SHELCAL-XT

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

Abbreviated Prescribing information for **SHELCAL-XT** (Calcium, Vitamin D3, Methylcobalamin, L-Methylfolate Calcium & Pyridoxal-5-Phosphate Tablets) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Calcium Carbonate: Dietary supplement: Prevents or treats negative Ca balance; oral Ca supplements may protect against renal calculi formation by chelating with oxalate in gut and preventing its absorption. Phosphate binder: Binds with dietary phosphate to form insoluble calcium phosphate, which is excreted in feces. Vitamin D3: The in vivo synthesis of the predominant two biologically active metabolites of vitamin D occurs in two steps. The first hydroxylation of vitamin D3 cholecalciferol (or D2) occurs in the liver to yield 25-hydroxyvitamin D while the second hydroxylation happens in the kidneys to give 1, 25-dihydroxyvitamin D, Mecobalamin: Mecobalamin is the one and only homologue of Vitamin B12 found in the brain that participates in transmethylation. Mecobalamin is well transported to nerve cell organelles than cyanocobalamin and plays the role of coenzyme in the synthesis of methionine from homocysteine. L-Methylfolate Calcium: L-Methylfolate Calcium is the primary biologically active isomer of folic acid and the primary form of folate in circulation.Folic acid is a precursor of tetrahydrofolic acid, which is involved as a cofactor for transformylationreactions, these reactions are involved in the biosynthesis of thymidylates and purines of nucleic acids, Pyridoxal-5-Phosphate: Pyridoxal Phosphate is a coenzyme of many enzymatic reactions. It is the active form of vitamin B6 which comprises three natural organic compounds, pyridoxal, pyridoxamine and pyridoxine. Pyridoxal phosphate acts as a coenzyme in all transamination reactions, and in some decarboxylation and deamination reactions of amino acids. The aldehyde group of pyridoxal phosphate forms a Schiff-base linkage with the epsilon-amino group of a specific lysine group of the aminotransferase enzyme. The alpha-amino group of the amino acid substrate displaces the epsilon-amino group of the active-site lysine residue. The resulting aldimine becomes deprotonated to become a quinoid intermediate, which in turn accepts a proton at a different position to become a ketimine. The resulting ketimine is hydrolysed so that the amino group remains on the protein complex.

INDICATIONS: It is indicated for the treatment of calcium and vitamins deficiency.

DOSAGE AND ADMINISTRATION: One tablet daily or as directed by the physician. Tablets should be taken orally.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients.

WARNINGS & PRECAUTIONS: Calcium: During long-term treatment, serum calcium levels should be followed and renal function should be monitored through measurement of serum creatinine. 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, Vitamin D3: Vitamin D3 should be used with caution in patients with impairment of renal function 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 D3 in the form of Cholecalciferol is not metabolised normally and other forms of Vitamin D3 should be used. Should be prescribed with caution to patients suffering from sarcoidosis because of the risk of increased metabolism of Vitamin D3 to its active form. These patients should be monitored with regard to the calcium content in serum and urine. Used with caution in immobilised patients with osteoporosis due to the 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. In such cases it is necessary to monitor serum calcium levels and urinary calcium excretion frequently. L-methylfolate calcium: L-methylfolate calcium is not interchangeable with folic acid. Folic acid is not effective in some patients in impacting cerebral folate levels due to low rates of folic acid transport across the blood-brain barrier and/or low brain levels of the enzyme required to convert folic acid into a biological and functional form. 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.The following warnings and precautions suggested with parent form – vitamin B12 • The treatment of vitamin B12 deficiency can unmask the symptoms of polycythemia vera. • Megaloblastic anemia is sometimes corrected by treatment with vitamin B12. But this can have very serious side effects. Don't attempt vitamin B12 therapy without close supervision by your healthcare provider. • Do not take vitamin B12 if Leber's disease, a hereditary eye disease. It can seriously harm the optic nerve, which might lead to blindness.

DRUG INTERACTIONS: Calcium and vitamin D3: Thiazide diuretics reduce the urinary excretion of calcium, Systemic corticosteroids reduce calcium absorption. 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: Pyridoxal-5-phosphate 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: Metabolism and nutrition disorders Uncommon: Hypercalcaemia and hypercalciuria. Very rare: Seen usually only in overdose : Milk-alkali syndrome Gastrointestinal disorders Rare: Constipation, dyspepsia, flatulence, nausea, abdominal pain and diarrhoea. Skin and subcutaneous disorders Rare: Pruritus, rash and urticarial. Methylcobalamin: Pulmonary edema and congestive heart failure early in treatment, L-methylfolate calcium: Allergic reactions have been reported. Pyridoxal-5-phosphate: Paresthesia, somnolence, nausea and headaches have been reported.

MARKETED BY:

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IN/SHELCAL-XT (1250 mg +500 mg +2000 I.U.+1500mcg+1mg+20mg)/Aug-2024/02/ABPI

(Additional information is available on request)