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(54) Titre : FORMULE POUR UN PRODUIT FAIBLE EN CALORIES ET EN DENSITE, DESTINE A L'ADMINISTRATION
INTESTINALE ET CONCU POUR REDUIRE LE RISQUE DE DIARRHEE CHEZ LES MALADES NOURRIS PAR
GAVAGE

(54) Title: LOW CALORIC DENSITY ENTERAL FORMULATION DESIGNED TO REDUCE DIARRHEA IN TUBE-FED
PATIENTS

(57) **Abrégé/Abstract:**

The present invention provides an enteral product for providing nutritional requirements to a patient comprising: a caloric content of less than 1.00 Kcal/ml; an osmolality of less than 300 mOsm; and a fiber content of preferably greater than 15 gms/liter. Additionally, the present invention provides a method of providing nutrition to a patient through a tube-fed enteral product and reducing the risk of diarrhea comprising the steps of: providing a sterile enteral product, that does not require diluting, having an osmolality of less than 300 mOsm and a caloric content of less than 1.0 Kcal/ml, but, having a fiber content of greater than 15 gms/liter; and enterally administering the product to a patient.



ABSTRACT OF THE DISCLOSURE

The present invention provides an enteral product for providing nutritional requirements to a patient comprising: a caloric content of less than 1.00 Kcal/ml; an osmolality of less than 300 mOsm; and a fiber content of preferably greater than 15 gms/liter. Additionally, the present invention provides a method of providing nutrition to a patient through a tube-fed enteral product and reducing the risk of diarrhea comprising the steps of: providing a sterile enteral product, that does not require diluting, having an osmolality of less than 300 mOsm and a caloric content of less than 1.0 Kcal/ml, but, having a fiber content of greater than 15 gms/liter; and enterally administering the product to a patient.

S P E C I F I C A T I O NTITLE

"LOW CALORIC DENSITY ENTERAL FORMULATION
DESIGNED TO REDUCE DIARRHEA IN TUBE-FED PATIENTS"

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BACKGROUND OF THE INVENTION

The present invention relates generally to the feeding of a patient, through a tube, with an enteral product. More specifically, the present invention relates to the prevention of diarrhea in a tube-fed patient.

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It is known to feed patients, requiring nutrition in a hospital or other healthcare setting (including a home), with an enteral or parenteral nutritional solution. Parenteral nutritional solutions include solutions that are infused into the venous system of a patient through an IV system. Enteral products include products that are fed to a patient through a tube that is fed through the nasogastric system.

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Although enteral products fed through a nasogastric tube can provide a patient with total nutritional requirements, there are, in certain patients, some side effects from such feedings. In this regard, it is known that certain patients will experience diarrhea when tube fed enteral nutritional products.

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Diarrhea is cited as the most common cause of interrupted tube feeding. Likewise, diarrhea is cited as the most frequent complaint of tube-fed patients. Many hospital nurses, dietitians, and physicians have identified the reduction of diarrhea as being one of the most desirable areas of patient care. In this regard, diarrhea affects approximately 10 to 40% of the tube-fed hospitalized patients. It is also known, to a lesser

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extent that tube-fed patients experience nausea and abdominal distension.

5 To help to reduce the incidence of diarrhea, it is known to put fiber or other anti-diarrhea composition in enteral formulations. Due to problems with keeping a particulate substance in suspension, only a certain amount of fiber can be loaded in a typical enteral formulation. For example, typical fiber containing enteral products include 14 grams of insoluble soy
10 polysaccharide (fiber) per liter and have a caloric density of 1.0 Kcal/ml.

The addition of insoluble fiber, however, does not eliminate the incidence of diarrhea. Therefore, it is common practice in U.S. hospitals, when faced with a
15 tube-fed patient with diarrhea, to initially reduce the flow rate and/or concentration of the enteral product. It is expected that because fluid volume and osmolality are reduced, the diarrhea will also be reduced.

