Only for the use of medical professionals

Cartine®

Levocarnitine

Description

Cartine® is a preparation of Levocarnitine which is a naturally occurring substance required in mammalian energy metabolism. Levocarnitine is a carrier molecule in the transport of long-chain fatty acids across the inner mitochondrial membrane, thereby delivering substrate for oxidation and subsequent energy production. Levocarnitine clears the acylCoA compound by formation of acylcarnitine, which is quickly excreted. It may alleviate the metabolic abnormalities of patients with inborn errors that result in accumulation of toxic organic acids.

Indications and usage

Cartine® is indicated in the treatment of primary systemic carnitine deficiency. In the reported cases, the clinical presentation consisted of recurrent episodes of Reye-like encephalopathy, hypoketotic hypoglycemia, and/or cardiomyopathy. Associated symptoms included hypotonia, muscle weakness and failure to thrive. Treatment should include, in addition to carnitine, supportive and other therapy as indicated by the condition of the patient. **Cartine®** is also indicated for acute and chronic treatment of patients with an inborn error of metabolism which results in a secondary carnitine deficiency. **Cartine®** can be used for the following conditions:

- Heart Diseases
- Congestive Heart Failure
- Kidney Disease
- Chronic Fatigue Syndrome
- High Cholesterol
- Intermittent Claudication
- Dementia and memory impairment
- Down Syndrome
- Male infertility
- Hyperthyroidism

Dosage and administration

Cartine tablet

Adults: The recommended dosage of Levocarnitine is 330 mg two or three times daily depending on clinical response.

Infants and children: The recommended dosage of Levocarnitine is 50 to 100 mg/kg/day in divided doses. Dosage should start at 50 mg/kg/day and be increased slowly to a maximum of 3 g/day while assessing tolerance and therapeutic response.

Cartine solution

Adults: The recommended dosage of Levocarnitine is 10 to 30 ml/day. Dosage should start at 10 ml/day and be increased slowly while assessing tolerance and therapeutic response.

Infants and children: The recommended dosage of Levocarnitine is 0.5 to 1 ml/kg/day (50 to 100 mg/kg/day). Dosage should start at 0.5 ml/kg/day (50 mg/kg/day), and be

increased slowly to a maximum of 30 ml/day (3 g/day) while assessing tolerance and therapeutic response.

Note: Higher doses should be administered only with caution and only where clinical and biochemical considerations make it seem likely that higher doses will be of benefit. Monitoring should include periodic blood chemistries, vital signs, plasma carnitine concentrations, and overall clinical condition.

Use in pregnancy and lactation
Levocarnitine is pregnancy Category B. There are, however, no adequate and well controlled studies in pregnant women; this drug should be used during pregnancy only if clearly needed.
Levocarnitine supplementation in nursing mothers has not been specifically studied. In nursing mothers receiving Levocarnitine, any risks to the child of excess carnitine intake need to be weighed against the benefits of Levocarnitine supplementation to the mother. Consideration may be given to discontinuation of nursing or of Levocarnitine treatment.

Side effects
Levocarnitine is well tolerated but few mild gastrointestinal complaints have been reported; these include transient nausea and vomiting, abdominal cramps, and diarrhea.

Precautions
Gastrointestinal reactions may result from a too rapid consumption of Levocarnitine. It should be consumed slowly and doses should be spaced evenly throughout the day to maximize tolerance. The safety and efficacy of oral Levocarnitine has not been evaluated in patients with renal insufficiency.

Warning
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.

Contraindications
Levocarnitine is contraindicated in patients with known hypersensitivity to Levocarnitine or any of the ingredients.

Pharmaceutical precautions
Store in a cool & dry place, protected from light.

Presentation
Cartine tablet: Each tablet contains Levocarnitine USP 330 mg.
Cartine® Solution: Each 5 ml contains Levocarnitine USP 500 mg.

Package quantity
Cartine tablet: Each box contains 10 Alu-Alu blister strips of 3 tablets.
Cartine® Solution: Each bottle contains 100 ml solution.

® Registered Trade Mark

ACI Limited
Narayanganj, Bangladesh