For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

CARNISURE LQ

1. Generic Name

L-Arginine, L-Carnitine L-Tartrate, Co-enzyme Q10, Lycopene, Folic Acid, Sodium Selenite, Zinc Sulphate, Vitamin D3 and Cyanocobalamin Granules

2. Qualitative and quantitative Composition:

Each sachet of 10 g contains (Approx.) :		**% RDA**
L-Arginine	3 g	**
L-Carnitine L-Tartrate	500 mg	**
Co-enzyme Q10	100 mg	**
Zinc Sulphate Monohydrate Eq to Elemental Zinc	10 mg	83.3%
Lycopene (10%)	2.5 mg	**
Folic Acid	0.1 mg	85%
Sodium Selenite Eq to Selenium	40 mcg	100%
Vitamin D_3	10 mcg	100%
Cyanocobalamin	1 mcg	100%

** % RDA values not established.

Ingredients : L-Arginine, Lactose, Bulking Agent (INS 421), Acidity Regulator (INS 330), L-Carnitine L-Tartrate, Anti-Caking Agent (INS 551), Sweetener (Aspartame), Nature Identical Flavouring Substances (Orange & Lemon), Co-enzyme Q10, Minerals (Zinc Sulphate, Sodium Selenite), Stabilizer (INS 1201), Lycopene, Vitamins (Cholecalciferol, Cyanocobalamin).

Appropriate overages of vitamins added to compensate for loss of potency during storage.

3. Dosage form and strength

Dosage form: Granules.

Strength:

L-Arginine	3 g
L-Carnitine L-Tartrate	500 mg
Co-enzyme Q10	100 mg

Zinc Sulphate Monohydrate Eq to Elemental Zinc	10 mg
Lycopene (10%)	2.5 mg
Folic Acid	0.1 mg
Sodium Selenite Eq to Selenium	40 mcg
Vitamin D_3	10 mcg
Cyanocobalamin	1 mcg

4. Clinical particulars

4.1 Therapeutic indication

NUTRACEUTICALS

4.2 Posology and method of administration

Posology

The Carnisure LQ must be taken as directed by the physician.

Serve Size : 10 g	No of serving: 1	
Nutritional Information	**Qty/serve**	***%RDA**
Energy+	38.31 Kcal	1.91%
Protein	6.49 g	10.81%
Carbohydrate	3.03 g	**
- Total Sugars	2.96 g	**
-Added Sugars+	0.0 g	0.00%
Total Fat+	0.026 g	0.03%
-Cholesterol	0.0 mg	**
Sodium+	7.86 mg	0.39%

* %RDA values established as per ICMR 2010 for moderate work – Men
+ %RDA values established as per Labeling and display regulation 2020 per serve for average adult.
** %RDA values not established.

- This product is not intended to diagnose, treat, cure or prevent any disease(s).
- Pregnant/ Lactating women, children and people with medical condition should consult a Healthcare Professional before use.
- Not to exceed the stated recommended daily usage.
- Not recommended for children.
- Recommended Usage: One sachet daily.
- Recommended Duration of use: Depends upon physiological condition of the individual.
- NOT FOR MEDICINAL USE

Method of Administration: For oral administration.

Direction for use:

1. Empty the powder from sachet into the glass.
2. Add 100ml of water.
3. Stir well until the powder is evenly dispersed in the water and drink immediately.

4.3 Contraindications

Long-term therapy is contraindicated in any patient with untreated cobalamin deficiency. This can be untreated pernicious anaemia or other cause of cobalamin deficiency, including lifelong vegetarians. In elderly people, a cobalamin absorption test should be done before long-term folate therapy. Folate given to such patients for 3 months or longer has precipitated cobalamin neuropathy. No harm results from short courses of folate.