Accordingly, hospitals dilute such enteral products
20 to three-quarter to one-half strength. This reduces nutrient load, theoretically reducing malabsorption, and also reduces osmolality. Although improvements should be expected when the fluid volume and osmolality of an enteral product are reduced, to achieve the reduced
25 osmolality, the hospital merely dilutes the product. For example, the product is mixed with water so as to be diluted to 50%.

The disadvantage of this procedure is that the fiber, or other anti-diarrhea composition, in the enteral
30 product is likewise reduced. Therefore, the dilution of the product does not always result in a reduction in the severity of the diarrhea. Furthermore, the dilution process can compromise the sterility of the enteral

product. Still further, because the product is diluted, essential vitamins and minerals are not supplied in adequate quantity.

SUMMARY OF THE INVENTION

5 The present invention provides an enteral nutritional product that can be used to tube feed a patient and reduce the incidence or severity of diarrhea. To this end, the present invention provides an enteral product that meets most of the daily nutritional
10 requirements of hospitalized patients. However, the product has a sufficiently reduced caloric density and osmolality, but a sufficiently high fiber content, to reduce or eliminate the risk of diarrhea.

 To this end, the present invention provides an
15 enteral product for providing nutritional requirements to a patient comprising: a caloric content of less than 1.00 Kcal/ml; an osmolality of less than 300 mOsm; and a fiber content of at least 14 gms/liter and preferably greater than 15 gms/liter.

20 In an embodiment, the product includes approximately 18 to about 25% of the total calories as protein.

 In an embodiment, the product includes approximately 35 to about 50% of the total calories as fat.

25 In an embodiment, the fiber includes one or more components chosen from the group consisting of: insoluble soy polysaccharide; insoluble pectin; hydrolyzed plant gums; carob pod; and tannin-enriched extract of carob pod.

30 Additionally, the present invention provides a method of providing nutrition to a patient through a tube-fed enteral product and reducing the risk of diarrhea comprising the steps of: providing a sterile enteral product, that does not require diluting, having

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an osmolality of less than 300 mOsm and a caloric content of less than 1.0 Kcal/ml but having a fiber content of greater than 15 gms/liter; and enterally administering the product to a patient.

5 An advantage of the present invention is that it provides a prediluted product with a high fiber content.

Furthermore, an advantage of the present invention is that it provides a sterile closed system that does not have to be diluted before use.

10 Still further, an advantage of the present invention is that it provides a product having a higher than typical protein content, as a percentage of calories, to help meet protein requirements in a calorie reduced product.

15 Moreover, an advantage of the present invention is that the composition has a vitamin and mineral composition which meets vitamin and mineral requirements in a calorie reduced product.

20 Additionally, an advantage of the present invention is that the composition has a higher lipid content that helps to reduce osmolality and slow transit time.

In accordance with an aspect of the invention there is provided an enteral product for providing nutritional requirements to a patient comprising:

25 a caloric content of less than 1.00 Kcal/ml;
an osmolality of less than 300 mOsm; and
a fiber content of at least 14 gms/liter.

In accordance with another aspect of the invention there is provided an enteral tube-fed product for
30 providing nutritional needs to a patient comprising:

a caloric content of approximately 0.5 to about 0.8 Kcal/ml;

an osmolality of approximately 100 to about 250

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mOsm;

a protein content of greater than 17% of the total calories;

5 a fat content of greater than 33% of the total calories; and

a fiber content of greater than 15 gms/liter.

In accordance with a further aspect of the invention there is provided a method of providing nutrition to a patient through a tube-fed enteral product and reducing
10 the risk of diarrhea comprising the steps of:

providing a sterile enteral product, that does not require diluting, having an osmolality of less than 300 mOsm, a caloric content of less than 1.0 Kcal/ml, and having a fiber content of greater than 15 gms/liter; and
15 administering the product to a patient.

In accordance with another aspect of the invention, there is provided a use of a sterile enteral product, that does not require dilution, to provide nutrition and reduce the risk of diarrhea in a patient, the sterile
20 enteral product having an osmolality of less than 300 mOsm, a caloric content of less than 1.0 Kcal/ml, and a fiber content of greater than 15 gms/liter.

Additional features and advantages of the present invention are described in, and will be apparent from,
25 the detailed description of the presently preferred embodiments.

