SHELCAL-XT

For the use of a Registered Medical Practitioners or a Hospital or a Laboratory only Abbreviated Prescribing information for SHELCAL-XT tablet [Calcium, Vitamin D3, Methylcobalamin, L-methylfolate calcium & Pyridoxal-5-phosphate] [Please refer the complete prescribing information available at <u>www.torrentpharma.com</u>]

PHARMACOLOGICAL PROPERTIES: Calcium: Calcium is a mineral that is present naturally in the food. The amount of calcium absorbed through the gastrointestinal tract is approximately 30% of the swallowed dose. **Vitamin D3:** It is easily absorbed in the small intestine. **Methylcobalamin:** Methylcobalamin is one of the biologically active form of vitamin B12. It acts as coenzymes in nucleic acid synthesis. **L-methylfolate calcium:** It is the primary biologically active diastereoisomer of folate and the primary form of folate in circulation. **Pyridoxal-5-phosphate:** It is the active form of vitamin B6 and is used as the prosthetic group for many of the enzymes where this vitamin is involved.

INDICATION: Hyperhomocysteinemia induced osteoporosis, Senile osteoporosis, Bone fracture Hypocalcemia and Post menopausal osteoporosis.

DOSAGE AND ADMINISTRATION: 1-2 tablet daily or as directed by the physician.

CONTRAINDICATION: It is contraindicated in diseases and/or conditions resulting in: hypercalcaemia and/or hypercalciuria, nephrolithiasis, hypervitaminosis D and in patients with known hypersensitivity to any of the components.

WARNINGS & PRECAUTIONS: Calcium: During long-term treatment, serum calcium levels should be followed and renal function should be monitored. **Vitamin D3:** Vitamin D3 should be used with caution in patients with impairment of renal function. Use with caution in immobilised patients with osteoporosis due to the increased risk of hypercalcaemia. The risk of soft tissue calcification should be taken into account. **L-methylfolate calcium:** Patients at risk for vitamin B12 deficiency should consult with their physician prior to taking L-methylfolate calcium. **Methylcobalamin:** Should be given with caution in patients suffering from folate deficiency. Megaloblastic anemia is sometimes corrected by treatment with vitamin B12. But this can have very serious side effects. Do not take vitamin B12 if Leber's disease. The treatment of vitamin B12 deficiency can unmask the symptoms of polycythemia vera.

DRUG INTERACTIONS: Calcium and vitamin D3: Thiazide diuretics reduce the urinary excretion of calcium. Systemic corticosteroids reduce calcium absorption. Calcium carbonate may interfere with the absorption of concomitantly administered tetracycline preparations and quinolone antibiotics. Hypercalcaemia may increase the toxicity of cardiac glycosides. The efficacy of levothyroxine can be reduced by the concurrent use of calcium. Methylcobalamin: Serum concentrations may be decreased by use of oral contraceptives. Parenteral chloramphenicol may attenuate the effect of vitamin B12 in anaemia. Folic acid, particularly in large doses, can cover up vitamin B12 deficiency, and cause serious health effects. Pyridoxal-5-phosphate: It should not be given to patients receiving the drug levodopa, because the action of levodopa is antagonized by pyridoxal-5-phosphate.

ADVERSE REACTIONS: Calcium and vitamin D3: Hypercalcaemia, hypercalciuria, Milkalkali syndrome, Constipation, dyspepsia, flatulence, nausea, abdominal pain, diarrhoea, Pruritus, rash and urticarial. **Methylcobalamin:** Polycythemia vera, itching; transitory exanthema, blood clots, serious allergic reactions. **L-methylfolate calcium:** Allergic reactions. **Pyridoxal-5-phosphate:** Paresthesia, somnolence, nausea and headaches.

MARKETED BY

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