

Arab Company for Pharmaceuticals, & Medicinal Plants s.A.E MEPACO - MEDIFOOD الشركة العربية للأدوية والنباتات الطبية شمم ميباكو -ميدي فود

Summary of Product Characteristics

















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> المصانع: أنشاص الرمل – الشرقية تليفون: ۲۰۵۵۲۸۲۰۵۰۱+ + F - DO FAF FV11 فاكس: ۱۰۵۵۲۸۲۱۹۰.

محمول: ۲۰۱۲۲۷۱۹۳۳۳۱. - 1 - 1 5 5 V 1 9 FFFV

أبو سلطان – فايد

-۱۰۱۶۳۲۰۰۳۱ - تليفون Primary L- carnitine deficiency:

skeletal and cardiac muscle myopathy, hepatic encephalopathy.

Secondary L- carnitine deficiency due to genetically determined disorders: مدخل ٥ - المبنى التجاري الثاني acidurea and disorders of beta- oxidation

المنطقة الخامسة ، مساكن Secondary L-carnitine deficiency due to acquired conditions: - الشيرانون رقم بريدي ١١٣١١

الحرية المبيوليس الحرية - المبيوليس الحرية - Heamodialysis and renal fanconi syndrome, anticonvulsants: sodium valproate, pivampicilline therapy + 1 - 11171171

- Idiopathic asthenozoospermia + 1 - 1 | 1 | 1 | 1 | 1 |

הוצשיי : בוצשיי L-Carnitine has cardio protective effect during antineoplastic therapy.

Improve athletic performance in healthy subjects مكتب الأسكندرية،

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	1000 mg	In-House Specifications			
= 683 mg L- carnitine	1000 mg				
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	75 ma	B.P 2015			
15cps	75 mg				
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:

عمارات ضباط مصطفى كامل عمارة ١١ شقة ٣٣ تليفون: ۲۰۳۵٤۵۷۱٤٠ محمول: ۲۰۱۲۲۷۹۳۳۹۹ فاكس : ۲۰۳۵٤۵۷۱٤٠.



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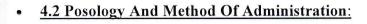
MEDIFOOD - Long standing leg ulcers

- Hemolytic anemia (thalassaemia &sickle cell anemia)





















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المصانع: أنشاص الرمل - الشرقية تليفون: ۲۰۵۵۲۸۲۰۱۰ + F - DO FAF FV1 1 فاكس: ١٠٥٥٢٨٢٢١٩٠. محمول: ۲۰۱۲۲۷۱۹۳۳۳۱.

أبو سلطان – فايد تليفون: ١٠٦٤٣٤٠٠٣١٠ فاكس: ٢٠٦٤٣٤٠٠٨٧١.

الكتب العلمي: مدخل ۵ – المبنى التجاري الثاني المنطقة الخامسة ، مساكن الشيراتون رقم بريدى ١١٣٦١ هليوبوليس - الحرية تليفون: ٢٠٢٢٧٣١٧٥ + 1-11177171 مول: ۲۰۱۲۲۷۹۳۳۷۷ + 1 - 1 | 1 | 1 | 1 | 1 | فاكس : ۲۰۲۲۷۷۹۳٤

مكتب الأسكندرية: عمارات ضباط مصطفى كامل عمارة ٢١ شقة ٣٣ تليفون: ۲۰۳۵٤۵۷۱٤٠ محمول: ۲۰۱۲۲۷۹۹۳۳۹۹ فاكس : ۲۰۳۵٤۵۷۱٤٠

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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Operating Under Law 43 Issued 1974 – Commercial Register No. 866 - Capital 400 EGP Million Page 2 of 7 خاصعة لأحكام فانون ٤٠٠ لسنة ١٩٧٤ وتعديلاته سجل رقم ٨١١٨ إستثمار راس المال المرخص به ٤٠٠ مليون جنيه مصرى



















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الشركة العربية للأدوية والنباتات الطبية شمم مبياكو -ميدى فود

(heart rhythm) better than propagenone 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, Lcarnitine 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.