DETAILED DESCRIPTION

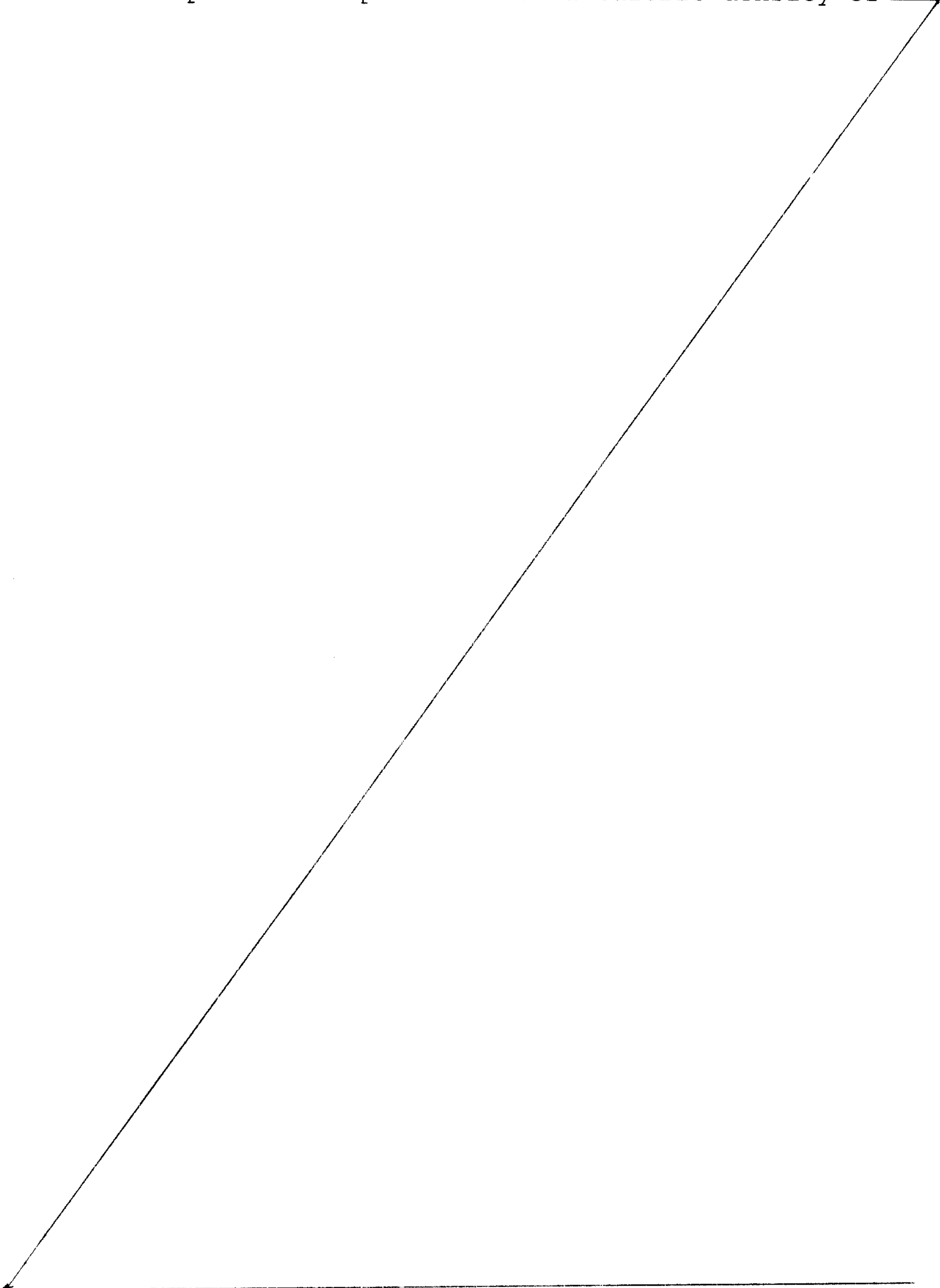
OF THE PRESENTLY PREFERRED EMBODIMENTS

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The present invention provides an enteral product suitable for tube feeding that provides most of the daily

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nutritional requirements of hospitalized and nursing home patients. The product has a caloric density of less than 1.0 Kcal/liter. In a preferred embodiment, the present invention provides a product with a caloric density of



approximately 0.5 to about 0.8 Kcal/ml.

