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(54) Titre : COMPOSITION DE POINTE A BASE DE VITAMINE C POSSEDANT DES CAPACITES AMELIOREES DE BIOTRANSFORMATION ET UTILISATION DE PROTEINES ET DE L-CARNITINE COMME ADDITIFS NUTRITIONNELS OU COMME SUBSTANCES DE MEME NATURE

(54) Title: ADVANCED VITAMIN C-BASED COMPOSITION WITH ENHANCED BIOTRANSFORMATION AND UTILIZATION OF PROTEIN AND L-CARNITINE FOR NUTRITIONAL SUPPLEMENTATION OR THE LIKE

(57) **Abrégé/Abstract:**

A nutritional supplement and a method of treatment using the same, the supplement comprising Vitamin C generally within a range of 250 milligrams and 5000 milligrams, in mixture, with L-Carnitine generally within a range of 100 milligrams and 5000 milligrams, and/or one or more Proteins comprising essential amino acids generally within a range of 1 gram and 150 grams.



**ABSTRACT OF THE DISCLOSURE**

A nutritional supplement and a method of treatment using the same, the supplement comprising Vitamin C generally within a range of 250 milligrams and 5000 milligrams, in mixture, with L-Carnitine generally within a range of 100  
5 milligrams and 5000 milligrams, and/or one or more Proteins comprising essential amino acids generally within a range of 1 gram and 150 grams.

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**ADVANCED VITAMIN C-BASED COMPOSITION WITH ENHANCED  
BIOTRANSFORMATION AND UTILIZATION OF PROTEIN AND  
L-CARNITINE FOR NUTRITIONAL SUPPLEMENTATION OR THE LIKE**

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By

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This Application is based on U.S. Provisional Application Serial No. 60/578,765, filed on June 9, 2004, the disclosure of which is incorporated by reference herein in its entirety.

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### **FIELD OF THE INVENTION**

The present invention relates generally to healthcare products and, more particularly, to an improved nutritional supplement and method of using the same.

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### **BACKGROUND OF THE INVENTION**

Conventional nutritional supplements usually comprise a mixture of vitamins and minerals in dosages set according to USDA minimum daily nutritional requirements. While these supplements may be suitable for some, what is often necessary for providing adequate nutrition and concomitant energy boost typically varies from one person to the next, and depends on their body mass, age, biochemical makeup and other considerations. These considerations have, in turn, prompted the development of a plethora of vitamin and nutritional concoctions that not only provide much needed vitamins and minerals, but also Proteins and other constituents intended to enhance health and generally make the user feel "good". Again, however, while useful for some, others need more, or in some cases less, of the particular ingredients, the ingestion of which, at a minimum, may be unnecessary.

Of particular concern has been the general health and nutritional needs of patients during hospitalization, after surgery and/or during relatively long periods of bed rest, as well as people generally in their later years of life. Patients, for instance, have not only been found to experience considerably lower energy levels and general fatigue, but are also known to lose considerable muscle tone during bed rest and to suffer other health detriments characteristic of long periods of inactivity or diminished activity.

Accordingly, a nutritional supplement is desired having key ingredients that are not only readily available, affordable, and manufacturable, but are also provided in concentrations that are highly effective for improving the overall health, comfort, vitality, well being, strength and stamina of individuals in need of key nutritional supplements. Such supplement would be particularly desirable for administration to persons including, but not limited to: (i) older individuals; (ii) individuals having no

or relatively low levels of activity, such as patients under treatment in hospitals and/or other healthcare institutions, or under medical supervision and/or outpatient care; (iii) individuals in need of nutritional supplementation, such as athletes and pregnant women; and (iv) patients suffering from wounds and/or diseases, including kidney failure.

Also desirable is a nutritional supplement that is relatively easy to administer and eliminates the ingestion of unnecessary vitamins and minerals as well as other substances and additives characteristic of conventional nutritional supplements.

### **OBJECTS AND SUMMARY OF THE INVENTION**

According to one aspect of the present invention, a nutritional supplement is provided which comprises a selected source of Vitamin C, in mixture, with (i) a selected Protein source comprising essential amino acids, or (ii) a selected source of L-Carnitine, or (iii) a mixture of (i) and (ii).

According to another aspect of the present invention, a nutritional supplement is provided which comprises at least a selected source of Vitamin C in mixture with a selected source of Protein.

In accordance with a further aspect of the present invention, a nutritional supplement is provided which comprises at least a selected source of Vitamin C in mixture with a selected source of L-Carnitine.

According to yet another aspect of the present invention, a nutritional supplement is provided which comprises Vitamin C, in mixture, with (i) Hydrolyzed Collagen Protein, or (ii) L-Carnitine, or (iii) a mixture of (i) and (ii).

In accordance with another aspect of the present invention, a nutritional supplement is provided which comprises at least Vitamin C in mixture with Hydrolyzed Collagen Protein.

According to still another aspect of the present invention, a nutritional supplement is provided which comprises at least Vitamin C in mixture with L-Carnitine.

In accordance with a further aspect of the present invention, a nutritional supplement is provided which comprises Vitamin C generally within a range of 100 milligrams and 5000 milligrams, in mixture, with:

(i) a selected Protein source having essential amino acids generally within a range of 1 gram and 150 grams; or

(ii) L-Carnitine generally within a range of 100 milligrams and 5000 milligrams; or

(iii) a mixture of (i) and (ii).

Another aspect of the present invention relates to a nutritional supplement  
5 which comprises Vitamin C, or a source thereof, generally within a range of 250 milligrams and 5000 milligrams, in mixture, with:

(i) a selected Protein source having essential amino acids generally within a range of 1 gram and 150 grams; or

(ii) L-Carnitine, or a source thereof, generally within a range of 100  
10 milligrams and 5000 milligrams; or

(iii) a mixture of (i) and (ii).

