

SHELCAL CT MAX

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

Abbreviated Prescribing information for SHELCAL CT MAX (Calcium Carbonate, Pyridoxal 5'-Phosphate, Folic Acid, Vitamin D3, Cyanocobalamin with Docosahexaenoic Acid (DHA) Tablets)

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Calcitriol: Calcitriol is the most active known form of vitamin D₃ in stimulating intestinal calcium transport. **Omega-3 Fatty Acids:** Omega-3 Fatty Acids reduces the synthesis of triglycerides in the liver **Methylcobalamin:** Vitamin B₁₂ can be converted to coenzyme B₁₂ in tissues, and as such is essential for conversion of methylmalonate to succinate and synthesis of methionine from homocysteine **Folic Acid:** Folic acid is a member of the vitamin B group. Folic acid is reduced in the body to tetrahydrofolate, which is a co-enzyme and hence in the synthesis of DNA; it is also involved in the formation and utilisation of formate **Calcium Carbonate:** Calcium carbonate is a basic inorganic salt that acts by neutralizing hydrochloric acid in gastric secretions.

DOSAGE AND ADMINISTRATION: One tablet once daily or as directed by physician.

CONTRAINDICATION: Hypersensitivity to any of the active substance, Diseases and/or conditions resulting in hypercalcemia and/or hypercalciuria, for example in hyperparathyroidism, vitamin D overdose, decalcifying tumours such as plasmacytoma and skeletal metastases, in severe renal failure untreated by renal dialysis and in osteoporosis due to immobilisation., renal calculi (nephrolithiasis), If there is evidence of vitamin D toxicity, Long-term folate therapy is contraindicated in any patient with untreated cobalamin deficiency. This can be untreated pernicious anaemia or other cause of cobalamin deficiency, including lifelong vegetarians. In elderly people, a cobalamin absorption test should be done before long-term folate therapy. Folate given to such patients for 3 months or longer has precipitated cobalamin neuropathy. No harm results from short courses of folate, Folic acid should never be given alone in the treatment of Addisonian pernicious anaemia and other vitamin B₁₂ deficiency states because it may precipitate the onset of subacute combined degeneration of the spinal cord, Folic acid should not be used in malignant disease unless megaloblastic anaemia owing to folate deficiency is an important complication.

WARNINGS & PRECAUTIONS:

Calcitriol: There is a close correlation between treatment with calcitriol and the development of hypercalcaemia, All other vitamin D compounds and their derivatives, An abrupt increase in calcium intake as a result of changes in diet, Immobilised patients. **Omega-3 Fatty Acids:** In the absence of efficacy and safety data, use of this medication in children and adolescents is not recommended, limited use in elderly patients over 70 years of age. **Methylcobalamin:** Methylcobalamin should not be used aimlessly for more than one month unless it is effective, Patients with early Leber's disease, Hypokalemia and sudden death, Anaphylactic shock **Folic Acid:** Patients with vitamin B₁₂ deficiency should not be treated, caution is necessary when it's given in patients who have folate dependent tumours, not intended for healthy pregnant women. **Calcium Carbonate:** In renal insufficiency the tablets should be given only under controlled conditions for hyperphosphataemia, Patients with rare hereditary problems of fructose intolerance should not take this medicine.

DRUG INTERACTION: Calcitriol: Dietary instructions, especially concerning calcium supplements, should be strictly observed, and uncontrolled intake of additional calcium-containing preparations avoided, Concomitant treatment with a thiazide diuretic increases the risk of hypercalcaemia **Omega-3 Fatty Acids:** Oral anticoagulants **Methylcobalamin:** Persons taking most antibiotics, methotrexate and pyrimethamine **Folic Acid:** phenytoin and folate, Antibacterials – chloramphenicol and co-trimoxazole **Calcium Carbonate:** Thiazide diuretics.

ADVERSE REACTIONS: Hypersensitivity, Urticaria, Hypercalcaemia, Decreased appetite, Polydipsia, Dehydration, Weight, Decreased, Apathy, Psychiatric, Disturbances, Headache, Muscular weakness, Sensory disturbance, Somnolence, Cardiac arrhythmias, Abdominal pain, Nausea, Vomiting, Constipation, Abdominal pain upper, Paralytic ileus, Rash, Erythema, Pruritus, Growth retardation, Urinary tract infection, Polyuria, Nocturia, Calcinosis, Pyrexia, Thirst, Blood creatinine increased

Marketed BY:



IN/SHELCAL-CT MAX 0.25 mcg/180, 120 mg/1500 mcg/400 mcg/1.5 mg/500 mg/APR-21/01/ABPI

(Additional information is available on request)