

Elmecob D

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

Abbreviated Prescribing information for Elmecob D (Alpha lipoic acid 100 mg, Pyridoxine hydrochloride 3 mg, Methylcobalamin 1500 microgram, Folic acid 1.5 mg & Vitamin D3 1000 IU Tablets) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Alpha Lipoic acid is used for its antioxidant effects in the treatment of diabetic neuropathy. Pyridoxine hydrochloride is Vitamin B6 which is essential for human nutrition. Methylcobalamin is one of the biologically active form of vitamin B12. Folic acid is a member of the vitamin B group. Vitamin D metabolites promote the active absorption of calcium and phosphorus by the small intestine, thus elevating serum calcium and phosphate levels sufficiently to permit bone mineralization.

INDICATION: For the treatment of diabetic neuropathy.

DOSAGE AND ADMINISTRATION: 1 tablet daily OR as directed by the physician.

CONTRAINDICATION: 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. Do not take vitamin B12 if Leber's disease, a hereditary eye disease, can 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. 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. Vitamin D should not be given to patients with hypercalcaemia. It should be used with caution in infants.

DRUG INTERACTION: Vitamin B12: Absorption from the gastrointestinal tract may be reduced by neomycin, aminosalicic acid, histamine H₂-antagonists, omeprazole, and colchicines. Serum concentrations may be decreased by use of oral contraceptives. Potassium supplements can reduce its absorption. Folic acid, particularly in large doses can cause serious health effects. Heavy drinking for at least a two-week period can decrease vitamin B12 absorption. Drugs may alter the metabolism or bioavailability of pyridoxine: isoniazid, penicillamine and oral contraceptives. Pyridoxine decrease serum concentrations of phenobarbital and phenytoin. Antiepileptics: serum antiepileptic levels may fall, if folic acid supplements are given. Chloramphenicol and co-trimoxazole may interfere with folate metabolism. Sulfasalazine - can reduce the absorption of folic acid. Folic acid may interfere with the toxic and therapeutic effects of methotrexate. If use with thiazide diuretics, calcium, or phosphate, increased risk of hypercalcaemia. Rifampicin and isoniazid may reduce the effectiveness of vitamin D. Corticosteroids may counteract the effect of vitamin D. Mineral oil interferes with the absorption of fat-soluble vitamins, including vitamin D preparations.

ADVERSE REACTIONS: Pulmonary edema, congestive heart failure, peripheral vascular thrombosis, Polycythemia vera, exanthema, diarrhea, blood clots, itching, serious allergic reactions. Severe peripheral neuropathies. Anorexia, nausea, abdominal distention, flatulence, comprising erythema, rash, pruritus, urticaria, dyspnea, and anaphylactic reactions. Hyperphosphataemia or hypercalcaemia, renal and cardiovascular damage. Skin irritation, contact dermatitis, Hypervitaminosis D.

MARKETED BY:



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(Additional information is available on request)