According to still a further aspect of the present invention, a nutritional supplement is provided which comprises Vitamin C generally within a range of 250 milligrams and 1500 milligrams, in mixture, with:

(i) Hydrolyzed Collagen Protein generally within a range of 7.5 grams and 45  
15 grams; or

(ii) L-Carnitine generally within a range of 500 milligrams and 3000 milligrams; or

(iii) a mixture of (i) and (ii).

20 In accordance with a yet another aspect of the present invention, a nutritional supplement is provided which comprises, in an aqueous-based mixture, a selected source of Vitamin C with (i) one or more selected Protein sources having essential amino acids, or (ii) a selected source of L-Carnitine, or (iii) a mixture of (i) and (ii).

According to another aspect of the present invention, a nutritional supplement  
25 is provided which comprises, in a non-aqueous-based mixture, a selected source of Vitamin C with (i) one or more selected Protein sources having essential amino acids, or (ii) a selected source of L-Carnitine, or (iii) a mixture of (i) and (ii).

In accordance with a further aspect of the present invention, a nutritional supplement is provided, in tablet form, which comprises a selected source of Vitamin  
30 C and (i) a selected source of L-Carnitine, and/or (ii) one or more selected Protein sources having essential amino acids.

According to still another aspect of the present invention is a nutritional supplement, in gel capsule form, which comprises a selected source of Vitamin C and

(i) a selected source of L-Carnitine, and/or (ii) one or more selected Protein sources having essential amino acids.

In accordance with a yet another aspect of the present invention, a nutritional supplement is provided which comprises, in a skin patch, a selected source of Vitamin C and (i) a selected source of L-Carnitine, and/or (ii) one or more selected Protein sources having essential amino acids.

According to a further aspect of the present invention, a nutritional supplement is provided which comprises, in a powder for reconstitution, a selected source of Vitamin C and (i) a selected source of L-Carnitine, and/or (ii) one or more selected Protein sources having essential amino acids.

According to another aspect of the present invention, a nutritional supplement is provided which comprises, in a nutritional bar or other food, a selected source of Vitamin C and (i) a selected source of L-Carnitine, and/or (ii) one or more selected Protein sources having essential amino acids.

According to still another aspect of the present invention, a nutritional supplement is provided which comprises, in mixture, Vitamin C and soy protein and/or L-Carnitine.

In accordance with yet another aspect of the present invention, a nutritional supplement is provided which comprises, in mixture, Vitamin C and L-Carnitine and/or a selected Protein source having essential amino acids.

According to yet a further aspect of the present invention, there is provided a method of treatment of a patient through administration of a nutritional supplement which comprises at least about 250 milligrams of Vitamin C, in mixture, with (i) a selected source of L-Carnitine, and/or (ii) a selected Protein source comprising essential amino acids.

According to still a further aspect of the present invention is a method of treatment using a nutritional supplement. The method comprises the steps of dispensing to a patient a dose, e.g., daily, of between about 15 and about 60 milliliters of an aqueous-based liquid containing dissolved concentrations of between about 250 milligrams and about 5000 milligrams of Vitamin C and (i) between about 100 and about 5000 milligrams of L-Carnitine, and/or (ii) between about 1 gram and about 150 grams of a Hydrolyzed Collagen Protein.

In accordance with a further aspect of the present invention is a method of treatment using a nutritional supplement. The method comprises the steps of

dispensing to a patient a dose, e.g., daily, of between about 15 and about 90 milliliters of an aqueous-based liquid containing dissolved concentrations of between about 250 milligrams and about 5000 milligrams of Vitamin C and (i) between about 100 and about 5000 milligrams of L-Carnitine, and/or (ii) between about 1 gram and about 150 grams of a Hydrolyzed Collagen Protein.

Yet another aspect of the present invention is a method of treatment using a nutritional supplement, the method comprising the step of dispensing to a patient a dose, e.g., daily, of between about 15 and about 60 milliliters of a non-aqueous-based liquid containing dissolved concentrations of between about 250 milligrams and about 5000 milligrams of Vitamin C and (i) between about 100 and about 5000 milligrams of L-Carnitine, and/or (ii) between about 1 gram and about 150 grams of a Hydrolyzed Collagen Protein.

Still another aspect of the present invention is a method of treatment using a nutritional supplement, the method comprising the step of dispensing to a patient a dose, e.g., daily, of between about 15 and about 90 milliliters of a non-aqueous-based liquid containing dissolved concentrations of between about 250 milligrams and about 5000 milligrams of Vitamin C and (i) between about 100 and about 5000 milligrams of L-Carnitine, and/or (ii) between about 1 gram and about 150 grams of a Hydrolyzed Collagen Protein.

A further aspect of the present invention concerns a method of treatment using a nutritional supplement, the method comprising the step of dispensing to a patient, in tablet form, a dose, e.g., daily, of the supplement including between about 250 milligrams and about 5000 milligrams of Vitamin C and (i) between about 100 and about 5000 milligrams of L-Carnitine, and/or (ii) between about 1 gram and about 150 grams of a Hydrolyzed Collagen Protein.

In accordance with still another aspect of the present invention is a method of treatment using a nutritional supplement, the method comprising the step of dispensing to a patient, in gel capsule form, a dose, e.g., daily, of the supplement including between about 250 milligrams and about 5000 milligrams of Vitamin C and (i) between about 100 and about 5000 milligrams of L-Carnitine, and/or (ii) between about 1 gram and about 150 grams of a Hydrolyzed Collagen Protein.

