SHELCAL SYRUP

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

Abbreviated Prescribing information for SHELCAL SYRUP [Suspension of Calcium with Vitamin D3]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Vitamin D3 increases the intestinal absorption of calcium. Administration of calcium and Vitamin D3 counteracts the increase of parathyroid hormone (PTH) which is caused by calcium deficiency, and which causes increased bone resorption.

INDICATIONS: It is indicated in calcium deficiency, supplementation of calcium during growth, pregnancy, lactation or as recommended by the Physician.

DOSAGE AND ADMINISTRATION: As directed by the physician.

CONTRAINDICATION: Diseases and/or conditions resulting in hypercalcaemia and/or hypercalciuria (e.g. myeloma, bone metastases, primary hyperparathyroidism). Nephrolithiasis/nephrocalcinosis, Renal failure, Hypervitaminosis D and Hypersensitivity to the active substances or to any of the excipients.

WARNINGS & PRECAUTIONS: Monitoring is especially important in elderly patients on concomitant treatment with cardiac glycosides or diuretics and in patients with a high tendency to calculus formation. In case of hypercalcaemia or signs of impaired renal function the dose should be reduced or the treatment discontinued. Patients with mild to moderate impairment of renal function should be supervised carefully and the effect on calcium and phosphate levels should be monitored. The risk of soft tissue calcification should be taken into account. In patients with severe renal insufficiency, vitamin D in the form of colecalciferol is not metabolised normally and other forms of vitamin D should be used. Calcium and Vitamin D3 should be prescribed with caution to patients suffering from sarcoidosis, due to the risk of increased metabolism of vitamin D into its active form. Calcium and Vitamin D3 should be used with caution in immobilised patients with osteoporosis due to increased risk of hypercalcaemia. Caution should be exercised while prescribing Cholecalciferol and other medicinal products containing Vitamin D3 or nutrients (such as milk). Additional doses of calcium or Vitamin D3 increase the risk of hypercalcaemia with subsequent kidney function impairment and milk-alkali syndrome; therefore they should be taken under close medical supervision.

DRUG INTERACTIONS: Thiazide diuretics reduce the urinary excretion of calcium. Due to increased risk of hypercalcaemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics. Hypercalcaemia must be avoided in digitalised patients. Systemic corticosteroids reduce calcium absorption. During concomitant use, it may be necessary to increase the dose of Calcium and Vitamin D3. Simultaneous treatment with ion exchange resins such as cholestyramine or laxatives such as paraffin oil may reduce the gastrointestinal absorption of vitamin D. Calcium carbonate may interfere with the absorption of concomitantly administered tetracycline preparations. For this reason, tetracycline preparations should be administered at least two hours before or four to six hours after oral intake of calcium. Hypercalcaemia may increase the toxicity of cardiac glycosides during treatment with calcium and vitamin D. Patients should be monitored with regard to electrocardiogram (ECG) and serum calcium levels. If a bisphosphonate or sodium fluoride is used concomitantly with Calcium and Vitamin D3, these medicinal products should be administered at least three hours before the intake of Calcium and Vitamin D3 since gastrointestinal absorption may be reduced. Rifampicin, phenytoin or barbiturates may reduce the activity of vitamin D3, since they increase the rate of its metabolism. Calcium salts may decrease the absorption of iron, zinc or strontium. Consequently, the iron, zinc or strontium preparation should be taken at a distance of two hours from the calcium preparation. Calcium salts may reduce the absorption of the estramustin or thyroid hormones. It is recommended that taking Calcium and Vitamin D3 be spaced at least 2 hours from these medicines. Oxalic acid (found in spinach, sorrel and rhubarb) and phytic acid

(found in whole cereals) may inhibit calcium absorption through formation of insoluble compounds with calcium ions. The patient should not take calcium products within two hours of eating foods high in oxalic acid and phytic acid. The efficacy of levothyroxine can be reduced by the concurrent use of calcium, due to decreased levothyroxine absorption. Administration of calcium and levothyroxine should be separated by at least four hours. The absorption of quinolone antibiotics may be impaired if administered concomitantly with calcium. Quinolone antibiotics should be taken two hours before or after intake of calcium.

ADVERSE REACTIONS: Hypercalcaemia, hypercalciuria, Constipation, flatulence, nausea, abdominal pain, diarrhoea, Pruritus, rash and urticaria.

MARKETED BY:

TORRENT PHARMA

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(Additional information is available on request)