أنشاص الرمل - الشرقية 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. محمول: ۲۰۱۲۲۷۱۹۳ ۳۳۱ +1-151719777

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

تليفون: ۲۰۱۲۳۲۰۰۳۱۰ فاكس : ۲۰۱۲۳۲۰۰۸۷۱

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. ملبوبوليس - الحرية الشيراتون رقم بريدى ١١٣٦١

تليفون: ٢٠٢٢٦٧٣١٧٥

Less frequent adverse reactions are body odor, nausea, and gastritis. . 1. [[] VFIVI

محمول: ۲۰۱۲۲۷۷۹۳۳۷۷ + 1-111119

فاكس : ۲۰۲۲۷۷۹۳٤

مكتب الأسكندرية: عمارات ضباط مصطفى كامل

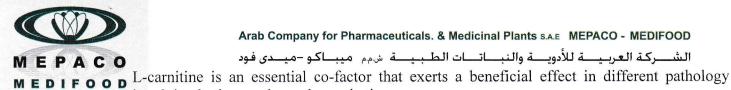
عمارة ٢١ شقة ٣٣ تليفون: ۲۰۳۵٤۵۷۱٤٠ محمول: ۲۰۱۲۲۷۱۹۳۳۹۹

فاكس : ۲۰۳۵٤۵۷۱٤٠

5. Pharmacological Properties:

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Operating Under Law 43 Issued 1974 - Commercial Register No. 866 - Capital 400 EGP Million خاضعة لأحكام قانون ٤٣ لسنة ١٩٧٤ وتعديلاته سجل رقم ٨١٦ إستثمار رأس المال المرخص به ٤٠٠ مليون جنيه مصرى



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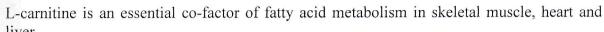
الشركة العربية للأدوية والنباتات الطبية شمم ميباكو -ميدى فود



involving both vascular and muscle tissues. L-carnitine is an amino acid derivative of lysine and methionine.

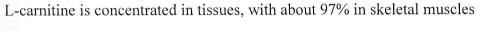
















In the muscle cell L-Carnitine is the molecule that transport long chain fatty acid across the membrane of the mitochondria which stimulate its energy production, so L-Carnitine is considered a natural modulator as it is the essential factor for fatty acid oxidation into cellular mitochondria.

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, Lcarnitine 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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أنشاص الرمل - الشرقية تليفون: ۲۰۵۵۲۸۲۰۵۰۱ + F - DO FAF FV11 فاكس: ١٠٥٥٢٨٢٢١٩٠. محمول: ۲۰۱۲۲۷۱۹۳۳۳۱. +1-1111119

> أبو سلطان – فايد تليفون: ۲۰۱۲۳۲۰۰۳۱۰ فاكس: ٢٠٦٤٣٤٠٠٨٠١

الكتب العلمي: مدخل ٥ – المبنى التجاري الثاني المنطقة الخامسة ، مساكن الشيراتون رقم بريدي ١١٣٦١ هليوبوليس – الحرية تليفون: ۲۰۲۲۷۳۱۷۵ + 1 - 11177171 حصول: ۲۰۱۲۲۷۱۹۳۳۷۷ -+ F · 1 F F V 7 9 TTAA

مكتب الأسكندرية: عمارات ضباط مصطفى كامل عمارة ٢١ شقة ٣٣ تليفون: ۲۰۳۵٤۵۷۱٤٠ محمول: ۲۰۱۲۲۷۹۹۳۳۹۹ فاكس : ۲۰۳۵٤۵۷۱٤٠

فاكس : ۲۰۲۲۷۷۹۳٤



















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المصانع: أنشاص الرمل - الشرقية تليفون: ۲۰۵۰۵۲۸۰۰۱ نليفون: ۲۰۵۵۲۸۲۷۱۱ فاكس: ۲۰۵۲۸۲۱۹۰۰ محمول: ۲۰۱۲۲۷۹۳۳۷۷

> أبو سلطان – فايد تليفون : ۲۰۱٤۳۲۰۰۳۰ فاكس : ۲۰۱۲۳۲۰۰۸۷

المكتب العلمي: مدخل ٥ - المبنى التجارى الثانى المنطقة الخامسة . مساكن الشيراتون رقم بريدى ١١٣١١ هليوبوليس - الحرية تليفون : ١٠٢١٧٣١٧٧ محمول : ١٠٢١٧٩٢٣٧٧

مكتب الأسكندرية: عمارات ضباط مصطفى كامل عمارة ١٦ شقة ٣٣ تليفون: ١٠٤٣٥٤٥٠١٠ محمول: ٢٠١١٢٧١٩٣٩٩ فاكس: ٢٠٢٥٤٥٧١٤٠

فاكس : ۲۰۲۲۷۷۹۳٤

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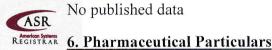
- Oral supplementation of L-carnitine in individual dosages greater than 2 g appears to offer no advantage, since the mucosal absorption of carnitine appears to be saturated at about a 2 g dose (Harper *et al.*, 1988). While bioavailability of L-carnitine from the diet is quite high, absorption from 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).



