Summary of Product Characteristics

1. Name Of The Medicinal Product:

L-Carnitine plus Film Coated Tablet

2. Qualitative And Quantitative Composition

Composition		
Each film coated tablet contains:		
Active ingredients :		
L- Carnitine L- tartarate = 683 mg L- carnitine	1000 mg	In-House Specifications
Zinc gluconate	50 mg	USP 35
Inactive ingredients :		
Mannitol anhydrous	50 mg	B.P 2015
Magnesium stearate	20 mg	B.P 2015
Aerosil 200	5 mg	USP 35
Avicel pH 101	95 mg	B.P 2015
Povidone K 25	50 mg	B.P 2015
Acdisol	50 mg	B.P 2015
Talc	30 mg	B.P 2015
Composition of film coat:		
Hydroxypropyl methyl cellulose 15cps	75 mg	B.P 2015
Titanium dioxide	5 mg	B.P 2015
Polyethylene glycol 6000	15 mg	In-House Specifications
Magnesium stearate	5 mg	B.P 2015

3. Pharmaceutical Form:

Film Coated Tablets for oral administration

4. Clinical Particulars:

4.1 Therapeutic Indications:

- Primary L- carnitine deficiency:
skeletal and cardiac muscle myopathy, hepatic encephalopathy.
- Secondary L- carnitine deficiency due to genetically determined disorders:
acidurea and disorders of beta- oxidation
- Secondary L-carnitine deficiency due to acquired conditions:
- Heamodialysis and renal fanconi syndrome, anticonvulsants: sodium valproate, pivampicilline therapy
- Idiopathic asthenozoospermia
- L-Carnitine has cardio protective effect during antineoplastic therapy.
- Improve athletic performance in healthy subjects

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المصانع:
أنشاص الرمل - الشرقية
تليفون: ٠٦-٢٠٥٥٢٨٢٠٤٠٦+
٢٠٥٥٢٨٢٢٧١١+
فاكس : ٢٠٥٥٢٨٢٢٦٩٠+
محمول : ٣٣٦-٢٠١٢٢٧٦٩٣٣٦+
٢٠١٢٢٧٦٩٣٣٣٧+
أبو سلطان - فايد
تليفون : ٢٠٦٤٣٤٠٠٣٦٠+
فاكس : ٢٠٦٤٣٤٠٠٨٧٦+
المكتب العلمي:
مدخل ٥ - المبنى التجارى الثانى
المنطقة الخامسة . مساكن
الشيرانون رقم بريدى ١١٣٦١
هليوبوليس - الحرية
تليفون : ٢٠٢٢٦٧٣١٧٥+
٢٠٢٢٦٧٣١٧٦+
محمول : ٢٠١٢٢٧٦٩٣٣٧٧+
٢٠١٢٢٧٦٩٣٣٨٨+
فاكس : ٢٠٢٢٦٧٤٩٣٤+
مكتب الأسكندرية:
عمارات ضباط مصطفى كامل
عمارة ٢١ شقة ٣٣
تليفون : ٢٠٣٥٤٥٧١٤٠+
محمول: ٢٠١٢٢٧٦٩٣٣٩٩+
فاكس : ٢٠٣٥٤٥٧١٤٠+

- Long standing leg ulcers
- Hemolytic anemia (thalassaemia &sickle cell anemia)

- **4.2 Posology And Method Of Administration:**

1-3 tablet daily during meal , or as directed by the physician

- **4.3 Contraindications:**

None known

- **4.4 Special Warnings And Precautions For Use:**

Patient should consult the doctor before taking l-carnitine plus

- **4.5 Interaction With Other Medicinal Products And Other Forms Of Interaction:**