- Folic acid should never be given alone in the treatment of Addisonian pernicious, anaemia and other vitamin B deficiency states because it may precipitate the onset of subacute combined degeneration of the spinal cord.
- Folic acid should not be used in malignant disease unless megaloblastic anaemia owing to folate deficiency is an important complication.
- Known hypersensitivity to the active ingredient or any of the excipients.
- Diseases and/or conditions resulting in hypercalcaemia or hypercalciuria.
- Nephrolithiasis.
- Nephrocalcinosis

- Hypervitaminosis D.
- Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis, laryngeal edema, and bronchospasm have been reported following CARNISURE LQ administration, mostly in patients with end stage renal disease who are undergoing dialysis. Some reactions occurred within minutes after intravenous administration of CARNISURE LQ. If a severe hypersensitivity reaction occurs, discontinue CARNISURE LQ treatment and initiate appropriate medical treatment. Consider the risks and benefits of re-administering CARNISURE LQ to individual patients following a severe reaction.

If the decision is made to re-administer the product, monitor patients for a reoccurrence of signs and symptoms of a severe hypersensitivity reaction. If a severe hypersensitivity reaction occurs, discontinue CARNISURE LQ treatment and initiate appropriate medical treatment. Consider the risks and benefits of re-administering CARNISURE LQ to individual patients following a severe reaction. If the decision is made to re-administer the product, monitor patients for a reoccurrence of signs and symptoms of a severe hypersensitivity reaction.

PRECAUTIONS General

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.

4.5 Drugs interactions

Folic Acid

Caution should be exercised when administering folic acid to epileptics. It may cause reduction in the plasma concentrations of phenytoin, primidone, phenobarbital, sodium valproate, carbamazepine and the barbiturates. Trimethoprim or sulfonamides, alone or in combination as co-trimoxazole, may reduce the effect of folic acid and this may be serious in patients with megaloblastic anaemia. Sulphasalazine and triamterene can reduce the absorption of folic acid Folic acid may interfere with the toxic and therapeutic effects of methotrexate. Methotrexate and trimethoprim are specific antifolates and the folate deficiency caused by their prolonged use cannot be treated by Folic Acid. Folinic acid should be used. Folate supplements enhance the efficacy of lithium therapy. Nitrous oxide anaesthesia may cause an acute folic acid deficiency. Both ethanol and aspirin increase folic elimination. Concurrent administration with cholestyramine may interfere with folic acid absorption. Patients on prolonged cholestyramine therapy should take folic acid 1 hour before or 4 to 6 hours after receiving cholestyramine. Antibiotics may interfere with the microbiological assay for serum and erythrocyte folic acid concentrations and may cause falsely low results. Fluorouracil toxicity may occur in patients taking folic acid and this combination should be avoided. Edible clay or antacids containing aluminium or magnesium may reduce folic acid absorption. Patients should be advised to take antacids at least two hours after administration of folic acid. Folic acid may reduce intestinal absorption of zinc (of particular importance in pregnancy).

Levocarnitine

Reports of INR increase with the use of warfarin have been observed. It is recommended that INR levels be monitored in patients on warfarin therapy after the initiation of treatment with levocarnitine or after dose adjustments.

Vitamin D3

Thiazide diuretics reduce the urinary excretion of calcium. Due to the increased risk of hypercalcaemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics.

Concomitant use of phenytoin or barbiturates may reduce the effect of vitamin D since the metabolism increases.

Excessive dosing of vitamin D can induce hypercalcaemia, which may increase the risk of digitalis toxicity and serious arrhythimias due to the additive inotropic effects. The electrocardiogram (ECG) and serum calcium levels of patients should be closely monitored.

Glucocorticoid steroids may increase vitamin D metabolism and elimination. Simultaneous treatment with ion exchange resins such as cholestyramine or laxatives such as paraffin oil may reduce the gastrointestinal absorption of vitamin D.

4.6 Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Folic acid

Pregnancy

Folic acid deficiency during pregnancy may lead to the appearance of foetal malformations. Imbalance in folate requiring trophoblast cells may also lead to detachment of the placenta.

Very high doses of folic acid have been shown to cause foetal abnormalities in rats; however harmful effects in the human foetus, mother or the pregnancy have not been reported following ingestion of folic acid.

Breastfeeding

Folic acid is excreted in breast milk.