An additional aspect of the present invention relates to a method of treatment using a nutritional supplement, the method comprising the step of dispensing to a patient, in skin patch form, a dose, e.g., daily, of the supplement including between

about 250 milligrams and about 5000 milligrams of Vitamin C and (i) between about 100 and about 5000 milligrams of L-Carnitine, and/or (ii) between about 1 gram and about 150 grams of a Hydrolyzed Collagen Protein.

5 Still a further aspect of the present invention relates to a method of treatment using a nutritional supplement, the method comprising the step of dispensing to a patient, in a powder for reconstitution, a dose, e.g., daily, of the supplement including between about 250 milligrams and about 5000 milligrams of Vitamin C and (i) between about 100 and about 5000 milligrams of L-Carnitine, and/or (ii) between about 1 gram and about 150 grams of a Hydrolyzed Collagen Protein.

10 A supplemental aspect of the present invention is directed to a method of treatment using a nutritional supplement, the method comprising the step of dispensing to a patient, in a nutritional bar or other food, a dose, e.g., daily, of the supplement including between about 250 milligrams and about 5000 milligrams of Vitamin C and (i) between about 100 and about 5000 milligrams of L-Carnitine, and/or (ii) between about 1 gram and about 150 grams of a Hydrolyzed Collagen Protein.

20 Yet a further aspect of the present invention relates to a nutritional supplement and method of treatment using the same, the supplement comprising Vitamin C, in mixture, with L-Carnitine and/or one or more selected proteins in selected proportions so as to provide a synergistic effect and, thereby, optimize their biotransformation and utilization in the body.

25 Accordingly, it is an object of the present invention to provide a nutritional supplement that is highly effective for improving the overall health, comfort, vitality and well being of patients under treatment in hospitals and others in need of nutritional aid.

Another object of the present invention is to accommodate the general health and nutritional needs of patients during hospitalization, after surgery and/or during relatively long periods of bed rest.

30 A further object of the present invention is to provide a nutritional supplement particularly well suited for people generally in their later years of life.

Still another object of the present invention is to provide a nutritional supplement that is not only suitable for health maintenance of athletes, but is also appropriate for pregnant women as well as highly active professionals in need of additional nutrition.

Yet another object of the present invention is to counteract the considerably lower energy levels and fatigue suffered by patients during hospitalization.

Still a further object of the present invention is to provide a nutritional supplement that maintains and improves muscle tone and prevents numerous health  
5 detriments characteristic of long periods of inactivity or diminished activity.

Another object of the present invention is to provide a nutritional supplement having only those ingredients essential for improving overall health, comfort, vitality, well being, strength and stamina.

Still another object of the present invention is to provide a nutritional  
10 supplement for general wellness that eliminates unnecessary vitamins and minerals as well as other substances and additives characteristic of conventional supplements.

Yet another object of the present invention is to provide a nutritional supplement having only ingredients considered necessary for improving overall health, comfort, vitality, well being, strength and stamina of a patient and only in  
15 those concentrations suitable for providing such effects over a wide range of individuals.

Still a further object of the present invention is to provide a novel nutritional supplement having a minimal number of ingredients that are not only readily available and affordable, but also economical to manufacture in forms that are convenient to  
20 administer and effective for nutritional absorption.

Another object of the present invention is to provide an enhanced nutritional supplement and method of treatment using the same that is efficient, effective and economical.

A further object of the present invention is to provide a novel nutritional  
25 supplement in liquid form comprising a mixture of Hydrolyzed Collagen Protein or other Protein source having essential amino acids, L-Carnitine, and Vitamin C for improving the overall health, comfort, vitality, well being, strength and stamina of a patient.

Yet a further object of the present invention is to provide a novel nutritional  
30 supplement in tablet or gel capsule form comprising a mixture of Hydrolyzed Collagen Protein or other Protein source having essential amino acids, L-Carnitine, and Vitamin C for improving the overall health, comfort, vitality, well being, strength and stamina of a patient.

Another object of the present invention is to provide a novel nutritional supplement in a skin patch, a powder for reconstitution, nutritional bar or other food comprising a mixture of Hydrolyzed Collagen Protein or other Protein source having essential amino acids, L-Carnitine, and Vitamin C for improving the overall health, comfort, vitality, well being, strength and stamina of a patient.

Yet another object of the present invention is to provide a nutritional supplement for preventing and/or countering the effects of Alzheimer's Disease, Chronic Fatigue Syndrome (CFS), Chronic Kidney Disease, Chronic Muscle Myopathy, Connective Tissue Diseases, Diabetes Mellitus, Dialysis, Dieting, Epilepsy, Heart Diseases, Immune Deficiency, Muscle Atrophy, Old Age, Renal Insufficiency and Stroke.

Another object of the present invention is to lower healthcare costs by improving patient care, decreasing the length of stay of patients in the hospital, allocation of nursing hours as well as the rate of re-hospitalization, decreasing the duration of ventilator dependence and the need for physical therapy, lessening the use of curative medications, such as antibiotics, and the use of dressing and skin care products for wound healing, and, thereby, lowering healthcare costs.

Still other objects and advantages of the present invention will become apparent from the following description of the preferred embodiments.

### **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

One of the most important nutrients for maintaining good health and vitality is Protein. Proteins are a primary requirement for growth and development of all body tissues. They are also essential for healthy brain tissue, hair, skin and nails. Although critical, Proteins are not normally consumed for energy by the human body when adequate levels of fats and carbohydrates are present.

