ELMECOB D

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

Abbreviated Prescribing information for ELMECOB D [Alpha Lipoic Acid, Pyridoxine Hydrochloride, Methylcobalamin, Folic Acid & Vitamin D3, Tablets]

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Methylcobalamin is notable for being one of the few examples in nature of an organometallic bond. Methylcobalamin is used in managing concerns associated with vitamin B12 deficiency (such as pernicious anaemia), or B12 deficiency. Methylcobalamin is retained in the body better than cyanocobalamin. Alpha-lipoic acid or ALA is a naturally occurring compound that's made in the body. It serves vital functions at the cellular level, such as energy production. Alpha-lipoic acid helps to prevent certain kinds of cell damage in the body, and also restores vitamin levels such as vitamin E and vitamin C. Alpha-lipoic acid breaks down carbohydrates and produces energy for the other organs in the body. Alpha-lipoic acid works as an antioxidant, which means that it might protect the brain under conditions of damage or injury. Vitamin D3 is important in preventing or managing low vitamin D levels and managing low calcium levels.

INDICATIONS: For the treatment of Diabetic neuropathy.

DOSAGE AND ADMINISTRATION: The recommended dosage for adults is 1 tablet can be administered orally once daily or as directed by the physician. For oral use only. The patients should be instructed to swallow the tablet whole and must not be crushed or chewed. Do not exceed the stated dose unless advised by the Physician.

CONTRAINDICATION: It is contraindicated in the patients who are having hypersensitivity to active constituents or any of the formulation ingredients. In patients with hypercalcemia, malabsorption syndrome, abnormal sensitivity to the toxic effects of vitamin D and hypervitaminosis D.

WARNINGS & PRECAUTIONS: If symptoms persist or worsen, seek medical advice. Do not exceed the stated dose. Should be given with caution in patients suffering from folate deficiency. The treatment of vitamin B12 (parent compound of methylcobalamin) 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. Patients with vitamin B12 deficiency should not be treated with folic acid unless administered with adequate amounts of hydroxocobalamin, as it can mask the condition but the subacute irreversible damage to the nervous system will continue. The deficiency can be due to undiagnosed megaloblastic anaemia including in infancy, pernicious anaemia or macrocytic anaemia of unknown etiology or other cause of cobalamin deficiency, including lifelong vegetarians. Caution should be exercised when administering folic acid to patients who may have folate dependent tumours. This product is not intended for healthy pregnant women where lower doses are recommended, but for pregnant women with folic acid deficiency or women at risk for the reoccurrence of neural tube defects. Vitamin D should not be given to patients with hypercalcemia. It should be used with caution in infants, who may have increased sensitivity to its effects, and patients with renal impairment or calculi, or heart disease, who might be at increased risk of organ damage if hypercalcemia occurred. Plasma phosphate concentrations should be controlled during vitamin D therapy to reduce the risk of ectopic calcification. It is advised that patients receiving pharmacological doses of vitamin D should have their plasma-calcium concentration monitored at regular intervals, especially initially or if symptoms suggest toxicity. Similar monitoring is recommended in infants if they are breast fed by mothers receiving pharmacological doses of vitamin D.

DRUG INTERACTIONS: Absorption from the gastrointestinal tract may be reduced by neomycin, aminosalicylic acid, histamine H2-antagonists, omeprazole, and colchicine. Serum concentrations may be decreased by use of oral contraceptives. Parenteral chloramphenicol may attenuate the effect in anaemia. Potassium supplements can reduce absorption of vitamin B12 in some people and might contribute to vitamin B12 deficiency. Folic acid, particularly in large doses, can cover up vitamin B12 deficiency, and cause serious health effects. Heavy drinking for at least a two-week period can decrease vitamin B12 absorption from the gastrointestinal tract. Pyridoxine reduces the activity of altretamine. It has also been reported to decrease serum concentrations of phenobarbital and phenytoin. Antiepileptics, Antibacterials, Sulfasalazine, and Folic acid may interfere with the

toxic and therapeutic effects of methotrexate. There is an increased risk of hypercalcaemia if vitamin D is given with thiazide diuretics, calcium, or phosphate. Plasma-calcium concentrations should be monitored in such situations.

ADVERSE REACTIONS: *Methylcobalamin:* Pulmonary edema and congestive heart failure early in treatment; peripheral vascular thrombosis. Polycythemia vera, mild transient diarrhea, rarely itching; transitory exanthema. Other adverse effects reported with vitamin B12 are diarrhea, blood clots, itching, serious allergic reactions. *Pyridoxine hydrochloride* Long-term use of large doses of pyridoxine is associated with the development of severe peripheral neuropathies (including severe sensory neuropathy). *Folic acid* Gastrointestinal disorders: Anorexia, nausea, abdominal distention and flatulence Immune system disorders: Allergic reactions, comprising erythema, rash, pruritus, urticaria, dyspnea, and anaphylactic reactions (including shock). *Vitamin D3* Excessive intake of vitamin D leads to the development of hyperphosphataemia or hypercalcaemia. Associated effects of hypercalcaemia include hypercalciuria, ectopic calcification, and renal and cardiovascular damage. Symptoms of overdosage include anorexia, lassitude, nausea and vomiting, constipation or diarrhoea, polyuria, nocturia, sweating, headache, thirst, somnolence, and vertigo. Interindividual tolerance to vitamin D varies considerably; infants and children are generally more susceptible to its toxic effects. The vitamin should be withdrawn if toxicity occurs. It has been stated that vitamin D dietary supplementation may be detrimental in persons already receiving an adequate intake through diet and exposure to sunlight, since the difference between therapeutic and toxic concentrations is relatively small. The most potent forms of vitamin D, such as alfacalcidol and calcitriol, might reasonably be expected to pose a greater risk of toxicity; however, their effects are reversed rapidly on withdrawal. Hypersensitivity reactions have occurred. Skin irritation or contact dermatitis has been reported with topical preparations. Hypercalcaemia. Vitamin D is the most likely of all vitamins to cause overt toxicity. Doses of 60000 units daily can cause hypercalcaemia, with muscle weakness, apathy, headache, anorexia, nausea and vomiting, bone pain, ectopic calcification, proteinuria, hypertension, and cardiac arrhythmias. Chronic hypercalcaemia can lead to generalized vascular calcification, nephrocalcinosis, and rapid deterioration of renal function. Hypercalcaemia has been reported in a patient after brief industrial exposure to cholecalciferol. Another such study has suggested that vitamin D has nephrotoxic properties independent of the degree of induced hypercalcaemia, and that the decline in renal function may be more marked with calcitriol. Topical calcitriol may affect calcium homoeostasis, and hypercalcaemia has been reported in some studies. Hypervitaminosis D is characterized by effects on the following organ system: *Renal:* Impairment of renal function with polyuria, nocturia, polydipsia, hypercalciuria, reversible azotemia, hypertension, nephrocalcinosis, generalized vascular calcification, or irreversible renal insufficiency which may result in death. *CNS:* Mental retardation. *Soft Tissues:* Widespread calcification of the soft tissues, including the heart, blood vessels, renal tubules, and lungs. *Skeletal:* Bone demineralization (osteoporosis) in adults occurs concomitantly. Decline in the average rate of linear growth and increased mineralization of bones in infants and children (dwarfism), vague aches, stiffness, and weakness. *Gastrointestinal:* Nausea, anorexia, constipation. Metabolic: Mild acidosis, anemia, weight loss.

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

IN/ELMECOB D 100 mg,3 mg,1500 mcg,1.5 mg,1000 IU/MAR-2026/04/ABPI

(Additional information is available on request)