No adverse effects have been observed in breast-fed infants whose mothers were receiving folic acid.

L-Arginine

Pregnancy Category B

Reproduction studies have been performed in rabbits and mice at doses 12 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to R-Gene 10 (10% Arginine Hydrochloride Injection, USP). There have been no adequate or well-controlled studies for the use of R-Gene 10 in pregnant women.
Because animal reproduction studies are not always predictive of human response, this drug should not be used during pregnancy.

Nursing Mothers

It is not known whether intravenous administration of R-Gene 10 could result in significant quantities of arginine in breast milk. Systemically administered amino acids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when R-Gene 10 is to be administered to nursing women.

Geriatric Use

Clinical studies of arginine did not include a sufficient number of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

Levocarnitine

Pregnancy

Reproductive studies have been performed in rats and rabbits at doses up to 3.8 time the human dose on the basis of surface area and have revealed no evidence of impaired fertility or harm to the fetus due to CARNISURE LQ. There are, however, no adequate and well controlled studies in pregnant women.

Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers

Levocarnitine supplementation in nursing mothers has not been specifically studied.

Studies in dairy cows indicate that the concentration of levocarnitine in milk is increased following exogenous administration of levocarnitine. In nursing mothers receiving levocarnitine, any risks to the child of excess carnitine intake need to be weighed against the benefits of levocarnitine supplementation to the mother. Consideration may be given to discontinuation of nursing or of levocarnitine treatment.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Folic Acid

Folic acid is generally well tolerated although the following side effects have been reported**.**

Blood and lymphatic system disorders:

Folic acid may worsen the symptoms of co-existing vitamin B12 deficiency and should never be used to treat anaemia without a full investigation of the cause.

Immune system disorders:

Rare: Allergic reactions, comprising erythema, rash, pruritus, urticarial, dyspnoea, and anaphylactic reactions (including shock).

Gastrointestinal disorder:

Abdominal distension, flatulence, anorexia and nausea.

L-Arginine

Adverse reactions associated with 1670 infusions in premarketing studies were as follows:

Non-specific side effects consisting of nausea, vomiting, headache, flushing, numbness and local venous irritation were reported in approximately 3% of the patients.

One patient had an allergic reaction, which was manifested as a confluent macular rash with reddening and swelling of the hands and face. The rash subsided rapidly after the infusion was terminated and 50 mg of diphenhydramine were administered. One patient had an apparent decrease in platelet count from 150,000 to 60,000. One patient with a history of acrocyanosis had an exacerbation of this condition following infusion of RGene ® 10.

Post Marketing Experience: The following adverse events have been reported during post-marketing use: extravasation leading to burn-like reaction and/or skin necrosis requiring surgical intervention, hypersensitivity reactions including anaphylaxis, and hematuria that in some cases occurred 1-2 days after an R-Gene 10 administration. Because these adverse events

Levocarnitine

Clinical Trials Experience

Transient nausea and vomiting have been observed. Less frequent adverse reactions are body odor, nausea, and gastritis. An incidence for these reactions is difficult to estimate due to the confounding effects of the underlying pathology.

The table below lists the adverse events that have been reported in two double-blind, placebo-controlled trials in patients on chronic hemodialysis. Events occurring at ≥5% are reported without regard to causality.

Adverse Events with a Frequency ≥5% Regardless of Causality by Body System Placebo (n=63)

	Levocarnitine 10 mg (n=34)		***Levocarnitine 20 mg (n=62***	***Levocarnitine 40 mg (n=34)***	***Levocarnitine 10, 20 & 40 mg (n=130)***
Body as Whole					
Abdominal pain	17	21	5	6	9
Accidental injury	10	12	8	12	10
Allergic reaction	5	6			2
Asthenia	8	9	8	12	9
Back pain	10	9	8	6	8
Chest pain	14	6	15	12	12
Fever	5	6	5	12	7
Flu syndrome	40	15	27	29	25
Headache	16	12	37	3	22
Infection	17	15	10	24	15
Injection site reaction	59	38	27	38	33
Pain	49	21	32	35	30
Cardiovascular					
Arrhythmia	5	3		3	2
Atrial fibrillation			2	6	2
Cardiovascular disorder	6	3	5	6	5
Electrocardiogram abnormal		3		6	2
Hemorrhage	6	9	2	3	4
Hypertension	14	18	21	21	20
Hypotension	19	15	19	3	14
Palpitations		3	8		5
Tachycardia	5	6	5	9	6
Vascular disorder	2		2	6	2 a
Digestive					

