

SHELICAL HD 12

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

Abbreviated Prescribing information for Shelcal HD 12 (Calcium with Vitamin D₃ and Vitamin B₁₂ tablets) [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 D₃:* Cholecalciferol is the naturally occurring form of Vitamin D₃. It is produced from 7-dehydro cholesterol, a sterol present in mammalian skin, by ultraviolet irradiation. *Vitamin B₁₂:* Cyanocobalamin is a synthetic form of vitamin B₁₂.

INDICATION: It is indicated in the management of associated deficiencies of calcium, vitamin B₁₂ and vitamin D in pregnancy, as well as chronic disease.

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

CONTRAINDICATION: Shelcal HD 12 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 cobalt and Vitamin B₁₂, 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, patient with impaired renal function, 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. The content of vitamin D (500 IU) in tablets should be considered when prescribing other medicinal products containing vitamin D. Caution should be exercised while prescribing Cholecalciferol and other medicinal products containing Vitamin D₃ or nutrients (such as milk). Patients with early Leber's disease who were treated with vitamin B₁₂ suffered severe and swift optic atrophy. In patients with severe megaloblastic anemia taking Vitamin B₁₂, hypokalemia and sudden death may occur. Infection, uremia and drugs having bone marrow suppressant properties may blunt or impede therapeutic response to vitamin B₁₂. Serum potassium levels and the platelet count should be monitored carefully during therapy. Vitamin B₁₂ deficiency may suppress the signs of polycythemia vera.

DRUG INTERACTIONS: It can interact with Thiazide diuretics, systemic corticosteroids, Ion exchange resins, tetracycline preparations, cardiac glycosides, levothyroxine, Quinolones, Oxalic acid and phytic acid. If a bisphosphonate or sodium fluoride is used concomitantly with Calcium and Vitamin D₃ tablets, it should be administered at least three hours before the intake of Shelcal. Rifampicin, phenytoin or barbiturates may reduce the activity of vitamin D₃. Calcium salts may decrease the absorption of iron, zinc or strontium and thyroid hormones. Vitamin B₁₂'s assay may be miss diagnosed in patients's taking antibiotics, methotrexate or pyrimethamine. Colchicine, para-aminosalicylic acid and heavy alcohol intake for longer than 2 weeks may produce malabsorption of vitamin B₁₂.

ADVERSE REACTIONS: Hypercalcaemia, hypercalciuria, constipation, flatulence, nausea, abdominal pain, diarrhea, pruritus, rash, urticarial, hematologic response, itching exanthema, anaphylactic shock, acne form and bullous eruptions.

MARKETED BY:



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(Additional information is available on request)