The osmolality of the product of the present invention is less than 300 mOsm. Preferably, the osmolality is approximately 100 to about 250 mOsm.

5 In order to provide sufficient nutritional requirements, the present invention includes a protein content that comprises greater than 17% of the total calories of the product. Preferably, the protein content is approximately 18 to about 25% of the total calories
10 of the product. The protein content can be provided by, for example, casein, hydrolyzed casein, hydrolyzed whey protein, or hydrolyzed soy protein.

 Additionally, the present invention has a fat content that comprises greater than 33% of the total
15 calories of the product. Preferably, the fat content of the product is approximately 35 to about 50% of the total calories. The fat content can be provided by, for example, a blend of medium chain triglycerides and soy oil.

20 In order to provide an anti-diarrhea product, the present invention includes a fiber content of at least 14 gms/liter. Preferably, the product has a fiber content of greater than 15 gms/liter. As used in the patent application, "fiber" includes, inter alia, the
25 following: insoluble soy polysaccharide; soluble pectin; hydrolyzed plant gums; carob pod, e.g., carob pod powder; or a tannin-enriched extract of carob pod.

 If desirable, the formulation can include arginine, ornithine, cysteine, L-2-oxothiazolidine-4-carboxylate,
30 and/or omega-3 rich lipids, such as marine oil or canola oil.

Due to the structure of the present invention, the typical hospital practice of diluting an enteral product

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to 1/2 to 3/4 strength is not necessary. The composition already includes a reduced nutrient load.

However, in contrast to dilutions that are made in the hospital, the fiber content of the product is not
5 reduced. Indeed, the product of the present invention provides a fiber content that is greater than normal. Because the caloric density is reduced, the inventor of the present invention has found that the amount of fiber can be increased. Furthermore, the sterility of the
10 closed system of the product as manufactured is maintained because dilution is not required.

The present invention also provides, in a preferred embodiment, a protein content that is greater than protein requirements in a typically calorie reduced
15 product. Likewise, the present invention includes a higher lipid content. This reduces osmolality and slows transit time period.

The addition of arginine, ornithine, cysteine, L-2-oxothiazolidine-4-carboxylate, and/or omega-3 rich lipids
20 can also provide an advantage in normalizing gut mucosal structure and function. If desirable, a carob pod product, e.g., carob pod powder, can be added. The carob pod product provides anti-diarrhea characteristics. Additionally, the carob pod product provides anti-
25 bacterial and anti-viral activity. The carob pod product can be constructed in accordance with U.S. Patent No. 4,999, 197.

Furthermore, the present invention can include the necessary USRDA of vitamins and minerals. This provides
30 an advantage over a diluted product wherein the necessary USRDAs of vitamins and minerals is not provided. However, preferably, a reduced level of magnesium is

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provided. Rather than the USRDA of 400 mg/day of magnesium, preferably only 150-250 mg/day will be provided.

5 By way of example, and not limitation, examples of products of the present invention are as follows:

EXAMPLE NO. 1

Caloric density 0.75 kcal/ml
Protein = casein
10 at 25% kcal of the product
Lipid = 50% MCT; 50% canola
at 40% kcal of the product
Carbo = Malto dextrin
at 35% kcal the product
15 Fiber = 20 gms/liter
(10 gms soy polysaccharide; 10 gms tannin-rich carob extract)
Vit/Min = delivers USRDA in 1500 ml with the
exception that magnesium is at
20 250 mg/1500 ml

EXAMPLE NO. 2

Caloric density 0.5 kcal/ml
Protein = hydrolyzed whey, at 20% kcal of the
25 product
Lipid = 70% MCT; 30% Canola
at 40% kcal of the product
Carbo = maltodextrin
at 40% kcal of the product
30 Fiber = 20 gms/liter
(10 gms tannin-rich carob extract;
5 gms soluble pectin;
5 gms soy polysaccharide)

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Vit/Min = delivers USRDA in 1500 ml with the
exception that magnesium is at
250 mg/1500 ml

5 In use, for the average patient, approximately 1500
ml of products of either Example 1 or 2 would be given
per day. Of course, depending on patient requirements
and other adjunct therapy and solutions that are used
more or less product can be given.