Anorexia	3	3	5	6	5
Constipation	6	3	3	3	3
Diarrhea	19	9	10	35	16
Dyspepsia	10	9	6		5
Gastrointestinal disorder	2	3		6	2
Melena	3	6			2
Nausea	10	9	5	12	8
Stomach	5				
Vomiting	16	9	16	21	15
Endocrine System					
Parathyroid disorder	2	6	2	6	4
Hemic/Lymphatic					
Anemia	3	3	5	12	6
Metabolic/ Nutritional					
Hypercalcemia	3	15	8	6	9
Hyperkalemia	6	6	6	6	6
Hypervolemia	17	3	3	12	5
Peripheral edema	3	6	5	3	5
Weight decrease	3	3	8	3	5
Weight increase	2	3		6	2
Musculo-Skeletal					

Leg cramps	13		8		4
Myalgia	6				
Nervous					
Anxiety	5		2		1
Depression	3	6	5	6	5
Dizziness	11	18	10	15	13
Drug dependence	2	6			2
Hypertonia	5	3			1
Insomnia	3	3	3	12	5
Vertigo		6			2
Respiratory					
Bronchitis			5	3	3
Cough increase					
Dyspnea	19	3	11	3	7
Pharyngitis	33	24	27	15	23
Respiratory disorder	5				
Rhinitis	10	6	11	6	9

Sinusitis	5		2	3	2
Skin And Appendages					
Pruritus	13		8	3	5
Rash	3	5	3	3	3
Special Senses					
Amblyopia	2		6		3
Eye disorder	3	6	3		3
Taste perversion			2	9	3
Urogenital					
Urinary tract infect	6	3	3		2
Kidney failure	5	6	6	6	6

Postmarketing Experience

The following adverse reactions have been reported:

***Neurologic Reactions*:** Seizures have been reported to occur in patients, with or without preexisting seizure activity, receiving either oral or intravenous levocarnitine. In patients with preexisting seizure activity, an increase in seizure frequency and/or severity has been reported**.**

Hypersensitivity reactions: Anaphylaxis, laryngeal edema and bronchospasm (see WARNINGS)

Vitamin D3

Adverse reactions frequencies are defined as: uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1,000) or not known (cannot be estimated from the available data).

Immune system disorders

Not known (cannot be estimated from the available data): Hypersensitivity reactions such as angio-oedema or laryngeal oedema.

Metabolism and nutrition disorders

Uncommon: Hypercalcaemia and hypercalciuria.

Skin and subcutaneous disorders

Rare: Pruritus, rash and urticaria.

Reporting of suspected adverse reactions

Torrent Pharma available at: https://torrentpharma.com/index.php/site/info/adverse_event_reporting
By reporting side effects, you can help provide more information on the safety of this medicine.

4.9 Overdose

Vitamin D_3

Overdose can lead to hyper-vitaminosis D. An excess of vitamin D causes abnormally high levels of calcium in the blood, which can eventually severely damage the soft tissues, and kidneys. Tolerable Upper Intake Level for vitamin D (cholecalciferol) is set at 4000 IU (100 µg) per day. Vitamin D should not be confused with its active metabolites.

Symptoms of hypercalcaemia may include anorexia, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental disturbances, polydipsia, polyuria, bone pain, nephrocalcinosis, renal calculi and in severe cases, cardiac arrhythmias. Extreme hypercalcaemia may result in coma and death. Persistently high calcium levels may lead to irreversible renal damage and soft tissue calcification.

