

CARNISURE SYRUP

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

Abbreviated Prescribing information for CARNISURE SYRUP [Levocarnitine Oral Solution U.S.P]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: 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: It is indicated for the treatment of carnitine deficiency.

DOSAGE AND ADMINISTRATION: For adults the recommended dosage of levocarnitine is 1 to 3 g/day for a 50 kg subject, which is equivalent to 10 to 30 mL/day of levocarnitine oral solution. Dosage should start at 1 g/day (10 mL/day) and be increased slowly. For infants and children, the recommended dosage of levocarnitine is 50 to 100 mg/kg/day which is equivalent to 0.5 mL/kg/day levocarnitine oral solution. Dosage should start at 50 mg/kg/day and be increased slowly to a maximum of 3 g/day (30 mL/day).

CONTRAINDICATION: None known

WARNINGS & PRECAUTIONS: Serious hypersensitivity reactions, including rash, urticaria, and facial edema have been reported with oral levocarnitine. Other serious hypersensitivity reactions, including anaphylaxis, laryngeal edema, and bronchospasm have been reported following intravenous levocarnitine administration, mostly in patients with end-stage renal disease undergoing dialysis. Discontinue use of levocarnitine and instruct patients to seek medical attention if they experience symptoms suggestive of a hypersensitivity reaction. Levocarnitine oral solution may be consumed alone or dissolved in drinks or other liquid foods to reduce taste fatigue. They should be consumed slowly, and doses should be spaced evenly throughout the day to maximize tolerance. 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: 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.

ADVERSE REACTIONS: Transient nausea and vomiting, abdominal cramps, diarrhea, mild myasthenia, seizures, rash, urticaria, and facial edema.

MARKETED BY:

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PHARMA

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(Additional information is available on request)