- Several drugs may affect the levels of carnitine in the body. For example, adefovir dipivoxil, which is given for hepatitis B, may reduce free carnitine levels. Cephalosporin antibiotics may reduce plasma carnitine levels. Anticonvulsants (phenobarbital, phenytoin, and carbamazepine) may decrease serum carnitine in children. Cisplastin may increase urinary excretion of carnitine. Ifosfamide, a chemotherapy drug, may increase urinary loss of carnitine; however, use of carnitine plus ifosfamide may help reduce fatigue (side effect of ifosfamide treatment). Patients suffering from neuropathy (nerve damage) induced by nucleosides may have reduced levels of acetyl carnitine. Penicillin derivatives (pivaloyloxymethyl esterified, pivampicillin, and pivmecillinam) may decrease the serum carnitine concentration, elevate excretion of acyl-carnitine, and reduce muscle carnitine concentration in adults and children.
- L-carnitine may decrease the need for certain drugs, such as glycosides, digoxin, diuretics, beta-blockers, channel blockers, hypolipidemic (cholesterol-altering) drugs, and nitro derivatives. L-carnitine supplementation may reduce side effects associated with interleukin-2 (IL-2) or nortriptyline. It may also improve liver and muscular side effects associated with isotretinoin in acne patients. Carnitine may reduce nerve damage symptoms associated with paclitaxel use. Carnitine may prevent arrhythmias (abnormal heart rhythms) provoked by Adriamycin, which is used in chemotherapy.
- L-carnitine may decrease the need for antiarrhythmics (medications used to treat abnormal rhythms in the heart). Carnitine plus propafenone may improve arrhythmia

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مكتب الأسكندرية:
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فاكس : +٢٠٣٥٤٥٧١٤٠

(heart rhythm) better than propafenone alone. L-carnitine may decrease the need for anticoagulants ("blood thinners"), such as warfarin or heparin. Several combinations have shown positive interactions. For example, sildenafil and propionyl-L-carnitine may be more effective than sildenafil alone. Although not well studied in humans, L-carnitine used concurrently with antiviral agents such as zidovudin (Retrovir®) or carnitine used with nortryptiline may also have a positive interaction that reduces side effects. L-carnitine plus acetyl-L-carnitine plus cinnoxicam has been found more effective in improving sperm parameters as compared with L-carnitine plus acetyl-L-carnitine alone.

- Patients with diabetes should use caution because L-carnitine may decrease blood sugar. However, carnitine levels did not change in diabetics using insulin or sulfonylurea therapy. It is unclear whether L-carnitine would have similar effects when combined with other medications that lower blood sugar. Although not well studied in humans, carnitine may increase valproic acid concentrations in the brain, which might increase the effects of valproic acid. Caution is advised (Benvenga *et al.*, 2001; Thomas S, *et al.*, 1999).

- **4.6 Pregnancy And Lactation**

No adequate and well controlled studies in pregnant or lactating women.

- **4.7 Effects On Ability To Drive And Use Machines:**

No information provided

- **4.8 Undesirable Effects:**

L-carnitine Mepaco has no significant side effects.

Rarely oral L-carnitine in high doses causes nausea and diarrhea ,especially at the beginning of usage , in this condition it is advisable to continue the treatment and symptoms will disappear gradually transient nausea and vomiting have been observed.

Less frequent adverse reactions are body odour, nausea, and gastritis.

- **4.9 Overdose**:

Rarely oral L-carnitine in high doses causes nausea and diarrhea ,especially at the beginning of usage , in this condition it is advisable to continue the treatment and symptoms will disappear gradually transient nausea and vomiting have been observed.

Less frequent adverse reactions are body odor, nausea, and gastritis.

- **5. Pharmacological Properties:**

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فاكس: ٠٥٥٢٨٢٢٦٩٠+
محمول: ٠١٢٢٧٦٩٣٣٦+
٠١٢٢٧٦٩٣٣٣٧+

أبو سلطان - فايد
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المكتب العلمي:
مدخل ٥ - المبنى التجارى الثانى
المنطقة الخامسة . مساكن
الشيراتون رقم بريدى ١١٣٦١
هليوبوليس - الحرية
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٠٢٢٦٧٣١٧٦+
محمول: ٠١٢٢٧٦٩٣٣٧٧+
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فاكس: ٠٢٢٦٧٤٩٣٤+

مكتب الأسكندرية:
عمارات ضباط مصطفى كامل
عمارة ٢١ شقة ٣٣
تليفون: ٠٣٥٤٥٧١٤٠+
محمول: ٠١٢٢٧٦٩٣٣٩٩+
فاكس: ٠٣٥٤٥٧١٤٠+

L-carnitine is an essential co-factor that exerts a beneficial effect in different pathology involving both vascular and muscle tissues.

