Elmecob LC

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

Abbreviated Prescribing information for Elmecob LC (Methylcobalamin 1500microgram, Folic acid 1.5mg and Levocarnitine 250mg Tablets) [Please refer the complete prescribing information available at <u>www.torrentpharma.com</u>]

PHARMACOLOGICAL PROPERTIES: Methylcobalamin is one of the biologically active forms of vitamin B12. Folic acid is a precursor of tetrahydrofolic acid which is involved in DNA synthesis. Levocarnitine is a naturally occurring substance required in mammalian energy metabolism.

INDICATION: Vitamin and micronutrient supplementation in the management of chronic disease.

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.

WARNINGS & PRECAUTIONS: Methylcobalamin: Should be given with caution in patients suffering from folate deficiency. 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. Do not take vitamin B12 if Leber's disease, as it can seriously harm the optic nerve, which might lead to blindness. Folic acid: Administration of folic acid alone is improper therapy for pernicious anemia and other megaloblastic anemias in which vitamin B12 is deficient. Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurologic manifestations remain progressive. This may result in severe nervous system damage. Levocarnitine: Chronic administration of high doses of oral levocarnitine may result in accumulation of the potentially toxic metabolites, trimethylamine (TMA) and trimethylamine-N-oxide (TMAO).

DRUG INTERACTION: Vitamin B12: Absorption from the gastrointestinal tract may be reduced by neomycin, aminosalicylic 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. Anticonvulsant action of phenytoin is antagonized by folic acid. False low serum and red cell folate levels may occur if the patient has been taking antibiotics, such as tetracycline. Levocarnitine: Reports of INR increase with the use of warfarin-like products have been observed. INR levels should be monitored.

ADVERSE REACTIONS: Pulmonary edema, congestive heart failure, peripheral vascular thrombosis, Polycythemia vera, exanthema, diarrhea, blood clots, itching, serious allergic reactions. Allergic sensitization, erythema, skin rash, general malaise, respiratory difficulty, anorexia, nausea, abdominal distention, flatulence, sleep patterns, difficulty in concentrating, irritability, over activity, excitement, mental depression, confusion, and impaired judgment, Decreased vitamin B12 serum levels, transient vomiting, abdominal cramps, Mild myasthenia and Seizures.

MARKETED BY:

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