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5.3 Preclinical Safety Data





No published data







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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 أنشاص الرمل - الشرقية

المسانع:

تليفون: ٢٠١٥٥٥١٠١-+1.00141111

فاكس: ۲۰۵۵۲۸۲۱۹۰. محمول: ۲۰۱۲۲۷۱۹۳ ۳۳۱.

+1.11111977

6.4 Special Precautions For Storage:

No special precaution for storage

أبو سلطان – فايد Store in dry place at temperature not exceeding 30 °C تليفون Store in dry place at temperature فاكس: ٢٠٦٤٣٤٠٠٨٧١.

6.5 Nature And Contents Of Container

المكتب العلمى: مدخل ٥ – المبنى التجاري الثاني المنطقة الخامسة ، مساكن الشيراتون رقم بريدي ١١٣٦١

هليوبوليس – الحرية تليفون: ۲۰۲۲۷۳۱۷۵

فاكس : ۲۰۲۲۷۷۹۳٤

Keep out of reach of children محمول: ۱۰۱۲۲۷۱۹۳۳۷۰ + F. 1 F F V 1 9 TTAA

مكتب الأسكندرية: عمارات ضباط مصطفى كامل عمارة ٢١ شقة ٣٣ تليفون: ۲۰۳۵٤۵۷۱٤٠ محمول: ۲۰۱۲۲۷۹۹۳۳۹۹

فاكس : ۲۰۳۵٤۵۷۱٤٠.

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Operating Under Law 43 Issued 1974 — Commercial Register No. 866 - Capital 400 EGP Million خاضعة لأحكام قانون ٤٣ لسنة ١٩٧٤ وتعديلاته سجل رقم ٨٦٨ إستثمار رأس المال المرخص به ٤٠٠ مليون جنيه مصرى

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

6.6 Special Precautions For Disposal And Other Handling:



















Factories:

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> المصانع: أنشاص الرمل - الشرقية تليفون: ٢٠٥٥٢٨٢٤٠١ ١٢٠٥٥٢٨٢١٧١ فاكس: ٢٠٥٢٨٢١٩٠ محمول: ٢٠١٢٢٧٩٣٣٣

> > أبو سلطان – فايد تليفــون : ۲۰۱۲۳۲۰۰۳۱ فاكــس : ۲۰۱۲۳۲۰۰۸۷۱

المكتب العلمي: مدخل ٥ - المبنى التجارى الثانى النطقة الخامسة . مساكن الشيراتون رقم بريدى ١١٣١١ هليوبوليس - الحرية تليفون : ١٠٢١٧٣٧٧٠٠ محمول : ١٠٢١٧١٩٣٧٠٠ محمول : ١٠١٢٧١٩٣٣٨٨

مكتب الأسكندرية: عمارات ضباط مصطفى كامل عمارة ١١ شقة ٣٣ تليفون: ١٥٠٣٥٤٥٠١٠ محمول: ١٥٠١٢٧١٩٣٩٩٠ فاكس : ١٥٠٢٥٤٥٧١٤٠ Arab Company for Pharmaceuticals. & Medicinal Plants s.A.E MEPACO - MEDIFOOD الشركة العربية للأدوية والنباتات الطبية شمم ميباكو –ميدى فود

• 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

√ Mohamed Eldegwy

www. mepaco-pharma.net

Operating Under Law 43 Issued 1974 — Commercial Register No. 866 - Capital 400 EGP Million مراكز من المال المرخص به ٤٠٠ مليون جنيه مصرى خاضعة لأحكام قانون ٤٠٠ لسنة ١٩٧٤ وتعديلاته سجل رقم ١٨١ إستثمار رأس المال المرخص به ٤٠٠ مليون جنيه مصرى