Proteins are relatively large complex molecules that must be broken down into individual components, commonly known as peptides and amino acids, before they can be absorbed and utilized by the body. This process typically occurs in the digestive tract and is the result of a certain enzyme action referred to as hydrolysis. Put another way, Proteins are "hydrolyzed" during digestion into their components, namely, peptides and amino acids.

Notably, when the body breaks down Protein, waste products are produced that build up in the blood and become harmful. Healthy kidneys or an artificial

kidney, as in kidney dialysis, draw these wastes out of the body to prevent serious medical complications.

However, without adequate dietary Proteins, the human body cannot produce sufficient antibodies to defend itself against disease organisms, thereby lowering the body's overall resistance to disease and increasing chances for infection. In addition, absent sufficient Proteins, the liver cannot manufacture enough plasma Proteins to maintain a requisite fluid balance in the blood and tissues. Muscle breakdown and weakness are also known to occur. Proper Protein intake and nutrition are, therefore, important both to the quality and length of life.

In addition, it has been found, there are long-term consequences of Protein deficiency on patient care, including: increased duration of hospitalization, especially in intensive care units, as well as increased rate of re-hospitalization; increased length of ventilator dependence, need for physical therapy and allocation of nursing hours; and increased consumption of curative medications, such as antibiotics, and use of dressing and skin care products for wound healing. The net result has been increased healthcare costs.

As for sources of Protein, while the nature of the Protein source may not be critical, it is considered important that essential amino acids be provided. Such amino acids include, but are not limited to, L-arginine, L-histidine, L-isoleucine, L-leucine, L-lysine, L-methionine, L-phenylalanine, L-threonine, L-valine and mixtures thereof. Such Protein source may comprise, for example, soy protein.

Of particular interest as a Protein source is Hydrolyzed Collagen Protein. Hydrolyzed Collagen Protein is a type of Protein found in virtually all organs of the body, it being the most prevalent Protein in the human body. Predominantly, it is found in the skin, nails, ligaments and bones. Hydrolyzed Collagen Protein is essentially a connective tissue substance. In other words, it is the "cement" that holds everything together. Hydrolyzed Collagen Protein, along with Elastin, are considered the key structural components of bones, cartilage, tendons, skin, lung tissue and blood vessels. Specifically, Hydrolyzed Collagen Protein provides the structure and firmness to body tissues, whereas Elastin is largely responsible for their flexibility.

Hydrolyzed Collagen Protein has many known benefits such as aiding the formation and maintenance of bones, skin and cartilage, and maintenance of healthy joints and tendons. Another advantage is that it assists in tissue repair following

injury and facilitates healing wounds. It is also useful for muscle spasticity problems and is considered extremely important in brain metabolism.

Another important nutrient is L-Carnitine. While found naturally in the body in relatively small quantities, L-Carnitine is a vitamin-like nutrient which maintains  
5 normal life functions including energy production and the metabolism of fat. It is also known for supporting healing of many health disorders and generally improving the quality of life.

Since the cardiac muscle derives its energy primarily through oxidation of fatty acids, L-Carnitine is particularly important for nourishment of the heart. In fact,  
10 L-Carnitine supplements have been shown to strengthen the heart and increase cardiac output. In addition, L-Carnitine has been shown to increase muscle tissue strength and endurance. It is also well regarded not only for enhancing liver function including improvement of the liver's fat burning process, but also for increasing Protein synthesis. L-Carnitine has even been shown to slow the aging process and to  
15 improve cognitive abilities such as concentration, memory and the ability to learn.

Consequences of L-Carnitine deficiency include hepatic enzyme derangement and increased risk of fatty liver, severe hypoglycemia, weakness, and risk of electrolyte imbalances, and hypertriglyceridemia including a risk of severe acute pancreatitis.

20 Turning now to perhaps the best known nutritional supplement, Vitamin C is uniquely important to the health and well-being of humans. It plays a key role as a component of enzymes involved in the natural synthesis of collagen and L-Carnitine in the body. Possibly the most important role of Vitamin C is in the maintenance of a healthy immune system. Specifically, Vitamin C stimulates the immune system and  
25 protects against damage by free radicals released by the body in its fight against infection. Medical research has shown that people who suffer from asthma, arthritis, cancer, diabetes, and heart disease have much lower levels of Vitamin C in their blood than do healthy people. It has also been determined that Vitamin C supplements significantly lower the risk of cataracts and glaucoma.

30 Vitamin C deficiency, in turn, results in increased risk of skin breakdown, prolonged wound healing time, decreased response to and, hence, prolonged duration of infection, iron-deficiency anemia, bleeding gums and other dental problems.

It has been found that Vitamin C also plays a key role as a component of enzymes involved in the biosynthesis and utilization of both collagen and L-Carnitine

in the body. When small amounts of carnitine and/or Protein are ingested, some utilization of these materials takes place in the body. However, when large amounts of carnitine and/or Protein are ingested without Vitamin C or in the presence of low levels of Vitamin C, much of the carnitine and/or Protein are not utilized by the body and are wasted. For example, it is known that in the absence of Vitamin C supplementation, there are instances wherein proper collagen fibers are not formed in the body. This may account for the varying clinical results in human clinical trials for these materials as reported in the literature. However, it has surprisingly been found that when relatively large amounts of carnitine and/or Protein are ingested in the presence of sufficient amounts of Vitamin C, the body is able to efficiently convert the carnitine and/or Protein through its collagen and/or carnitine building enzyme systems into many compounds/compositions useful in the body. Furthermore, in addition to its role in potentiating the biotransformation of Protein and/or carnitine, Vitamin C potentiates the bioabsorption of Protein and/or carnitine.

