Carnitab®

Tablet

Description

Carnitab tablet contains Levocarnitine USP, which is a carrier molecule in the transport of long chain fatty acids across the inner mitochondrial membrane. The chemical name of Levocarnitine is 3-carboxy-2(R)-hydroxy-N,N,N-trimethyl-1-propanaminium.

Indications

Carnitab is indicated for the treatment of

- Primary carnitine deficiency syndromes
- Systemic carnitine deficiency
- Myopathic carnitine deficiency
- Secondary carnitine deficiency or insufficiency states
- Genetically determined metabolic errors (mainly organic acidurias)
- Chronic intermittent haemodialysis in end stage renal failure
- Cardiac and skeletal muscle ischaemia

Dosage and Administration

Adults : The recommended oral dosage for adults is 990 mg, two or three times a day using the 330 mg tablets, depending on clinical response.

Infants and children : The recommended oral dosage for infants and children is 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.

Monitoring should include periodic blood chemistries, vital signs, plasma carnitine concentrations and overall clinical condition.

Contraindications

There is no known disease or syndrome in which Levocarnitine administration is contraindicated. It is contraindicated in patients with hypersensitivity to any of its components.

Precautions

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.

Side Effects

Transient nausea and vomiting, abdominal cramps and diarrhoea have been observed. Mild myasthenia has been described only in uraemic patients receiving DL-carnitine. Decreasing the dosage often diminishes or eliminates drug related patient body odour or gastrointestinal symptoms when present. Tolerance should be monitored very closely during the first week of administration and after any dose increment.

Use in Special Populations

Pregnancy : This drug should be used during pregnancy only if clearly needed.

Lactation : It is not known whether this drug is excreted in human milk or not. Taking into account the importance of the drug to the mother, decision should be made whether to discontinue nursing or to discontinue the drug.

Commercial Pack

Carnitab® Tablet : Box containing 3 aluminium strips of 10 tablets. Each tablet contains Levocarnitine USP 330 mg.