CARNISURE LQ

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

Abbreviated Prescribing information for L-Arginine, L-Carnitine L-Tartrate, Co-enzyme Q10, Lycopene, Folic Acid, Sodium Selenite, Zinc Sulphate, Vitamin D3 and Cyanocobalamin Granules)

[Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: ***Vitamin D3:*** Vitamin D increases the intestinal absorption of calcium and phosphate. ***Folic Acid:*** Folic acid is a member of the vitamin B group. Folic acid is reduced in the body to tetrahydrofolate, which is a co-enzyme for various metabolic processes including the synthesis of purine and pyrimidine nucleotides, and hence in the synthesis of DNA; it is involved in the formation and utilisation of formate. ***Levocarnitine:*** Levocarnitine is a naturally occurring substance required in mammalian energy metabolism. It has been shown to facilitate long-chain fatty acid entry into cellular mitochondria, thereby delivering substrate for oxidation and subsequent energy production. Fatty acids are utilized as an energy substrate in all tissues except the brain. In skeletal and cardiac muscle, fatty acids are the main substrate for energy production.

INDICATIONS: NUTRACEUTICALS

DOSAGE AND ADMINISTRATION Granules, For oral administration.

CONTRAINDICATION: Long-term therapy is contraindicated in any patient with untreated cobalamin deficiency. This can be untreated pernicious anaemia or other cause of cobalamin deficiency, including lifelong vegetarians. In elderly people, a cobalamin absorption test should be done before long-term folate therapy. Folate given to such patients for 3 months or longer has precipitated cobalamin neuropathy. No harm results from short courses of folate. Folic acid should never be given alone in the treatment of Addisonian pernicious, anaemia and other vitamin B deficiency states because it may precipitate the onset of, subacute combined degeneration of the spinal cord, Folic acid should not be used in malignant disease unless megaloblastic anaemia owing to folate deficiency is an important complication. Known hypersensitivity to the active ingredient or any of the excipients. Diseases and/or conditions resulting in hypercalcaemia or hypercalciuria. Nephrolithiasis, Nephrocalcinosis, Hypervitaminosis D, Hypersensitivity to the active substance or to any of the excipients.

WARNINGS & PRECAUTIONS Hypersensitivity Reactions*:* Serious hypersensitivity reactions, including anaphylaxis, laryngeal edema, and bronchospasm have been reported following CARNISURE LQ administration, mostly in patients with end stage renal disease who are undergoing dialysis. Some reactions occurred within minutes after intravenous administration of CARNISURE LQ. If a severe hypersensitivity reaction occurs, discontinue CARNISURE LQ treatment and initiate appropriate medical treatment. Consider the risks and benefits of re-administering CARNISURE LQ to individual patients following a severe reaction. If the decision is made to re-administer the product, monitor patients for a reoccurrence of signs and symptoms of a severe hypersensitivity reaction. If a severe hypersensitivity reaction occurs, discontinue CARNISURE LQ treatment and initiate appropriate medical treatment. Consider the risks and benefits of re-administering CARNISURE LQ to individual patients following a severe reaction. If the decision is made to re-administer the product, monitor patients for a reoccurrence of signs and symptoms of a severe hypersensitivity reaction. ***PRECAUTIONS General*** the safety and efficacy of oral levocarnitine has not been evaluated in patients with renal insufficiency. Chronic administration of high doses of oral levocarnitine in patients with severely compromised renal function or in ESRD patients on dialysis may result in accumulation of the potentially toxic metabolites, trimethylamine (TMA) and trimethylamine-N-oxide (TMAO), since these metabolites are normally excreted in the urine.

