

**LACARNIT**  
Levocarnitine 330 mg Tablets

**LACARNIT Injection**  
Levocarnitine Inj. 200 mg / ml (5 mg Amp)

**Description:**

L-carnitine is a naturally occurring substance required in mammalian energy metabolism. Plasma carnitine accounts only for approximately 1% of the total body carnitine pool, with over 98% of carnitines present in the skeletal and cardiac muscles. Dialysis therapy can cause a decrease in both free carnitine and plasma acylcarnitines. Recent studies have shown that oral & intravenous L-carnitine plays an important role on anemia and cardiovascular disease in CKD patients.

**Indication:**

**Lacarnit® Tablet** is indicated to treat primary systemic carnitine deficiency & acute and chronic treatment of patients with an inborn error of metabolism which results in a secondary carnitine deficiency.

**Lacarnit® Injection** is used to recommend for the prevention and treatment of carnitine deficiency in patients with end stage renal disease who are undergoing dialysis.

**Mechanism of action:**

In humans, carnitine plays a pivotal role in energy metabolism through the transportation of long-chain fatty acids across the inner mitochondrial membrane and in controlling the rates of beta oxidations of long-chain fatty acids with subsequent energy production.

**Dosage:**

**Lacarnit® Tablet-**

**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.

**Lacarnit® Injection-**

**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. Initiation of therapy may be prompted by trough (pre-dialysis) plasma levocarnitine concentrations that are below normal (40-50 µmol/L). Dose adjustments should be guided by trough (pre-dialysis) levocarnitine concentrations, and downward dose adjustments (e.g. to 5 mg/kg after dialysis) may be made as early as the third or fourth week of therapy.

**Presentation:**

**Lacarnit® Tablet**

Lacarnit is available as a strip of 10 tablets in Alu-Alu blister packing.

**Lacarnit® Injection**

Lacarnit injection is available in 5x5 ml ampoule.

**La Renon Healthcare Pvt. Ltd.**

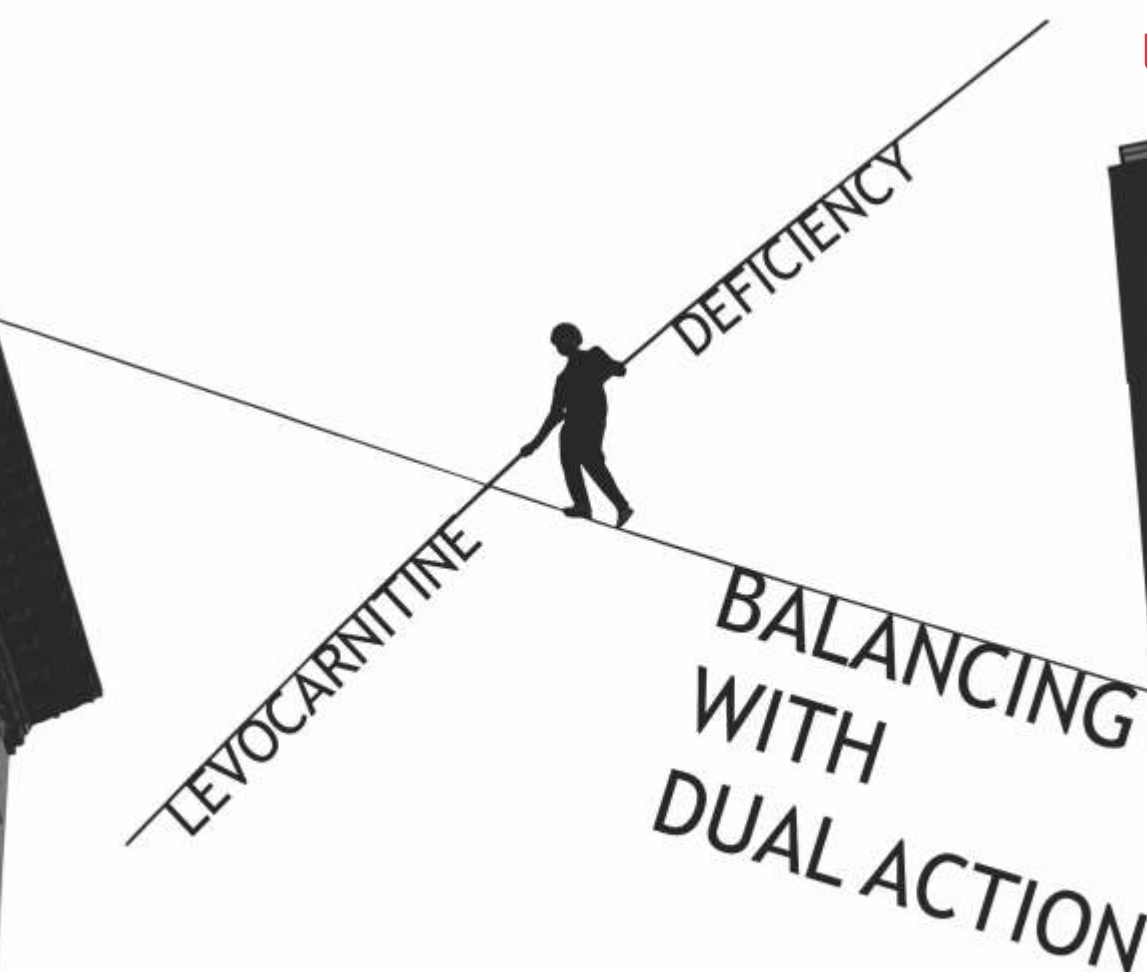
207-208 Iscon Elegance | Circle P | Prahlad Nagar Cross Roads | S.G. Highway | Ahmedabad-380015 | Gujarat, India.  
Phone: + 91-79-3046-1000 (30 lines) | Fax: +91-79-3046-1001 | E-mail: info@larenon.com | Web: www.larenon.com