The foregoing description is provided for purposes of illustration and not to limit the intended content or application of the present invention. The remaining aspects of the structure, function and chemistry of the foregoing are considered known by those skilled in the art and further description is considered unnecessary for illustration of the present invention.

Referring now to the present invention with greater particularity including, but not limited to, its constituents, dosages, manner of use and/or treatment, a nutritional supplement is provided having, according to one embodiment of the present invention, enhanced Vitamin C fortified with Hydrolyzed Collagen Protein (or Protein Hydrolysate) and/or L-Carnitine for nutritional supplementation. At the kernel of the present invention is a relatively high concentration of Vitamin C formulated with essential amino acids and/or L-Carnitine so as to optimize the uptake of Vitamin C, L-Carnitine and Protein by the body. Generally speaking, Vitamin C is considered to be an essential constituent of the present invention.

In one embodiment, a nutritional supplement is provided which comprises, preferably in an aqueous-based mixture, Vitamin C or a selected source of Vitamin C generally within a range of 250 milligrams and 1500 milligrams and (i) a selected source of L-Carnitine generally within a range of 500 milligrams and 3000 milligrams, and/or (ii) a selected source of Protein(s) having essential amino acids, such source containing Proteins generally within a range of 7.5 grams and 45.0 grams.

Suitable sources of Vitamin C that have been found acceptable include, but are not limited to, Ascorbic Acid, Sodium Ascorbate, Calcium Ascorbate, as well as any salt or ester of Ascorbic Acid. Sources of L-Carnitine, for example, include, but are not limited to, L- Acetyl L-Carnitine, L-Carnitine Fumarate, L-Carnitine L-Tartrate, **5** L-Carnitine HCL, and/or any salt or ester of L-Carnitine and mixtures thereof. Of particular interest and preferred, according to various aspects of the present invention, is the use of Hydrolyzed Collagen Protein.

In general, the composition preferably contains Vitamin C, for example, in bulk powder form as sold by Royal DSM N.V., in sufficient quantities such that **10** daily dose of the composition contains at least about 250 milligrams of Vitamin C. Alternatively or concurrently, the composition contains between about 250 and about 5000 milligrams of Vitamin C. According to another embodiment, the composition of the present invention contains Vitamin C in quantities generally within a range of 250 and 3000 milligrams. It has been found that a daily dose containing between about **15** 250 and about 1500 milligrams of Vitamin C is optimal.

In accordance with various aspects of the present invention, namely, when the composition contains L- Carnitine, or a source thereof, e.g., sold by Lonza Group Ltd. under the trade name Carnipure, in sufficient quantities such that a daily dose of the composition contains between about 100 and about 5000 milligrams of L-Carnitine. **20** According to another embodiment, the composition of the present invention contains L-Carnitine or a source thereof in quantities generally within a range of 250 and 4000 milligrams. It is believed especially desirable that the daily dose contain between about 500 and about 3000 milligrams of L-Carnitine.

Alternatively or concurrently, when a Protein source is present, for instance, **25** Hydrolyzed Collagen Protein distributed by P.B. Leiner under the Polypro label, it is preferred that such source be in sufficient quantities that a daily dose of the composition, according to the present invention, will contain between about 1 gram and about 150 grams of Protein. In another embodiment of the present invention, the composition contains a Protein source in sufficient quantities such that a daily dose of **30** the composition contains between about 5 and about 100 grams of Protein. It is considered particularly desirable that such daily dose contain generally within a range of 7.5 and 45 grams of Protein.

It is preferred that compositions, in accordance with the present invention, be consumed by a patient in sufficient quantities and at such concentration that the patient's intake of the operative constituents are as follows:

5                    Vitamin C:    about 250 to about 5000 milligrams,  
                      L-Carnitine: about 100 to about 5000 milligrams, and  
                      Protein:     about 1 to about 150 grams;

or

10                   Vitamin C:    about 250 to about 5000 milligrams, and  
                      L-Carnitine: about 100 to about 5000 milligrams;

or

15                   Vitamin C:    about 250 to about 5000 milligrams, and  
                      Protein:     about 1 to about 150 grams.

In liquid form, desirable concentrations of the composition are such that daily dosages could be administered through ingestion of between about 1 and about 6 tablespoons of such composition daily. While the present invention is described with reference to 20 such selected dosages in tablespoons, it is understood that any number of tablespoon dosages may be utilized, giving consideration to the purpose for which the present invention is intended.

The present invention may be dispensed, as is, in conventional tablet or gel 25 capsule form, in food or a nutritional bar, or may be readily mixed with water or other aqueous-based liquids (e.g., orange juice, grape fruit juice, grape juice, etc.). For instance, in the case of a nutritional bar, a specific, illustrative disclosure of food of this type is provided in U.S. Patent No. 6,143,335, entitled SOLID NUTRITIONAL FOODS AND METHODS OF MAKING THE SAME, which issued on November 7, 30 2000 to Russell G. McKenzie. Alternatively, the composition according to the present invention may be mixed with non-aqueous-based liquids or dispensed in a conventional skin patch form in generally lower concentrations, as will be appreciated by those skilled in the art of skin patches. A nutritional type skin patch of this general description may be found, for example, in U.S. Patent No. 6,893,656, entitled 35 ATHLETIC PATCH, which issued on May 15, 2005 to Andrew Blitzer and Terry Pretorius, the disclosure of which is incorporated by reference herein in its entirety. Further in the alternative or concurrently therewith, the composition of the present

invention is distributed, for instance, in an eight (8) fluid ounce container (236.5 milliliters), containing approximately 16 tablespoonful doses of premixed liquid.