L-carnitine is an amino acid derivative of lysine and methionine.

L-carnitine is an essential co-factor of fatty acid metabolism in skeletal muscle, heart and liver

L-carnitine is concentrated in tissues, with about 97% in skeletal muscles

In the muscle cell L-Carnitine is the molecule that transport long chain fatty acid across the membrane of the mitochondria which stimulate its energy production, so L-Carnitine is considered a natural modulator as it is the essential factor for fatty acid oxidation into cellular mitochondria.

Zinc is mineral that utilized in minute quantities in practically every cell in the human body. It is essential for the proper functioning of nervous system and optimal immune response.

Zinc also has special role in reproductive process, being as it is crucial in the development of sperm in males and ovum in females.

- **5.1 Pharmacodynamics Properties**

In the muscle cell L-carnitine is the molecule that transports long chain fatty acids across the membrane of metochondria which stimulate its energy production, so L-carnitine is considered a natural metabolic modulator as it is the essential factor for fatty acid oxidation into cellular mitochondria.

L-carnitine is readily absorbed, the maximal concentration is reached after 4 hours, L-carnitine is eliminated in urine, its half-life is nearly 15 hours

- **5.2 Pharmacokinetic Properties:**

- Evidence indicates L-carnitine is absorbed in the intestine by a combination of active transport and passive diffusion (Li *et al.,* 1992). Reports of bioavailability following an oral dose (0.5-6 gram dosage) have varied substantially, with estimates as low as 14-18 percent (Sahajwalla *et al.*,1995), and (Rebouche 2004) and as high as 54-87 percent (Bach *et al.*,1983; Rebouche *et al.*,1991), Less is known regarding the metabolism of the acetylated form of L-carnitine, acetyl-L-carnitine (ALCAR); however, bioavailability of ALCAR is thought to be higher than L-carnitine. The results of in vitro experiments suggest that ALCAR is partially hydrolyzed upon intestinal absorption (Gross *et al.*, 1986). In humans, administration of 2 grams of ALCAR per day for 50 days increased plasma ALCAR levels by 43%, suggesting that some acetyl-L-carnitine is absorbed without hydrolysis or that L-carnitine is reacetylated in the enterocyte (Rebouche 2004).

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تليفون: ٠٥٥٢٨٢٠٤٠٦+
٠٥٥٢٨٢٢٧١١+
فاكس : ٠٥٥٢٨٢٢٦٩٠+
محمول : ٠١٢٢٧٦٩٣٣٦+
٠١٢٢٧٦٩٣٣٣٧+

أبو سلطان - فايد
تليفون : ٠٦٤٣٤٠٠٣٦٠+
فاكس : ٠٦٤٣٤٠٠٨٧٦+

المكتب العلمي:
مدخل ٥ - المبنى التجارى الثانى
المنطقة الخامسة , مساكن الشيراتون رقم بريدى ١١٣٦١
هليوبوليس - الحرية
تليفون : ٠٢٢٦٧٣١٧٥+
٠٢٢٦٧٣١٧٦+
محمول : ٠١٢٢٧٦٩٣٣٧٧+
٠١٢٢٧٦٩٣٣٨٨+
فاكس : ٠٢٢٦٧٤٩٣٤+

مكتب الأسكندرية:
عمارات ضباط مصطفى كامل
عمارة ٢١ شقة ٣٣
تليفون : ٠٣٥٤٥٧١٤٠+
محمول: ٠١٢٢٧٦٩٣٣٩٩+
فاكس : ٠٣٥٤٥٧١٤٠+