DRUG INTERACTIONS: ***Folic Acid:*** Caution should be exercised when administering folic acid to epileptics. It may cause reduction in the plasma concentrations of phenytoin, primidone, phenobarbital, sodium valproate, carbamazepine and the barbiturates. Trimethoprim or sulfonamides, alone or in combination as co-trimoxazole, may reduce the effect of folic acid and this may be serious in patients with megaloblastic anaemia. Sulphasalazine and triamterene can reduce the absorption of folic acid Folic acid may interfere with the toxic and therapeutic effects of methotrexate. Methotrexate and trimethoprim are specific antifolates and the folate deficiency caused by their prolonged use cannot be treated by Folic Acid. Folinic acid should be used. Folate supplements enhance the efficacy of lithium therapy. Nitrous oxide anaesthesia may cause an acute folic acid deficiency. Both ethanol and aspirin increase folic elimination. Concurrent administration with cholestyramine may interfere with folic acid absorption. Patients on prolonged cholestyramine therapy should take folic acid 1 hour before or 4 to 6 hours after receiving cholestyramine. Antibiotics may interfere with the microbiological assay for serum and erythrocyte folic acid concentrations and may cause falsely low results. Fluorouracil toxicity may occur in patients taking folic acid and this combination should be avoided. Edible clay or antacids containing aluminium or magnesium may reduce folic acid absorption. Patients should be advised to take antacids at least two hours after administration of folic acid. Folic acid may reduce intestinal absorption of zinc (of particular importance in pregnancy). ***Levocarnitine:*** Reports of INR increase with the use of warfarin have been observed. It is recommended that INR levels be monitored in patients on warfarin therapy after the initiation of treatment with levocarnitine or after dose adjustments. ***Vitamin D3:*** Thiazide diuretics reduce the urinary excretion of calcium. Due to the increased risk of hypercalcaemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics.Concomitant use of phenytoin or barbiturates may reduce the effect of vitamin D since the metabolism increases. Excessive dosing of vitamin D can induce hypercalcaemia, which may increase the risk of digitalis toxicity and serious arrhythimias due to the additive inotropic effects. The electrocardiogram (ECG) and serum calcium levels of patients should be closely monitored. Glucocorticoid steroids may increase vitamin D metabolism and elimination. Simultaneous treatment with ion exchange resins such as cholestyramine or laxatives such as paraffin oil may reduce the gastrointestinal absorption of vitamin D.

ADVERSE REACTIONS: Folic Acid*:* Blood and **lymphatic system disorders:** vitamin B12 deficiency. **Immune system disorders:** Allergic reactions, comprising erythema, rash, pruritus, urticarial, dyspnoea, and anaphylactic reactions (including shock). **Gastrointestinal disorder:** Abdominal distension, flatulence, anorexia and nausea. **L-Arginine:** nausea, vomiting, headache, flushing, numbness and local venous irritation were reported in approximately 3% of the patients. ***Levocarnitine*** : body odor, nausea, and gastritis. An incidence for these reactions is difficult to estimate due to the confounding effects of the underlying pathology. **Body as Whole** ;Abdominal pain,Accidental injury, Allergic reaction,Asthenia, Back pain, Chest pain, Fever, Flu syndrome, Headache, Infection, Injection site reaction,Pain. **Cardiovascular:** Arrhythmia,Atrial fibrillation, Cardiovascular disorder,Electrocardiogram abnormal, Hemorrhage, Hypertension, Hypotension, Palpitations, Tachycardia, Vascular disorder. **Digestive:** Anorexia, Constipation, Diarrhea, Dyspepsia, Gastrointestinal disorder, Melena, Nausea, Stomach, Vomiting. **Endocrine System :** Parathyroid disorder. Hemic/Lymphatic. Anemia. **Metabolic/ Nutritional :** Hypercalcemia, Hyperkalemia, Hypervolemia, Peripheral edema, Weight decrease, Weight increase. **Musculo-Skeletal:** Leg cramps, Myalgia, Nervous, Anxiety, Depression, Dizziness, Drug dependence, Hypertonia, Insomnia, Vertigo, Respiratory, Bronchitis, Cough increase, Dyspnea, Pharyngitis. Respiratory disorder, Rhinitis, Sinusitis, Skin And Appendages, Pruritus, Rash, Special Senses, Amblyopia, Eye disorder, Taste perversion, Urogenital, Urinary tract infect ,Kidney failure, **Neurologic Reactions:** Seizures ***Hypersensitivity reactions:*** Anaphylaxis, laryngeal edema and bronchospasm (see WARNINGS). **Vitamin D3:** Adverse reactions frequencies are defined as: uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1,000) or not

known (cannot be estimated from the available data). **Metabolism and nutrition disorders** Uncommon: Hypercalcaemia and hypercalciuria. **Skin and subcutaneous disorders** Rare: Pruritus, rash and urticaria.

MARKETED BY:

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(Additional information is available on request)