A further benefit of the present invention is its relatively mild taste. This makes it readily usable with conventional flavorings such as a pleasant tasting orange  
 5 flavor or the like. Its mild taste also makes it highly versatile for addition to non-citrus beverages, soups, gravies, sauces and other regular menu items to increase Protein intake when such foods can be consumed. Similarly, it is considered suitable for use in electrolyte restricted diets and does not contain sugar, fats, carbohydrates, lactose, gluten, yeast, corn, wheat starch, eggs, fish or dairy.

10

#### EXAMPLE I

A nutritional supplement formulation is provided in an aqueous-based mixture, the supplement comprising up to about 7.5 grams of Hydrolyzed Collagen Protein (Polypro), about 500 milligrams of L-Carnitine (Carnipure) and about 250  
 15 milligrams of Vitamin C (in bulk powder form) in a total volume of about 15 milliliters. The supplement is dispensed in liquid form, in a dosage of one (1) or more tablespoons (or about a 15 milliliter equivalent or more) per day. Each liquid tablespoon provides the following essential amino acids in the approximate amounts expressed in milligrams available:

20	L-Arginine	615
	L-Histidine	77
	L-Isoleucine	112
	L-Leucine	233
	L-Lysine	315
25	L-Methionine	122
	L-Phenylalanine	148
	L-Threonine	151
	L-Valine	175

30

#### EXAMPLE II

A nutritional supplement formulation is provided in an aqueous-based mixture, the supplement comprising about 15 grams of Hydrolyzed Collagen Protein, about 1000 milligrams of L-Carnitine and about 500 milligrams of Vitamin C. The supplement is dispensed in liquid form, two (2) tablespoons (or about a 30 milliliter  
 35 equivalent) per day. Each liquid tablespoon provides the following essential amino acids (approximately in milligrams):

L-Arginine	1230
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**16**

	L-Histidine	155
	L-Isoleucine	224
	L-Leucine	466
<b>5</b>	L-Lysine	630
	L-Methionine	244
	L-Phenylalanine	296
	L-Threonine	302
	L-Valine	350

**10****EXAMPLE III**

A nutritional supplement formulation is provided in an aqueous-based mixture. The supplement comprises about 30 grams of Hydrolyzed Collagen Protein, about 2000 milligrams of L-Carnitine and about 1000 milligrams of Vitamin C. The supplement is dispensed in liquid form, four (4) tablespoons (or about a 60 milliliter equivalent) per day. Each liquid tablespoon provides the following amino acids (approximately in milligrams):

	L-Arginine	2460
	L-Histidine	310
	L-Isoleucine	448
<b>20</b>	L-Leucine	932
	L-Lysine	1260
	L-Methionine	488
	L-Phenylalanine	592
	L-Threonine	604
<b>25</b>	L-Valine	700

**EXAMPLE IV**

A nutritional supplement formulation comprising, in an aqueous-based mixture, about 45 grams of Hydrolyzed Collagen Protein, about 3000 milligrams of L-Carnitine and about 1500 milligrams of Vitamin C. The supplement is dispensed to a patient in liquid form, six (6) tablespoons (or about a 90 milliliter equivalent) per day. Each liquid tablespoon provides the following amino acids:

	L-Arginine	3700
<b>35</b>	L-Histidine	470
	L-Isoleucine	670
	L-Leucine	1400
	L-Lysine	1890
	L-Methionine	730
<b>40</b>	L-Phenylalanine	890
	L-Threonine	910
	L-Valine	1050

Although the present invention has been shown and described in connection with a particular carrier for treatment, i.e., in an aqueous-based mixture, it is understood that the composition may be in other forms, whether in a non-aqueous-based mixture, in tablet form, in gel capsule form, in a fluid, or other conventional and non-conventional method of administration, as is practicable, giving consideration to the purpose for which the present invention is intended.

In addition, while the present invention is disclosed with reference to particular ranges of constituents, it will be appreciated that other suitable ranges of ingredients may be utilized, giving consideration to the purpose for which the present invention is intended. For example, although the invention is described as containing constituents in relatively high potency levels such as Vitamin C generally within a range of 250 milligrams and 5000 milligrams, other suitable ranges, e.g., between about 100 milligrams and about 1000 milligrams of Vitamin C, may also be used, within the spirit and scope of the present invention.

By one embodiment, the present invention is provided as a powder for reconstitution prior to administration. For instance, the three active ingredients, i.e., Protein, L-Carnitine and Vitamin C, are prepared in powder form and blended generally uniformly with selected natural or synthetic conventional flavoring(s) and a conventional sweetener, e.g., non-caloric, also in powder form. The resulting uniform powder mix is then packaged in a canister or conventional foil or foil laminate packet and sealed. The packet preferably contains product information, batch number information, and the expiration date of the powder.

In use, a patient or healthcare professional simply tears the packet open, adds the powder contents to an appropriate liquid (e.g., water, juice, milk or the like), stirs the same to a uniform blend, and then drinks (or otherwise administers) the liquid. Alternatively, such as in the case when the patient is unable to feed himself or herself, an appropriate conventional liquid carrier containing the active ingredients of the present invention is used as a transfer medium to be dispensed to the patient through a suitable feeding tube.

According to one aspect of the present invention, the nutritional supplement described is particularly useful for providing extra Protein to persons having increased Protein needs or for patients who are unable to meet their daily Protein needs with a normal diet. Such patients include those requiring pre- or post-operative Protein

supplementation or nutritional support during cancer therapy; those suffering from chronic kidney disease, in severe burn conditions, and those patients requiring increased Protein due to excessive Protein loss such as in stress and trauma conditions.