I AM

MAIL ME @

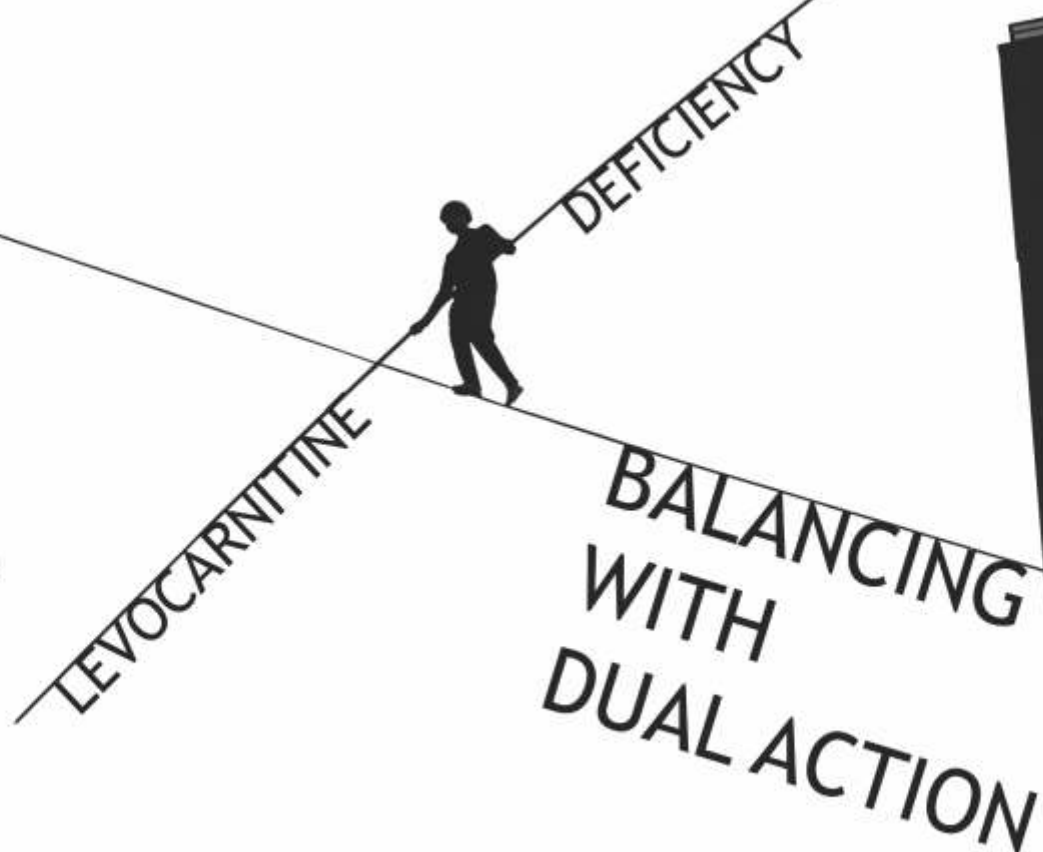
CALL ME ON

La Renon



**LACARNIT**  
Levocarnitine 330 mg Tablets

**LACARNIT Injection**  
Levocarnitine Inj. 200 mg / ml (5 mg Amp)



# LACARNIT

Levocarnitine 330 mg Tablets

# LACARNIT Injection

Levocarnitine Inj. 200 mg / ml (5 mg Amp)

# LACARNIT

Levocarnitine 330 mg Tablets

# LACARNIT Injection

Levocarnitine Inj. 200 mg / ml (5 ml Amp)

## Utility of L-Carnitine

- L-carnitine is a transporter of long chain fatty acids into mitochondria especially in skeletal and cardiac muscle tissues which rely on fatty acids as an energy source under aerobic metabolic conditions.
- The concentration of plasma and tissues carnitine in chronic hemodialyzed patients decreased severely because of the impaired synthesis in kidney and liver, the great loss across the dialysis membrane during hemodialysis, and the poor intake through the protein restricted diet.
- L-carnitine has been used for the secondary deficiency in chronic hemodialysis patients worldwide as an oral or intravenous use.