Treatment of hypercalcaemia: The treatment with vitamin D must be discontinued. Treatment with thiazide diuretics, lithium, vitamin A, and cardiac glycosides must also be discontinued. Rehydration, and, according to severity, isolated or combined. Treatment with loop diuretics, bisphosphonates, calcitonin and corticosteroids should be considered. Serum electrolytes, renal function and diuresis must be monitored. In severe cases, ECG and CVP should be followed.

Levocarnitine

There have been no reports of toxicity from levocarnitine overdosage. Levocarnitine is easily removed from plasma by dialysis. The intravenous LD50 of levocarnitine in rats is 5.4 g/kg and the oral LD50 of levocarnitine in mice is 19.2 g/kg. Large doses of levocarnitine may cause diarrhea.

L-Arginine

An overdosage may cause a transient metabolic acidosis with hyperventilation, which could lead to death (See "WARNINGS"). In most cases the acidosis will self- compensate and the base deficit will return to normal following completion of the infusion. If the condition persists, the deficit should be determined and corrected by a calculated dose of an alkalizing agent.

5 Pharmacological properties

5.1 Mechanism of Action

Vitamin D3

Vitamin D increases the intestinal absorption of calcium and phosphate.

Folic Acid

Folic acid is a member of the vitamin B group. Folic acid is reduced in the body to tetrahydrofolate, which is a co-enzyme for various metabolic processes including the synthesis of purine and pyrimidine nucleotides, and hence in the synthesis of DNA; it is involved in the formation and

utilisation of formate

Levocarnitine

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. 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.

5.2 Pharmacodynamic properties

Vitamin D3

Pharmacotherapeutic group: Vitamin supplements

ATC-code: A11C C05

Vitamin D increases the intestinal absorption of calcium and phosphate. Administration of vitamin D counteracts development of rickets in children and osteomalacia in adults. It also counteracts the increase of parathyroid hormone (PTH) which is caused by calcium deficiency and which causes increased bone resorption.

In addition to bone and intestinal mucosa, many other tissues have vitamin D receptors, to which the active hormonal form of vitamin D, calcitriol binds**.**

Folic Acid

ATC Code: B03B B01

Folic acid is a member of the vitamin B group. Folic acid is reduced in the body to tetrahydrofolate, which is a co-enzyme for various metabolic processes including the synthesis of purine and pyrimidine nucleotides, and hence in the synthesis of DNA; it is also involved in the formation and utilisation of formate.

Deficiency of folic acid leads to megaloblastic anaemia. Deficiency may result from a diminished intake, as in malnutrition, from malabsorption, or from the concomitant use of anticonvulsants or dihydrofolate reductase inhibitors such as pyrimethamine, trimethoprim, or methotrexate.

(Folic acid does not correct folate deficiency due to dihydrofolate reductase inhibitors; calcium folinate is used for this purpose).

5.3 Pharmacokinetic properties

Vitamin D3

Pharmacotherapeutic group: Vitamin supplements

ATC-code: A11C C05

Vitamin D increases the intestinal absorption of calcium and phosphate. Administration of vitamin D counteracts development of rickets in children and osteomalacia in adults. It also counteracts the increase of parathyroid hormone (PTH) which is caused by calcium deficiency and which causes increased bone Resorption. In addition to bone and intestinal mucosa, many other tissues have vitamin D receptors, to which the active hormonal form of vitamin D, calcitriol, binds.

Levocarnitine

In a relative bioavailability study in 15 healthy adult male volunteers, Levocarnitine were found

to be bio-equivalent to Levocarnitine Oral Solution. Following 4 days of dosing with 6 tablets of Levocarnitine 330 mg b.i.d. or 2 g of Levocarnitine oral solution b.i.d., the maximum plasma concentration (Cmax) was about 80 μmol/L and the time to maximum plasma concentration (Tmax) occurred at 3.3 hours. A two-compartment model described the plasma concentration profiles of levocarnitine after a slow 3-minute intravenous bolus dose of 20 mg/kg of Levocarnitine. Following a single i.v. administration, approximately 76% of the levocarnitine dose was excreted in the urine during the 0-24h interval. Using plasma concentrations uncorrected for endogenous levocarnitine, the mean distribution half-life was 0.585 hours and the mean apparent terminal elimination half-life was 17.4 hours.

