Levocarnitine Oral Solution USP

Active ingredient: L-carnitine 1 g/10mL.
Inactive Ingredients: Artificial Cherry Flavor, D, L-Malic Acid, Methylparaben NF, Propylparaben NF, Purified Water, Sucrose Syrup

Usual Dosage: See package insert.
Avoid excess heat. Protect from freezing. Store at 20°-25°C (68°-77°F) excursion permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature].

Distributed by:
Rising Pharmaceuticals, Inc.
Allendale, NJ 07401
Manufactured by:
Lyne Laboratories, Inc.
Brockton, MA 02301

Rx Only

NDC 64980-503-12

Lot No.: 364980503129

PROOF DATE: 7/15/11
CUSTOMER: LYNE LABS
JOB NUMBER: 55840
LABEL SIZE: 2.125" x 5.0"
LEAFLET FLAT SIZE: 2.125" x 16.21875"
LEAFLET FOLDED SIZE: 2.125" x 1.875"
LABEL COLORS: BLACK PMS 123 PMS 279
LEAFLET "IN" COLORS: BLACK
LEAFLET "OUT" COLORS: BLACK
DIELINE DOES NOT PRINT

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Levocarnitine Oral Solution USP

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 increasing the availability of fatty acids for oxidation. This process is essential for the production of energy in tissues except the brain. In skeletal and cardiac muscle, fatty acids are the main substrate for energy production.

Levocarnitine is a carrier molecule in the transport of long-chain fatty acids across the inner mitochondrial membrane. The subsequent hydrolysis of the acylCoA compound to acylcarnitine in the urine and feces in 5 to 11 days. Maximum concentration (Tmax) occurred at 3.3 hours. In a relative bioavailability study in 15 healthy adult male volunteers, Levocarnitine Tablets were found to be bio-equivalent to Levocarnitine Oral Solution USP. Following 4 days of dosing with 6 tablets of Levocarnitine 330 mg b.i.d. or 2 g of Levocarnitine oral solution b.i.d., the maximum plasma concentration (Cmax) and the area under the curve (AUC) of levocarnitine were 15.9 ± 4.9% for Levocarnitine Oral Solution USP.

Levocarnitine was not bound to plasma protein or albumin endogenous baseline concentrations) was a mean of 4.00L/h. Total body clearance of levocarnitine (Dose/AUC including circulating endogenous plasma concentrations of levocarnitine, the mean distribution half life was 0.585 hours and the plasma concentration uncorrected for endogenous levocarnitine, was 0.0179 hours. However, for 6 tablets of Levocarnitine 330 mg b.i.d. or 2 g of Levocarnitine oral solution b.i.d., the maximum plasma concentration was 4.00L/h. For oral use only.}

DESCRIPTION
Levocarnitine Oral Solution USP is available as 1 g/10 mL in artificial Cherry Flavor, D, L-Malic Acid, Purified Water, Sucrose, Glycerin, Sorbic Acid, Methylparaben NF, Propylparaben NF, Sodium Benzoate, Potassium Sorbate, FD&C Red 40, FD&C Yellow 6, FD&C Blue 1, and Benzoic Acid. Bottled in bottles of 118 mL with the following inactive ingredients: Artificial Cherry Flavor, D, L-Malic Acid, Purified Water, Sucrose.

Molecular Weight: 161.20
Molecular Formula: C7H15NO3

PHARMACOKINETICS
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 increasing the availability of fatty acids for oxidation. This process is essential for the production of energy in tissues except the brain. In skeletal and cardiac muscle, fatty acids are the main substrate for energy production.

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Saccharomyces cerevisiae, and Schizosaccharomyces pombe.


OVERDOSAGE

Seizures have been reported to occur in patients with or without pre-existing seizure activity receiving either oral or intravenous Levocarnitine Oral Solution USP. Tolerance should be monitored very closely during the first week of administration and after any dosage increases.

There have been no reports of toxicity from levocarnitine overdoses. Various mild gastrointestinal complaints have been reported. These include transient nausea and vomiting, abdominal cramps, and diarrhea. Mild myasthenia has been described in patients with pre-existing myasthenia gravis. In some patients with pre-existing gastrointestinal disorders, increases in frequency and severity have been reported.

ADVERSE REACTIONS

Pediatric Use

In nursing mothers receiving levocarnitine, the concentration of levocarnitine in milk is increased following exogenous administration. Studies in dairy cows indicate that the concentration of levocarnitine in milk is increased following exogenous administration of levocarnitine to the mother. Consideration may be given to discontinuation of nursing or of levocarnitine treatment. In nursing mothers receiving Levocarnitine Oral Solution USP, monitoring of overall clinical condition and biochemical considerations make it seem likely that the level of carnitine in milk is increased following administration of levocarnitine. Because animal reproduction studies are not always predictive of human response, Levocarnitine Oral Solution USP should be administered only with caution and only where clinical and biochemical considerations make it seem likely that the level of carnitine in milk is increased following administration of levocarnitine.

Pregnancy

Studies in rats have indicated that levocarnitine is not mutagenic. No long-term studies in animals have been specifically studied.

Pregnancy Category B.

There have been no adequate and well controlled studies in pregnant women. There are however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, Levocarnitine Oral Solution USP should be administered only with caution and only where clinical and biochemical considerations make it seem likely that the level of carnitine in milk is increased following administration of levocarnitine.