## Clinical Study-1

### Levocarnitine Improves Cardiac Function in Hemodialysis Patients with Left Ventricular Hypertrophy: A Randomized Controlled Trial

#### Background:

Levocarnitine deficiency in hemodialysis patients is common. Although the effect of levocarnitine therapy on uremic anemia has been studied in small trials, its effects on cardiac function remain unclear.

#### Study Design:

Multicenter, prospective, open-label, parallel, randomized, controlled trial.

#### Setting & Participants:

Patients undergoing maintenance hemodialysis with carnitine deficiency (free carnitine plasma concentration, 40 mmol/L) enrolled in 3 hemodialysis centers.

#### Intervention:

Random assignment to treatment for 12 months with oral levocarnitine therapy at a dose of 20 mg/kg/d or control group (no levocarnitine therapy).

#### Outcomes & Measurements:

Cardiac function was assessed by echocardiography. The primary end point was change in ejection fraction from baseline at the end of the study. Secondary end points included changes in left ventricular mass index and clinical parameters from baseline at the end of the study.

#### Results:

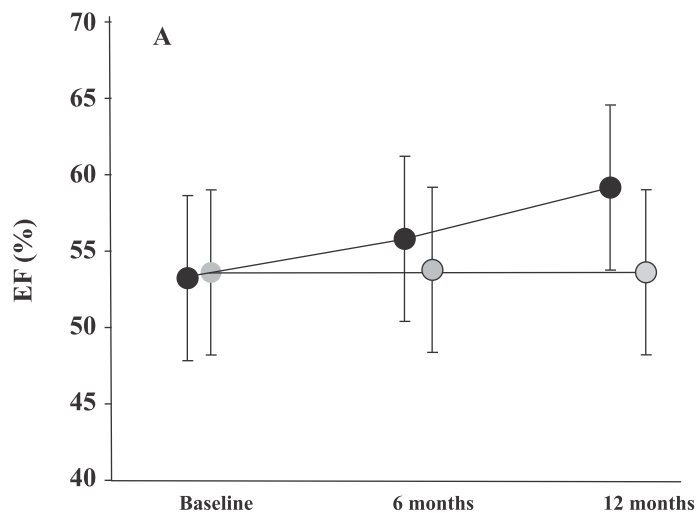
222 patients were randomly assigned, of whom 148 patients (levocarnitine group, n=75; control group, n=73) were analyzed.