The absolute bioavailability of levocarnitine from the two oral formulations of Levocarnitine, calculated after correction for circulating endogenous plasma concentrations of levocarnitine, was 15.1 ± 5.3% for Levocarnitine Tablets ± 4.9% for Levocarnitine Oral Solution.

Total body clearance of levocarnitine (Dose/AUC including endogenous baseline concentrations) was a mean of 4.00 L/h.

Levocarnitine was not bound to plasma protein or albumin when tested at any Human concentration or with any species including the human.

Metabolism and Excretion

In a pharmacokinetic study where five normal adult male volunteers received an oral dose of [H-methyl]-L-carnitine following 15 days of a high carnitine diet and additional carnitine supplement, 58 to 65% of the administered radioactive dose was recovered in the urine and feces in 5 to 11 days. Maximum concentration of [H-methyl]-L-carnitine in serum occurred from 2.0 to 4.5 hr after drug administration. Major metabolites found were trimethylamine N-oxide, primarily in urine (8% to 49% of the administered dose) and [H]-γ-butyrobetaine, primarily in feces (0.44% to 45% of the administered dose).
Urinary excretion of levocarnitine was about 4 to 8% of the dose. Fecal excretion of total carnitine was less than 1% of the administered dose.

After attainment of steady state following 4 days of oral administration of levocarnitine Tablets (1980 mg q12h) or Oral Solution (2000 mg q12h) to 15 healthy male volunteers, the mean urinary excretion of levocarnitine during a single dosing interval (12h) was about 9% of the orally administered dose (uncorrected for endogenous urinary excretion).

Folic acid

Folic acid is absorbed mainly from the proximal part of the small intestine. Dietary folates are stated to have about half the bioavailability of crystalline folic acid. Folate polyglutamates are considered to be deconjugated to monoglutamates during absorption.

Folic acid given therapeutically enters the portal circulation largely unchanged, since it is a poor substrate for reduction by dihydrofolate reductases.

Folic acid rapidly appears in the blood, where it is extensively bound to plasma proteins. The principal storage site of folate is in the liver; it is also actively concentrated in the CSF. The amounts of folic acid absorbed from normal diets are rapidly distributed in body tissues and about 4 to 5 ug is excreted in the urine daily.

There is an enterohepatic circulation for folate. When larger amounts are absorbed, a high proportion is metabolised in the liver to other active forms of folate and a proportion is stored as reduced and methylated folate. Larger amounts of folate are rapidly excreted in the urine. Folic acid is removed by haemodialysis. Folate is distributed into breast milk.

6. Nonclinical properties

Vitamin D3

At doses far higher than the human therapeutic range, teratogenicity has been observed in animal studies. There is no further information of relevance to the safety assessment in addition to what is stated in other parts of the SPC.

Levocarnitine

Carcinogenesis, Mutagenesis, Impairment of Fertility

Mutagenicity tests performed in *Salmonella typhimurium*, *Saccharomyces cerevisiae*, and *Schizosaccharomyces pombe* indicate that levocarnitine is not mutagenic. No long- term animal studies have been performed to evaluate the carcinogenic potential of levocarnitine.

Pregnancy

Reproductive studies have been performed in rats and rabbits at doses up to 3.8 times the human dose based on surface area and have revealed no evidence of impaired fertility or harm to the fetus due to Levocarnitine. There are, however, no adequate and well-controlled studies in pregnant women.

Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed

Toxicity studies in animals (rats and rabbits) have shown that massive doses (100mg/kg upwards) produce precipitation of folate crystals in renal tubules, particularly proximal tubules and ascending limb of the loop of Henle. Tubular necrosis is followed by recovery.

Folic Acid

Toxicity studies in animals (rats and rabbits) have shown that massive doses (100mg/kg upwards) produce precipitation of folate crystals in renal tubules, particularly proximal tubules and ascending limb of the loop of Henle. Tubular necrosis is followed by recovery.

