

Levocarnitine USP

### Composition

**Levocar®** Tablet: Each tablet contains Levocarnitine USP 330 mg.

# Description

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 in the form of Adenosine Tri phosphate or ATP. 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.

#### Indication and Use

The supplemental Levocarnitine use is widely established in the management of cardiac ischemia and peripheral arterial disease. It is generally indicated for cardio protection. It lowers triglyceride levels and increases levels of HDL-cholesterol. It is used with benefits in those with primary and secondary carnitine deficiency syndromes. There is also evidence of its use in liver, kidney and immune disorders or in diabetes and Alzheimer's disease. There is little evidence that supplemental Levocarnitine boosts energy, increases athletic performance or inhibits obesity. The indications of **Levocar**® may be summarized as follows:

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

# **Dosage and Administration**

#### Levocar® Tablet

Adults: 330 mg two or three times a day depending on clinical response.

Infants and children: Between 50 and 100 mg/kg/day in divided doses, with a maximum of 3 g/day. Dosage should begin at 50 mg/kg/day. The exact dosage will depend on clinical response.

#### Side Effect

Supplemental Levocarnitine is generally well tolerated. However, few side effects including transient nausea and vomiting abdominal cramps, and diarrhea may occur.

#### Precaution

The safety and efficacy of oral Levocarnitine has not been evaluated in patients with renal insufficiency. 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 Interaction

Not known

# Use in Pregnancy & Lactation

Levocarnitine is categorized by the USFDA as Pregnancy Category B. There are no adequate and well-controlled studies in pregnant women. Supplemental Levocarnitine should be used by pregnant women only if clearly indicated and only under medical supervision. It is not known whether Levocarnitine is excreted in human milk. Supplemental Levocarnitine is not advised for nursing mothers. Those with seizure disorders should only use Levocarnitine under medical advisement and supervision.

### Overdosage

There have been no reports of toxicity from Levocarnitine overdosage.

### Storage

**Levocar®** Tablet: Store in a cool & dry place, protected from light & moisture.

# **How Supplied**

**Levocar®** Tablet: Each box contains 5x6 tablets in blister pack.

Manufactured by