#### Changes in LVMI and % EF Levels at Baseline, at 6 Months and at 12 months:

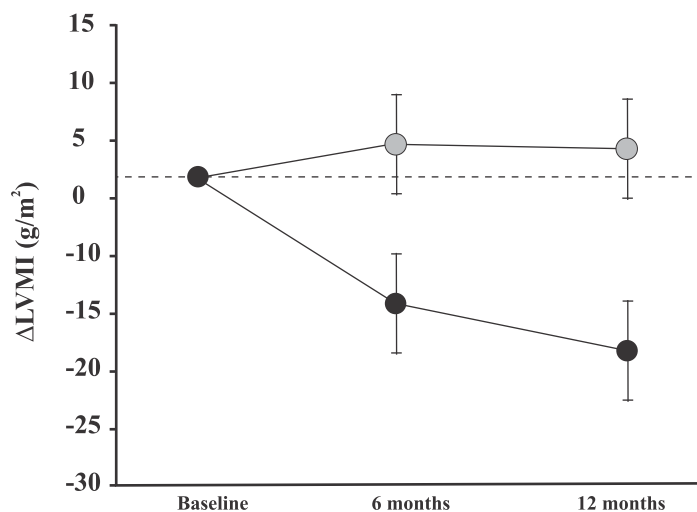
Parameter and Group	Baseline	At 6 months	At 12 months
<b>LVMI, g/m<sup>2</sup></b>			
Levocarnitine Group	112 ± 26	107 ± 24	104 ± 23
Control Group	110 ± 24	111 ± 25	112 ± 25
<b>% EF</b>			
Levocarnitine Group	53.1% ± 5.3%	55.5% ± 5.8 %	58.6% ± 5.5 %
Control Group	53.6% ± 6 %	53.5% ± 5.7 %	53.5% ± 6.2 %
<b>Free carnitine, mmol/L</b>			
Levocarnitine Group	27 ± 7		163 ± 40
Control Group	26 ± 6		26 ± 6
<b>Acyl to free Carnitine ratio</b>			
Levocarnitine Group	0.59 ± 0.26		0.49 ± 0.18
Control Group	0.57 ± 0.16		0.58 ± 0.18



# BALANCING WITH DUAL ACTION



**Cardiac Ejection Fraction increased by 5.43% in the levocarnitine group**



**Left ventricular mass index decreased by 8.89 g/m<sup>2</sup> in the levocarnitine group**

## Conclusion:

- Levocarnitine therapy is useful for hemodialysis patients with carnitine deficiency
- These patients may benefit from such therapy, with amelioration of cardiac function and reduction of left ventricular mass index

## References:

- 1) Y. Kudoh et al. ; *Journal of Biochemical and Pharmacological Research*, Vol. 2 (2): 117-124, June 2014
- 2) *Am J Kidney Dis.* May 2015

# LACARNIT

Levocarnitine 330 mg Tablets

## LACARNIT Injection

Levocarnitine Inj. 200 mg / ml (5 mg Amp)

### Description:

L-carnitine is a naturally occurring substance required in mammalian energy metabolism. Plasma carnitine accounts only for approximately 1% of the total body carnitine pool, with over 98% of carnitines present in the skeletal and cardiac muscles. Dialysis therapy can cause a decrease in both free carnitine and plasma acylcarnitines. Recent studies have shown that oral & intravenous L-carnitine plays an important role on anemia and cardiovascular disease in CKD patients.