7. Description

CARNISURE LQ

It contain L-Arginine, L-Carnitine L-Tartrate, Co-enzyme Q10, Lycopene, Folic Acid, Sodium Selenite, Zinc Sulphate, Vitamin D_3 and Cyanocobalamin Granules.

Ingredients : L-Arginine, Lactose, Bulking Agent (INS 421), Acidity Regulator (INS 330), L-Carnitine L-Tartrate, Anti-Caking Agent (INS 551), Sweetener (Aspartame), Nature Identical Flavouring Substances (Orange & Lemon), CO-enzyme Q10, Minerals (Zinc Sulphate, Sodium Selenite), Stabilizer (INS 1201), Lycopene, Vitamins (Cholecalciferol, Cyanocobalamin).

8. Pharmaceutical particulars

8.1 Incompatibilities

Not Applicable

8.2 Shelf-life

Do not use later than date of expiry.

8.3 Packaging information

CARNISURE LQ is available in 10 g Sachets.

8.4 Storage and handing instructions

STORE IN A COOL, DRY PLACE, AWAY FROM DIRECT SUNLIGHT.

- NOT FOR MEDICINAL USE
- Keep out of reach of children.

9. Patient Counselling Information

Package leaflet: Information for the user

CARNISURE LQ

L-Arginine, L-Carnitine L-Tartrate, Co-enzyme Q10, Lycopene, Folic Acid, Sodium Selenite, Zinc Sulphate, Vitamin D_3 and Cyanocobalamin Granules

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

9.1 What is CARNISURE LQ and what it is used for

Its contains combination of L-Arginine, L-Carnitine L-Tartrate, Co-enzyme Q10, Lycopene, Folic Acid, Sodium Selenite, Zinc Sulphate, Vitamin D_3 and Cyanocobalamin Granules. Folic acid is a member of the vitamin B complex that is needed for healthy red blood cells. They can also be used to prevent the long-term breakdown of red blood cells (in certain conditions) or in kidney dialysis. Vitamin D3, which regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue. Used to prevent and treat vitamin D3 deficiency in adults and adolescents. Your doctor may prescribe vitamin D3 as an adjunct to specific bone loss medication. Levocarnitine is a carrier molecule in the transport of long-chain fatty acids across the inner mitochondrial membrane.

9.2 What you need to know before you take CARNISURE LQ

Do not take CARNISURE LQ

You must not take CARNISURE LQ and should talk to your doctor immediately:

- If you have been told you suffer from Vitamin B12 deficiency including pernicious anaemia, or any other blood disorder.

- If you are sensitive/allergic to folic acid or any other ingredients in Sachets
- If you are suffering from cancer.
- If you have Addison's disease and low vitamin B12 levels in your body
- if you are allergic to colecalciferol or any of the other ingredients of this medicine.
- if you have hypercalcaemia (increased levels of calcium in the blood) or hypercalciuria (increased levels of calcium in the urine).
- if you have hypervitaminosis D (increased levels of vitamin D in the blood).
- if you have kidney stones. If any of the above applies to you, talk to your doctor or pharmacist before taking CARNISURE LQ.

Warnings and precautions

Talk to your doctor or pharmacist before taking CARNISURE LQ

- if you suffer from sarcoidosis (a special type of connective tissue disease that affects the lungs, skin and joints)
- when using other drugs containing vitamin D
- if you have kidney problems or have had kidney stones.

Pregnancy and breast-feeding:

If you are pregnant, planning to become pregnant or are breast feeding ask your doctor or pharmacist for advice before taking any medicine. Folic Acid can be used during pregnancy. Ask your doctor or pharmacist for advice if you are not sure. Important information about some of the ingredients of Folic Acid:

you have an intolerance to some sugars, contact your doctor before taking this medicine.

