis of the predominant two biologically active metabolites of vitamin D occurs in two steps. The first hydroxylation of vitamin D3 cholecalciferol (or D2) occurs in the liver to yield 25-hydroxyvitamin D while the second hydroxylation happens in the kidneys to give 1, 25-dihydroxyvitamin D.

INDICATIONS: It is indicated for the treatment of calcium and mineral deficiency.

DOSAGE AND ADMINISTRATION: One tablet daily or as directed by the physician. Tablet should be taken orally.

CONTRAINDICATION: a) Absolute contra-indications are hypercalcaemia resulting for example from myeloma, bone metastases or other malignant bone disease, sarcoidosis; primary hyperparathyroidism and vitamin D overdosage. Severe renal failure. b) Hypersensitivity to the active substance or to any of the excipients. c) Relative contra-indications are osteoporosis due to prolonged immobilisation, renal stones, and severe hypercalciuria.

WARNINGS & PRECAUTIONS: Patients with mild to moderate renal failure or mild hypercalciuria should be supervised carefully including periodic checks of plasma calcium levels and urinary calcium excretion. In patients with a history of renal stones urinary calcium excretion should be measured to exclude hypercalciuria. With long-term treatment it is advisable to monitor serum and urinary calcium levels and kidney function and reduce or stop treatment temporarily if urinary calcium exceeds 7.5mmol/24 hours (300mg/24 hours). Use with caution in the elderly and debilitated and in patients with impaired liver function. as hypermagnesemia may result. The possibility of manganese retention should be a consideration in patients with biliary obstruction and caution should be exercised since manganese is eliminated via the bile. Hormone-sensitive condition such as breast cancer, uterine cancer, ovarian cancer, endometriosis, or uterine fibroids.

DRUG INTERACTIONS: The risk of hypercalcaemia should be considered in patients taking thiazide diuretics since these drugs can reduce urinary calcium excretion. Hypercalcaemia must be avoided in digitalised patients. Certain foods (e.g. those containing oxalic acid, phosphate or phytinic acid) may reduce the absorption of calcium. Concomitant treatment with phenytoin or barbiturates can decrease the effect of vitamin D because of metabolic activation. Concomitant use of glucocorticoids can decrease the effect of vitamin D. The effects of digitalis and other cardiac glycosides may be accentuated with the oral administration of calcium combined with vitamin D. Calcium salts may reduce the absorption of thyroxine, bisphosphonates, sodium fluoride, quinolone or tetracycline antibiotics or iron. It is advisable to allow a minimum period of four hours before taking the calcium. This can be avoided by giving other drugs 2-3 hours before the administration of magnesium hydroxide on the advice of a doctor.

ADVERSE REACTIONS: Angio-edema or laryngeal oedema, hypercalcaemia and hypercalciuria, milk-alkali syndrome, constipation, dyspepsia, flatulence, nausea, abdominal pain and diarrhoea, pruritus, rash and urticaria.

MARKETED BY:

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PHARMA

Torrent Pharmaceuticals Limited.
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(Additional information is available on request)