### Indication:

**Lacarnit<sup>®</sup> Tablet** is indicated to treat primary systemic carnitine deficiency & acute and chronic treatment of patients with an inborn error of metabolism which results in a secondary carnitine deficiency.

**Lacarnit<sup>®</sup> Injection** is used to recommend for the prevention and treatment of carnitine deficiency in patients with end stage renal disease who are undergoing dialysis.

### Mechanism of action:

In humans, carnitine plays a pivotal role in energy metabolism through the transportation of long-chain fatty acids across the inner mitochondrial membrane and in controlling the rates of beta oxidations of long-chain fatty acids with subsequent energy production.

### Dosage:

#### Lacarnit<sup>®</sup> Tablet-

**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.

#### Lacarnit<sup>®</sup> Injection-

##### 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. Initiation of therapy may be prompted by trough (pre-dialysis) plasma levocarnitine concentrations that are below normal (40-50  $\mu\text{mol/L}$ ). Dose adjustments should be guided by trough (pre-dialysis) levocarnitine concentrations, and downward dose adjustments (e.g. to 5 mg/kg after dialysis) may be made as early as the third or fourth week of therapy.

### Presentation:

#### Lacarnit<sup>®</sup> Tablet

Lacarnit is available as a strip of 10 tablets in Alu-Alu blister packing.

#### Lacarnit<sup>®</sup> Injection

Lacarnit injection is available in 5x5 ml ampoule.

**La Renon Healthcare Pvt. Ltd.**

207-208 Iscon Elegance | Circle P | Prahlad Nagar Cross Roads | S.G. Highway | Ahmedabad-380015 | Gujarat, India.  
Phone: + 91-79-3046-1000 (30 lines) | Fax: +91-79-3046-1001 | E-mail: info@larenon.com | Web: www.larenon.com

I AM

MAIL ME @

CALL ME ON

# LACARNIT      LACARNIT Injection

Levocarnitine 330 mg Tablets

Levocarnitine Inj. 200 mg / ml (5 ml Amp)

## Utility of L-Carnitine

·L-carnitine is a transporter of long chain fatty acids into mitochondria especially in skeletal and cardiac muscle tissues which rely on fatty acids as an energy source under aerobic metabolic conditions.

·The concentration of plasma and tissues carnitine in chronic hemodialyzed patients decreased severely because of the impaired synthesis in kidney and liver, the great loss across the dialysis membrane during hemodialysis, and the poor intake through the protein restricted diet.

·L-carnitine has been used for the secondary deficiency in chronic hemodialysis patients worldwide as an oral or intravenous use.

## Clinical Study-1

### Levocarnitine Improves Cardiac Function in Hemodialysis Patients with Left Ventricular Hypertrophy: A Randomized Controlled Trial

#### Background:

Levocarnitine deficiency in hemodialysis patients is common. Although the effect of levocarnitine therapy on uremic anemia has been studied in small trials, its effects on cardiac function remain unclear.

#### Study Design:

Multicenter, prospective, open-label, parallel, randomized, controlled trial.

#### Setting & Participants:

Patients undergoing maintenance hemodialysis with carnitine deficiency (free carnitine plasma concentration, 40 mmol/L) enrolled in 3 hemodialysis centers.

#### Intervention:

Random assignment to treatment for 12 months with oral levocarnitine therapy at a dose of 20 mg/kg/d or control group (no levocarnitine therapy).

#### Outcomes & Measurements:

Cardiac function was assessed by echocardiography. The primary end point was change in ejection fraction from baseline at the end of the study. Secondary end points included changes in left ventricular mass index and clinical parameters from baseline at the end of the study.

