L-Carnitine

Tablet 250 mg
Oral solution (500 mg / 5 ml)

Category: Carnitine deficiency therapy agent.
Composition:
Each tablet contains 250 mg L-Carnitine(as tartrate).
Each 5 ml of oral solution contains 500 mg L-Carnitine.
Mechanism of action:
L-Carnitine is necessary for normal mammalian fat utilization and energy metabolism. It facilitates entry of long-chain fatty acids into cellular mitochondria, where they are used during oxidation and energy production. It also exports acyl groups from subcellular organelles and from cells to urine before they accumulate to toxic concentrations.
Pharmacokinetics:
Absorption:Oral bioavailability - 15%
Distribution:VolD - 29L(0.39 liters per kg).
Protein binding: Not bound to plasma protein or albumin.
Half **–** life elimination: 17.4 hours.
Time to peak concentration: Oral- 3.3 hours
Elimination: Fecal-<1%. Renal - 8.6% to 9.4% (after oral dosing).
Indications:
L-Carnitine is indicated for treatment of primary systemic carnitine deficiency, a genetic impairment of normal biosynthesis or utilization of L-Carnitine from dietary sources, or for the treatment of secondary carnitine deficiency resulting from an inborn error of metabolism.
Drug interactions:
Valproic acid (requirements for carnitine may be increased in patients receiving valproic acid).
Precautions:
- Pregnancy: Adequate and well-controlled studies have not been done in humans. Studies in rats and rabbits at
L-Carnitine doses up to 3.8 times the usual adult dose (based on body surface area (mg/m2) have not demonstrated impaired fertility or fetal harm. FDA Pregnancy Category B.
- Breast - feeding: It is not known whether L-Carnitine is distributed into breast milk. Problems in humans have not been documented. Carnitine occurs naturally in human milk.
- Pediatrics: Appropriate studies on the relationship of age to the effects of L-Carnitine have not been performed in the pediatric population.However, pediatrics - specific problems that would limit the usefulness of this medicine in children are not expected.
- Geriatrics: Appropriate studies on the relationship of age to the effects of L-Carnitine have not been performed in the geriatric population. However, geriatrics - specific problems that would limit the usefulness of this medication in the elderly are not expected.

Risk-benefit should be considered when the following medical problems exist:
- Seizures
(Seizures may occur in patients with or without pre-existing seizure activity; increased seizure frequency and/or severity has been reported in patients with pre-existing seizure activity).
- End stage renal disease
(Administration of high doses of the oral formulations of L-Carnitine for long periods of time is not recommended in patients with severely compromised renal function or in end stage renal disease patients on dialysis due to the fact that major metabolites formed following oral administration (trimethylamine [TMA] and trimethylamine - N - oxide [TMAO] will accumulate since they cannot be efficiently removed by the kidneys.
Side/adverse effects:
Those indicating need for medical attention:
-Incidence more frequent
Hypertension-in dialysis patients with end - stage renal disease (ESRD).
-Incidence less frequent
Fever-in dialysis patients with ESRD, tachycardia (fast heartbeat)-in dialysis patients with ESRD
-Incidence rare: Seizures
Those indicating need for medical attention only if they continue or are bothersome:
-Incidence more frequent
Abdominal or stomach cramps, diarrhea, headache-in dialysis patients with ESRD, nausea or vomiting.
-Incidence less frequent: Body odor,gastritis (abdominal discomfort; loss of appetite).
Dosage and administration:
Usual adult and adolescent dose
Carnitine deficiency
L-Carnitine Tablets: 990 milligrams two or three times a day with meals.
L-Carnitine oral solution: initially 1 gram once a day with food, the dosage being increased slowly as needed and tolerated. For a 50 - kg patient, the usual dose is 1 gram one to three times a day with meals.
Usual pediatric dose
Carnitine deficiency- Oral, initially 50 mg per kg of body weight a day with food, the dosage being increased slowly as needed and tolerated. The usual dose is 50 to 100 mg per kg of body weight a day with meals (maximum 3 grams a day).
Packaging:
L-Carnitine 250 tablets are available in packages of 100's (10 blisters of 10 's).
L-Carnitine oral solution is available as clear solution in 120 ml bottles.

Manufactured by Amin
Isfahan-Iran