5 More particularly, patients suffering from chronic kidney disease with renal insufficiency have higher needs for increased Protein, L-Carnitine and Vitamin C intake. Unfortunately, when there are increased requirements for Proteins, L-Carnitine and Vitamin C, their customary supply through normal dietary intake, it has been found, is not necessarily sufficient in such extreme conditions. In addition,  
10 during altered state conditions, the human body's synthesis process for Proteins and L-Carnitine often does not deliver the requisite synthesized amounts to guarantee the levels required for maintaining vitality.

The ingredients of the present invention have been proven clinically to rejuvenate muscles using the synergy from nutrients known to enhance cell function.  
15 Each nutrient enhances a different aspect of cell function and, together, they support muscle, not fat. In this manner, the patient's body receives the "energy" edge it needs without side effects. It also provides the nutritional building blocks a patient needs to fight muscle loss and build a more muscular body.

Accordingly, the present invention is an ideal nutritional supplement to oral  
20 and tube-fed enteral administered products for patients that require Protein supplementation for a particular clinical condition. It is also useful generally as a highly effective first line of defense or as a support to other therapies as a first step in wellness.

Overall, the present invention advantageously provides concentrated Protein  
25 supplementation in a unique formula including L-Carnitine along with other essential amino acid nutrients, and Vitamin C. It is formulated so as to be easily digestible and, therefore, rapidly absorbed to enhance delivery of its nutritionally balanced contents. In this manner, Amino Acids, L-Carnitine and Vitamin C, which are all important for good nutritional health and well-being, are now available in a unique, concentrated  
30 dose that is easy to administer, safe and non-toxic.

In this manner, relatively high levels of therapeutic ingredients are provided in a synergistic formulation at concentrations which optimize the body's function and utilization of each of these ingredients.

In addition, the present invention provides numerous additional beneficial features including, but not limited to, a composition that is rapidly absorbed by the body in solution, easily digestible such that the amino acid constituents are readily available for absorption, and is well-tolerated by the body with no known side effects, such as diarrhea. Moreover, the composition according to the present invention is formulated such that it is ready to use with no premixing required by the user, with a relatively small dosage, concentrated solution being provided (e.g., 2 tablespoons = 15 grams of Protein), that also contains an active form of L-Carnitine.

Furthermore, in solution, the present invention prepared for non-oral administration will not clog patient feeding tubes, has zero carbohydrates, contains no fats, sugar, or phosphorus, and is both lactose free and gluten free. Beneficially, the solution is also pleasant tasting and can be formulated in a wide range of concentrations.

Medical conditions and user groups believed to derive particular benefit from use of the above-described compositions, in accordance with the present invention, include, but are not limited to: muscle atrophy, weakness, disease including muscular dystrophy and ALS, general fatigue and poor endurance; diabetes mellitus; kidney disease and nutritional deficiencies resulting from dialysis; nutritional deficiencies resulting from dieting; lipid abnormalities such as elevated cholesterol and/or triglyceride levels; liver disease; atherosclerosis/heart disease, namely, ischemic heart disease, angina pectoris, and cardiac arrhythmias; immune diseases, suppressed immune system; obesity; burn injuries; Crohn's disease; decubitus ulcers; connective tissue/joint-related diseases including arthritis and sports injuries; individuals on total parenteral nutrition; anemia (by enhancing absorption of ferrous sulfate, and when used in conjunction with Epoetin Alfa therapy, can lead to higher levels of hemoglobin and hematocrit); pancreatic; peri-operative patients; and developmentally delayed babies and children. The present invention may also be used to aid in the healing of wounds and to provide a nutritional supplement for preventing and/or countering the effects of Alzheimer's Disease, Chronic Fatigue Syndrome (CFS), Chronic Muscle Myopathy, Connective Tissue Diseases, Epilepsy and Stroke.

Additionally, use of the present invention will further lower healthcare costs by improving patient care, decreasing the length of stay of patients in the hospital, allocation of nursing hours as well as the rate of re-hospitalization, decreasing the duration of ventilator dependence and the need for physical therapy, lessening the use

of curative medications, such as antibiotics, and the use of dressing and skin care products for wound healing and, thereby, lower healthcare costs.

Various modifications and alterations to the present invention may be appreciated based on a review of this disclosure. These changes and additions are  
5 intended to be within the scope and spirit of this invention as defined by the following claims.

**WHAT IS CLAIMED IS:**

1. A nutritional supplement which comprises Vitamin C, in mixture, with (i) L-Carnitine, or (ii) Protein comprising essential amino acids, or (iii) a mixture of (i) and (ii).
- 5 2. The supplement set forth in claim 1 wherein the Protein source is Hydrolyzed Collagen Protein.
3. The supplement set forth in claim 1 wherein the Protein source is soy protein.
- 10 4. The supplement set forth in claim 1 wherein the L-Carnitine source is selected from a group consisting of Acetyl L-Carnitine, L-Carnitine Fumarate, L-Carnitine L-Tartrate, L-Carnitine HCL, a salt of L-Carnitine, an ester of L-Carnitine, and mixtures thereof.
- 15 5. The supplement set forth in claim 1 wherein the Vitamin C source is selected from a group consisting of ascorbic acid, sodium ascorbate, calcium ascorbate, a pharmaceutically acceptable salt or ester of ascorbic acid, and mixtures thereof.
- 20 6. A nutritional supplement which comprises a selected Vitamin C source generally within a range of 250 milligrams and 5000 milligrams, in mixture, with (i) a selected L-Carnitine source generally within a range of 100 milligrams and 5000 milligrams, and/or (ii) a selected Protein source having essential amino acids generally within a range of 1 gram and 150 grams.
- 25 7. The supplement set forth in claim 6 wherein the selected Vitamin C source is generally within a range of 250 milligrams and 3000 milligrams, the selected L-Carnitine source is generally within a range of 250 milligrams and 4000 milligrams, and/or the selected Protein source having essential amino acids generally within a range of 5 grams and 100 grams.
- 30 8. The supplement set forth in claim 6 wherein the selected Vitamin C source is generally within a range of 250 milligrams and 1500 milligrams, the selected L-Carnitine source is generally within a range of 500 milligrams and 3000 milligrams, and/or the selected Protein source having essential amino acids generally within a range of 7.5 grams and 45 grams.
9. The supplement set forth in claim 8 wherein the source of Vitamin C is ascorbic acid and the source of Protein is Hydrolyzed Collagen Protein.

