

SHELCAL CT

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

Abbreviated Prescribing information for SHELCAL CT [Calcium with Calcitriol tablets]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: *Calcium carbonate*- Calcium Carbonates is well absorbed from the GI tract in the presence of gastric acid where it is converted to Calcium Chloride, Calcium Carbonate is absorbed as free calcium bicarbonate ions. Approximately half the calcium in serum is protein bound 5-10% complexes. In the form of small readily diffusible organic salts and the remainder as free ions. *Calcitriol*- Calcitriol is completely absorbed from the small intestine and enhances the absorption of calcium. Calcitriol is approximately 99.9% bound in blood. Calcitriol and other vitamin D metabolites are transported in blood by an alpha-globulin vitamin D binding protein. Calcitriol catabolized to calcitroic acid. Calcitriol is excreted in the bile and it subject to enterohepatic circulation.

INDICATION: For the treatment of hypocalcaemia and/or osteoporosis.

DOSAGE AND ADMINISTRATION: The oral dose is one tablet twice daily or as directed by the physician. Oral use only.

CONTRAINDICATION: a) Absolute contra-indications are hypercalciuria and hypercalcemia and diseases or conditions resulting in hypercalcemia and/or hypercalciuria (e.g. myeloma, bone metastases, primary hyperparathyroidism). b) Hypersensitivity to calcium, calcitriol or to any of the excipients. c) Kidney stones (nephrolithiasis, nephrocalciosis). d) Severe renal impairment and renal failure. e) Hypervitaminosis D

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 7.5 mmol/24 hours (300mg/24 hours). Caution is required in patients receiving treatment for cardiovascular disease.

DRUG INTERACTIONS: The risk of hypercalcemia should be considered in patients taking thiazide diuretics since these drugs can reduce urinary calcium excretion. Hypercalcaemia must be avoided in digitalized 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.

ADVERSE REACTIONS: Abdominal pain, vomiting, flatulence, nausea, constipation, tachycardia, palpitation, hypercalciuria and allergic reactions.

MARKETED BY



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