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المصانع:
أنشاص الرمل - الشرقية
تليفـون: ٠٦+٢٠٥٥٢٨٢٠٤٠٦
+٢٠٥٥٢٨٢٢٧١١
فاكـس : ٠+٢٠٥٥٢٨٢٢٦٩٠
محمول : ٣٣٦ ٧٦٩٣٠١٢٢٧+٢٠
+٢٠١٢٢٧٦٩٣٣٣٧

أبو سلطان - فايد
تليفـون : ٠٣٦٠+٢٠٦٤٣٤٠٠
فاكـس : ٠٨٧١+٢٠٦٤٣٤٠٠

المكتب العلمي:
مدخل ٥ - المبنى التجارى الثانى
المنطقة الخامسة . مساكن
الشيراتون رقم بريدى ١١٣٦١
هليوبوليس - الحرية
تليفون : ٠+٢٠٢٢٦٧٣١٧٥
+٢٠٢٢٦٧٣١٧٦
محمول : ٠+٢٠١٢٢٧٦٩٣٣٧٧
+٢٠١٢٢٧٦٩٣٣٨٨
فاكس : ٠+٢٠٢٢٦٧٤٩٣٤

مكتب الأسكندرية:
عمارات ضباط مصطفى كامل
عمارة ٢١ شقة ٣٣
تليفون : ٠+٢٠٣٥٤٥٧١٤٠
محمول: ٠+٢٠١٢٢٧٦١٩٣٣٩٩
فاكس : ٠+٢٠٣٥٤٥٧١٤٠

- Oral supplementation of L-carnitine in individual dosages greater than 2 g appears to offer no advantage, since the mucosal absorption of carnitine appears to be saturated at about a 2 g dose (Harper *et al.*, 1988). While bioavailability of L-carnitine from the diet is quite high, absorption from oral L-carnitine supplements is considerably lower. Supplemental L-carnitine is mainly absorbed by passive diffusion (Rebouche 2006). Maximum blood concentration is reached approximately 3.5 hours after an oral dose and slowly decreases, with a half life of about 15 hours (Bach *et al.*, 1983), In healthy people, carnitine homeostasis (balance) is maintained through endogenous biosynthesis of L-carnitine, absorption of carnitine from dietary sources, and elimination and reabsorption of carnitine by the kidneys (Rebouche *et al.*,2004).

- Elimination of carnitine occurs primarily through the kidneys (Rebouche CJ, *et al.*, 1991). Renal reabsorption of L-carnitine is normally very efficient; in fact, an estimated 95% is thought to be reabsorbed by the kidneys (Rebouche 2006). Therefore, carnitine excretion by the kidney is normally very low. However, several conditions can decrease carnitine reabsorption efficiency and, correspondingly, increase carnitine excretion. Such conditions include high fat (low carbohydrate) diets, high-protein diets, pregnancy, and certain disease states (Rebouche *et al.*, 1993). In addition, when circulating L-carnitine levels increase, as in the case for oral supplementation, renal reabsorption of L-carnitine becomes saturated, resulting in increased urinary excretion of L-carnitine (Rebouche 2004). Dietary or supplemental L-carnitine that is not absorbed by enterocytes is degraded by colonic bacteria to form two principal products, trimethylamine and gamma-butyrobetaine. Gamma-butyrobetaine is eliminated in the feces; trimethylamine is efficiently absorbed and metabolized to trimethylamine-N-oxide, which is excreted in the urine (Rebouche 1992).

- The heart, skeletal muscle, liver, kidneys, and epididymis have specific transport systems for carnitine that concentrate carnitine within these tissues. Despite evidence indicating increased levels of free carnitine and carnitine metabolites in the blood and urine following an oral dose, no significant change in red blood cell carnitine levels was noted in healthy subjects, suggesting either a slow repletion of tissue stores of carnitine following an oral dose or a low capability to transport carnitine into tissues under normal conditions (Baker *et al.*, 1993).