10. A nutritional supplement which comprises Vitamin C, in mixture, with L-Carnitine and/or one or more selected Proteins in selected proportions so as to provide a synergistic effect and, thereby, optimize their biotransformation and utilization in the body.

5 11. The supplement set forth in claim 10 wherein the Vitamin C is in an aqueous mixture with L-Carnitine and/or one or more selected Proteins.

12. The supplement set forth in claim 10 wherein the Vitamin C is in a non-aqueous mixture with L-Carnitine and/or one or more selected Proteins.

10 13. The supplement set forth in claim 10 wherein the Vitamin C, in mixture, with L-Carnitine and/or one or more selected Proteins is in tablet form.

14. The supplement set forth in claim 10 wherein the Vitamin C, in mixture, with L-Carnitine and/or one or more selected Proteins is in gel capsule form.

15 15. The supplement set forth in claim 10 wherein the Vitamin C, in mixture, with L-Carnitine and/or one or more selected Proteins is administered in the form of a skin patch.

16. The supplement set forth in claim 10 wherein the Vitamin C, in mixture, with L-Carnitine and/or one or more selected Proteins is in the form of a powder for reconstitution.

20 17. The supplement set forth in claim 10 wherein the Vitamin C, in mixture, with L-Carnitine and/or one or more selected Proteins is in a nutritional bar or the like.

25 18. A nutritional supplement which comprises a selected Vitamin C source generally within a range of 250 and 5000 milligrams, in mixture, with (i) a selected source of L-Carnitine between about 100 and 5000 milligrams, or (ii) a selected Protein source comprising essential amino acids generally within a range of 1 gram and 150 grams, or (iii) a mixture of (i) and (ii).

30 19. The supplement set forth in claim 11 wherein the Vitamin C source is ascorbic acid in the amount of between about 250 and about 1500 milligrams, the L-Carnitine source is L-Carnitine generally within a range of 500 and 3000 milligrams, and/or the Protein source is Hydrolyzed Collagen Protein in the amount of between about 7.5 and about 45 grams.

20. A method of treatment which comprises the step of dispensing to a patient a nutritional supplement comprising Vitamin C generally within a range of 250 and 5000 milligrams, in mixture, with (i) L-Carnitine between about 100 and

5000 milligrams, or (ii) one or more Proteins comprising essential amino acids generally within a range of 1 gram and 150 grams, or (iii) a mixture of (i) and (ii).

21. The method set forth in claim 20 wherein the Vitamin C is generally within a range of 250 milligrams and 3000 milligrams, the L-Carnitine is generally  
5 within a range of 250 milligrams and 4000 milligrams, and/or the Protein is generally within a range of 5 grams and 100 grams.

22. The method set forth in claim 20 wherein the Vitamin C is generally within a range of 250 milligrams and 1500 milligrams, the L-Carnitine is generally within a range of 500 milligrams and 3000 milligrams, and/or the Protein is generally  
10 within a range of 7.5 grams and 45 grams.

23. The method set forth in claim 20 wherein the Vitamin C source is ascorbic acid in the amount of between about 250 and about 1500 milligrams, the L-Carnitine source is L-Carnitine generally within a range of 500 and 3000 milligrams, and/or the Protein source is Hydrolyzed Collagen Protein in the amount of between  
15 about 7.5 and about 45 grams.

24. The method set forth in claim 20 wherein the Vitamin C is in an aqueous mixture with L-Carnitine and/or one or more selected Proteins.

25. The method set forth in claim 20 wherein the Vitamin C is in a non-aqueous mixture with L-Carnitine and/or one or more selected Proteins.

26. The method set forth in claim 20 wherein the Vitamin C, in mixture, with L-Carnitine and/or one or more selected Proteins is in tablet form.  
20

27. The method set forth in claim 20 wherein the Vitamin C, in mixture, with L-Carnitine and/or one or more selected Proteins is in gel capsule form.

28. The method set forth in claim 20 wherein the Vitamin C, in mixture, with L-Carnitine and/or one or more selected Proteins is administered in the form of a  
25 skin patch.

29. The method set forth in claim 20 wherein the Vitamin C, in mixture, with L-Carnitine and/or one or more selected Proteins is in the form of a powder for reconstitution.

30. The method set forth in claim 20 wherein the Vitamin C, in mixture, with L-Carnitine and/or one or more selected Proteins is in a nutritional bar or the like.  
30

31. The method set forth in claim 20 further comprising the step of administering the supplement in the form of a liquid having a volume ranging between about 15 and about 100 milliliters.

5 32. A method of treatment using a nutritional supplement, the method comprising the step of dispensing to a patient the nutritional supplement of claim 1.

33. A nutritional supplement which consists essentially of Vitamin C, in mixture, with (i) one or more Proteins comprising essential amino acids, or (ii) L-Carnitine, or (iii) a mixture of (i) and (ii).

10 34. A method of treatment using a nutritional supplement, the method comprising the step of dispensing to a patient the nutritional supplement of claim 33.