10 It should be understood that various changes and
modifications to the presently preferred embodiments
described herein will be apparent to those skilled in the
art. Such changes and modifications can be made without
departing from the spirit and scope of the present
invention and without diminishing its attendant
15 advantages. It is therefore intended that such changes
and modifications be covered by the appended claims.

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I CLAIM:

1. An enteral product for providing nutritional requirements to a patient comprising:

- 5 a caloric content of less than 1.00 Kcal/ml;
an osmolality of less than 300 mOsm; and
a fiber content of at least 14 gms/liter.

2. The enteral product of claim 1 including
10 approximately 18 to about 25% of the total calories as protein.

3. The enteral product of claim 1 including
approximately 35 to about 50% of the total calories as
15 fat.

4. The enteral product of claim 1 wherein fiber includes one or more components chosen from the group consisting of: insoluble soy polysaccharide; pectin;
20 hydrolyzed plant gum; carob pod; and tannin-enriched extract of carob pod.

5. The enteral product of claim 1 further comprising at least one component chosen from the group
25 consisting of: arginine; ornithine; cysteine; L-2-oxothiazolidine-4-carboxylate; and omega-3 rich lipids.

6. The enteral product of claim 1 including greater than 15 gms/liter of fiber.

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7. The enteral product of claim 1 wherein 1500 ml of product provides the USRDA of all vitamins and minerals except magnesium.

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8. The enteral product of claim 7 wherein the product provides approximately 150 to about 250 mg of magnesium/1500 ml of the product.

5 9. An enteral tube-fed product for providing nutritional needs to a patient comprising:

a caloric content of approximately 0.5 to about 0.8 Kcal/ml;

10 an osmolality of approximately 100 to about 250 mOsm;

a protein content of greater than 17% of the total calories;

a fat content of greater than 33% of the total calories; and

15 a fiber content of greater than 15 gms/liter.

10. The enteral tube-fed product of claim 9 wherein fiber includes one or more components chosen from the group consisting of: insoluble soy polysaccharide; soluble pectin; hydrolyzed plant gum; carob pod and tannin-enriched extract of carob pod.

11. The enteral tube-fed product of claim 9 further comprising at least one component chosen from the group consisting of: arginine; ornithine; cysteine; L-2-oxothiazolidine-4-carboxylate; and omega-3 rich lipids.

12. The enteral tube-fed product of claim 9 wherein the protein content is approximately 18 to about 25% of the total calories.

13. The enteral tube-fed product of claim 9 wherein the fat content is approximately 35 to about 50% of the

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total calories.

14. The enteral tube-fed product of claim 9 wherein
1500 ml of the product provides the USRDA of all vitamins
5 and minerals except magnesium.

15. A use of a sterile enteral product, that does
not require dilution, to provide nutrition and reduce the
risk of diarrhea in a patient, the sterile enteral
10 product having an osmolality of less than 300 mOsm, a
caloric content of less than 1.0 Kcal/ml, and a fiber
content of greater than 15 gms/liter.

16. A use according to claim 15 wherein the product
15 includes greater than 17% of the caloric content as
protein.

17. A use according to claim 15 wherein the product
includes greater than 33% of the caloric content as fat.
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18. A use according to claim 15 wherein the fiber
content is provided by one or more components chosen from
the group consisting of: insoluble soy polysaccharide;
soluble pectin; hydrolyzed plant gum; carob pod; and
25 tannin-enriched extract of carob pod.

19. A use according to claim 15 wherein the enteral
product provides the USRDA of vitamins and minerals
except for magnesium.
30

20. A use according to claim 19 wherein magnesium
is provided at a rate of only 150-250 mg/day.