- **5.3 Preclinical Safety Data**

No published data

6. Pharmaceutical Particulars

- **6.1 List Of Excipients**
- **Inactive ingredients:**

Mannitol anhydrous	50 mg	BP 2015
Magnesium stearate	20 mg	BP 2015
Aerosil 200	5 mg	USP 35
Avicel pH 101	95 mg	BP 2015
Povidone K 25	50 mg	BP 2015
Acdisol	50 mg	BP 2015
Talc	30 mg	BP 2015

- **Film Coat:**

Magnesium stearate	5 mg	BP 2015
Titanium dioxide	5 mg	BP 2015
Polyethylene glycol 6000	15 mg	BP 2015
Hydroxypropyl methyl cellulose 15cps	75 mg	BP 2015

- **6.2 Incompatibilities:**
  - All excipients comply with their USP, BP Pharmacopoeia monograph.
  - None of the excipients contains materials of animal or human origin.
  - No genetically modified organisms (GMO) have been used in the preparation of these products.
  - No incompatibilities with the excipients or packaging materials have been shown during research of pre-formulation and formulation studies and nor during manufacturing processing and stability.
- **6.3 Shelf Life**

Three years

- **6.4 Special Precautions For Storage:**

No special precaution for storage

Store in dry place at temperature not exceeding 30 °C

- **6.5 Nature And Contents Of Container**

Carton box contains 2 (Aluminum- PVC) strips each of 10 tablets and inner leaflet

- **6.6 Special Precautions For Disposal And Other Handling:**

Keep out of reach of children

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المكتب العلمي:
مدخل ٥ - المبنى التجارى الثانى
المنطقة الخامسة . مساكن
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تليفون : ٠٢٢٦٧٣١٧٥+
٠٢٢٦٧٣١٧٦+
محمول : ٠١٢٢٧٦٩٣٣٧٧+
٠١٢٢٧٦٩٣٣٨٨+
فاكس : ٠٢٢٦٧٤٩٣٤+

مكتب الأسكندرية:
عمارات ضباط مصطفى كامل
عمارة ٢١ شقة ٣٣
تليفون : ٠٣٥٤٥٧١٤٠+
محمول: ٠١٢٢٧٦٩٣٣٩٩+
فاكس : ٠٣٥٤٥٧١٤٠+

- **7. Marketing Authorization Holder:**

Arab Company for Pharmaceuticals & Medicinal Plants (Mepaco – Medi food) Egypt

- **8. Marketing Authorization Number(S)**

Reg. No: 27101/2011

- **9. Date Of First Authorization/Renewal Of The Authorization:**

Reg. No: 27101/2011 Authorization date: 20/01/2011

R&D Manager

Dr. / Mohamed Eldegwy

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Mob: +2 0122 7693399
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المصانع:
أنشاص الرمل - الشرقية
تليفون: ٠٥٥٢٨٢٠٤٠٦+
٠٥٥٢٨٢٢٧١١+
فاكس : ٠٥٥٢٨٢٢٦٩٠+
محمول : ٠١٢٢٧٦٩٣٣٦+
٠١٢٢٧٦٩٣٣٣٧+

أبو سلطان - فايد
تليفون : ٠٦٤٣٤٠٠٣٦٠+
فاكس : ٠٦٤٣٤٠٠٨٧٦+

المكتب العلمي:
مدخل ٥ - المبنى التجارى الثانى
المنطقة الخامسة . مساكن
الشيراتون رقم بريدى ١١٣٦١
هليوبوليس - الحرية
تليفون : ٠٢٢٦٧٣١٧٥+
٠٢٢٦٧٣١٧٦+
محمول : ٠١٢٢٧٦٩٣٣٧٧+
٠١٢٢٧٦٩٣٣٨٨+
فاكس : ٠٢٢٦٧٤٩٣٤+

مكتب الأسكندرية:
عمارات ضباط مصطفى كامل
عمارة ٢١ شقة ٣٣
تليفون : ٠٣٥٤٥٧١٤٠+
محمول: ٠١٢٢٧٦١٩٣٣٩٩+
فاكس : ٠٣٥٤٥٧١٤٠+