Taking other medicines:

Tell your doctor if:

- you are taking phenytoin or other drugs for epilepsy such as sodium valproate, carbamazepine or a barbiturate.
- you are taking lithium for mental health problems.
- you are taking aspirin for pain relief or to thin your blood.
- you are taking the antibiotic trimethoprim, chloramphenicol or co-trimoxazole.
- you are taking methotrexate (for rheumatoid arthritis or cancer).
- you are taking sulphasalazine (for bowel problems or rheumatoid arthritis).
- you are taking triamterene, a diuretic (or 'water tablet').
- you drink alcohol.

you need to breathe a gas and air mixture to put you to sleep for an operation or to relieve pain while you are awake. You should talk to your doctor if you are taking any of the above medicines. Please note that these statements may also apply to products used some time ago or at some time m in the future. Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicine – even those not prescribed.

CARNISURE LQ with food and drink

CARNISURE LQ can be taken with food.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. During pregnancy the daily intake should not exceed 600 IU vitamin D. CARNISURE LQ should only be used during pregnancy ifvitamin D deficiency has been clinically established. CARNISURE LQ can be used during breast-feeding. Vitamin D3 passes over into breast milk. This should be considered when giving additional vitamin D to the breast-fed child.

Driving and using machines

CARNISURE LQ has no known effects on ability to drive or use machines.

9.3 How to take CARNISURE LQ

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Your doctor will decide the right dose for you; this will be on the pharmacist's label. Check this carefully, it will tell you how much of this medicine to take and how often to take it.

Use in children

CARNISURE LQ is not intended for use in children under 12 years due to lack of study data.

If you take more CARNISURE LQ than you should:

If you have taken more of this medicine than directed, or if a child accidentally has taken this medicine, please contact your doctor or emergency unit for judgement of the risk and advice.

If you forget to take CARNISURE LQ

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you stop taking CARNISURE LQ

Talk to your doctor before you stop taking the Sachets and follow their advice as you may experience withdrawal symptoms.

9.4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. As can happen with any medicine, a few people may develop an allergic reaction (hypersensitivity) or a severe allergic reaction (anaphylactic reaction). If you experience any of the following, seek medical help immediately:

itchy/red skin, rash, swelling of the face, lips, tongue or throat or difficulty breathing or swallowing, shock (cold sweaty skin, weak pulse, dry mouth, dilated pupils; dizziness; weakness and/or fainting).

The side effects that some patients have had with Folic Acid are:

- Loss of appetite (anorexia)
- feeling sick
- bloating of the stomach
- Flatulence (wind)

- worsening of the symptoms of vitamin B12 deficiency. Folic acid should never be used to treat anaemia without a full investigation of the cause

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: https://torrentpharma.com/index.php/site/info/adverse_event_reporting
By reporting side effects, you can help provide more information on the safety of this medicine.

9.5 How to store CARNISURE LQ

STORE IN A COOL, DRY PLACE, AWAY FROM DIRECT SUNLIGHT.

9.6 Contents of the pack and other information

The active substance in CARNISURE LQ is L-Arginine, L-Carnitine L-Tartrate, Co-enzyme Q10, Lycopene, Folic Acid, Sodium Selenite, Zinc Sulphate, Vitamin D3 and Cyanocobalamin Granules respectively.

CARNISURE LQ

The ingredients used in formulation are L-Arginine, Lactose, Bulking Agent (INS 421), Acidity Regulator (INS 330), L-Carnitine L-Tartrate, Anti-Caking Agent (INS 551), Sweetener (Aspartame), Nature Identical Flavouring Substances (Orange & Lemon), Co-enzyme Q10, Minerals (Zinc Sulphate, Sodium Selenite), Stabilizer (INS 1201), Lycopene, Vitamins (Cholecalciferol, Cyanocobalamin).

CARNISURE LQ is available in 10 g Sachets.

10. Details of manufacturer

Manufactured by:

Zeon Lifesciences Limited, Healthcare-2,

Village Kunja, Rampur Road, Paonta Sahib – 173025, Sirmaur, (H.P), India.

11. Details of permission or license number with date

FSSAI licence no. 10013062000225 issued on 25.05.2021

12. Date of revision

NA

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/ CARNISURE LQ 10 g/JAN 22/01/PI