## SHELCAL HD

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

Abbreviated Prescribing information for Shelcal HD Tablets (Calcium with Vitamin  $D_3$ ) [Please refer the complete prescribing information available at www.torrentpharma.com]

**PHARMACOLOGICAL PROPERTIES**: *Calcium:* A mineral that is present naturally in the food and necessary for many normal functions of body mainly, bone formation and maintenance. *Vitamin*  $D_3$ : Cholecalciferol is the naturally occurring form of Vitamin D<sub>3</sub>. It is produced from 7-dehydro cholesterol, a sterol present in mammalian skin, by ultraviolet irradiation.

**INDICATION:** It is used as a calcium and vitamin D3 supplement in deficiency states i.e. prevention and treatment of rickets, osteoporosis and osteomalacia.

**DOSAGE AND ADMINISTRATION:** The oral dose is one to two tablets daily or as directed by the physician.

**CONTRAINDICATION:** Shelcal HD is contraindicated in conditions resulting in hypercalcaemia and/or hypercalciuria (e.g. myeloma, bone metastases, primary hyperparathyroidism). It is also contraindicated in patients having nephrolithiasis/nephrocalcinosis, renal failure, hypervitaminosis D and having hypersensitivity to the active substances or to any of the excipients.

**WARNINGS & PRECAUTIONS**: During long-term treatment, serum and urinary calcium levels should be followed and renal function should be monitored through measurements of serum creatinine. Cautiously monitoring is required in elderly patients taking cardiac glycosides, with impaired renal function, renal stone and patients suffering from sarcoidosis and immobilised patients with osteoporosis. In case of hypercalcaemia or signs of impaired renal function the dose should be reduced or the treatment should be discontinued. In patients with severe renal insufficiency, cholecalciferol is not metabolized normally hence other forms of vitamin D should be used. The content of vitamin D (500 IU) in tablets should be considered when prescribing other medicinal products containing vitamin D3 or nutrients (such as milk).

**DRUG INTERACTIONS:** It can interact with thiazide diuretics, concomitant use of systemic corticosteroids, Ion exchange resins and tetracycline preparations, Rifampicin, phenytoin or barbiturates. Hypercalcaemia may increase the toxicity of cardiac glycosides during treatment with Shelcal. Calcium salts may decrease the absorption of iron, zinc or strontium and thyroid hormones. Oxalic acid and phytic acid may inhibit calcium absorption. The efficacy of levothyroxine can be reduced by the concurrent use of calcium, due to decreased levothyroxine absorption. Quinolone's absorption may be impaired if administered concomitantly with calcium.

**ADVERSE REACTIONS:** Hypercalcaemia, hypercalciuria, Constipation, flatulence, nausea, abdominal pain, and diarrhea, Pruritus, rash and urticarial.

MARKETED BY: TORRENT PHARMACEUTICALS LTD. Torrent House, Off Ashram Road, Ahmedabad-380 009, INDIA

## IN/SHELCAL HD/MAR 2015/01/AbPI

(Additional information is available on request)