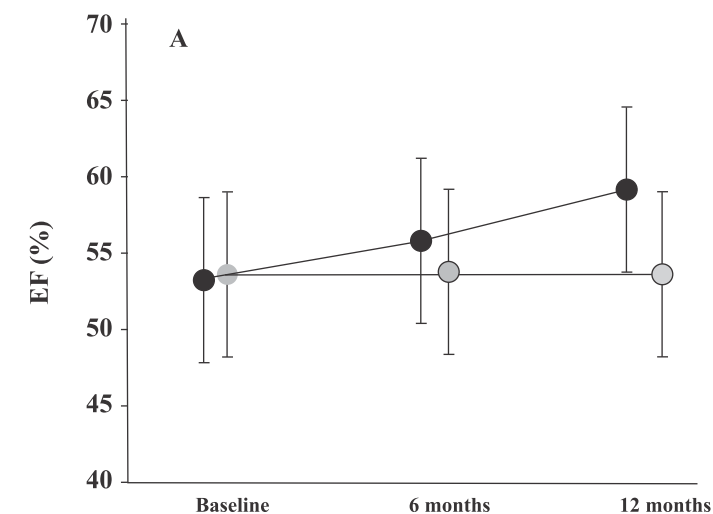
#### Results:

222 patients were randomly assigned, of whom 148 patients (levocarnitine group, n=75; control group, n=73) were analyzed.

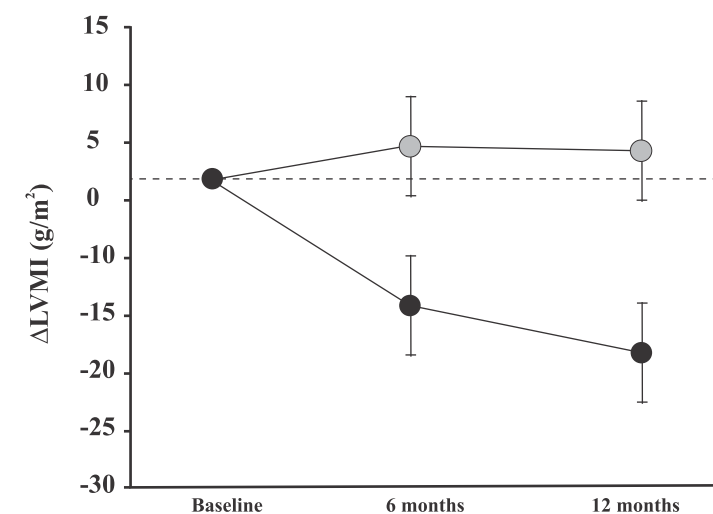
#### Changes in LVMI and% EF Levels at Baseline, at 6 Months and at 12 months:

Parameter and Group	Baseline	At 6 months	At 12 months
<b>LVMI, g/m<sup>2</sup></b>			
Levocarnitine Group	112 ± 26	107 ± 24	104 ± 23
Control Group	110 ± 24	111 ± 25	112 ± 25
<b>% EF</b>			
Levocarnitine Group	53.1% ± 5.3%	55.5% ± 5.8 %	58.6% ± 5.5 %
Control Group	53.6% ± 6 %	53.5% ± 5.7 %	53.5% ± 6.2 %
<b>Free carnitine, mmol/L</b>			
Levocarnitine Group	27 ± 7		163 ± 40
Control Group	26 ± 6		26 ± 6
<b>Acyl to free Carnitine ratio</b>			
Levocarnitine Group	0.59 ± 0.26		0.49 ± 0.18
Control Group	0.57 ± 0.16		0.58 ± 0.18

## BALANCING WITH DUAL ACTION



### Cardiac Ejection Fraction increased by 5.43% in the levocarnitine group



### Left ventricular mass index decreased by 8.89 g/m<sup>2</sup> in the levocarnitine group

#### Conclusion:

·Levocarnitine therapy is useful for hemodialysis patients with carnitine deficiency  
·These patients may benefit from such therapy, with amelioration of cardiac function and reduction of left ventricular mass index

#### References:

- 1)Y. Kudoh et al. ; *Journal of Biochemical and Pharmacological Research*, Vol. 2 (2): 117-124, June 2014
- 2)*Am J Kidney Dis*. May 2015