

## CARNISURE™ INJECTION

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

Abbreviated Prescribing information for CARNISURE™ INJECTION [Levocarnitine Injection U.S.P.]  
[Please refer the complete prescribing information available at [www.torrentpharma.com](http://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:** CARNISURE™ Injection is indicated in the treatment of secondary carnitine deficiency e.g. in hemodialysis patients.

**DOSAGE AND ADMINISTRATION:** The recommended dose is 20-40 mg/kg given as a slow 2–3-minute bolus injection or by infusion. For metabolic disorders the recommended dose is 50 mg/kg given as a slow 2–3-minute bolus injection or by infusion. Often a loading dose is given in patients with severe metabolic crisis, followed by an equivalent dose over the following 24 hours. For ESRD patients on hemodialysis the recommended starting dose is 10-20 mg/kg dry body weight as a slow 2–3-minute bolus injection into the venous return line after each dialysis session. Levocarnitine Injection is administered intravenously.

**CONTRAINDICATION:** None known

**WARNINGS & PRECAUTIONS:** Serious hypersensitivity reactions, including anaphylaxis, laryngeal edema, and bronchospasm have been reported following Levocarnitine administration, mostly in patients with end stage renal disease who are undergoing dialysis. If a severe hypersensitivity reaction occurs, discontinue Levocarnitine treatment and initiate appropriate medical treatment. Consider the risks and benefits of re-administering Levocarnitine 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. 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.

**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:** Abdominal pain, accidental injury, allergic reaction, asthenia, back pain, chest pain, fever, flu syndrome, headache, infection, injection site reaction, pain, arrhythmia, atrial fibrillation, cardiovascular disorder, abnormal electrocardiogram findings, hemorrhage, hypertension, hypotension, palpitations, tachycardia, vascular disorders, anorexia, constipation, diarrhea, dyspepsia, gastrointestinal disorders, melena, nausea, stomach atony, vomiting, parathyroid disorders, anemia, hypercalcemia, hyperkalemia, hypervolemia, peripheral edema, weight decrease, or weight increase, leg cramps, myalgia, anxiety, depression, dizziness, drug dependence, hypertonia, insomnia, paresthesia, vertigo, bronchitis, increased cough, dyspnea, pharyngitis, respiratory disorders, rhinitis, sinusitis, pruritus or rash, amblyopia, eye disorders, taste perversion, urinary tract infection and kidney failure.

**MARKETED BY:**

**TORRENT**  
PHARMA

Torrent Pharmaceuticals Limited.

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(Additional information is available on request)