

PHYSICIANS' ELEMENTAL DIET™ & PHYSICIANS' ELEMENTAL DIET™ DEXTROSE FREE

ELEMENTAL POWDERS FOR GI DYSFUNCTION

Medical Food: Intended for use under medical supervision.

Gastrointestinal/digestive impairment (GDI) conditions are characterized by a limited or impaired capacity to digest, absorb, or metabolize ordinary foods or certain nutrients. The existence of distinctive nutritional requirements associated with these GDI conditions drives the need for the specific dietary management of these patients while under the care of a medical professional. Physicians' Elemental Diet is available in two formulas: Original and Dextrose Free. Both formulas are elemental powdered medical foods intended for use under medical supervision for the dietary management of patients with GDI dysfunction. Physicians' Elemental Diet and Physicians' Elemental Diet Dextrose Free are specifically formulated to contain free form amino acids, partially hydrolyzed carbohydrate, and readily assimilated medium chain triglycerides to aid in their absorption from the GI lumen.

Therefore, both Physicians' Elemental Diet formulas require minimal digestive functionality for assimilation and meet the distinctive nutritional requirements of patients with impaired gastrointestinal function. These formulas contain a balanced blend of macronutrients fortified with essential vitamins, minerals and electrolytes to assure comprehensive support as a sole source of nutritional intake for limited periods.

Intended for use under medical supervision for the dietary management of patients who have limited or impaired capacity to digest, absorb, or metabolize ordinary foods or certain nutrients. The elemental diet is designed for the dietary management of irritable bowel, Crohn's disease,¹⁻⁶ small intestinal bacterial overgrowth (SIBO)⁷⁻⁹ and moderate to severe impaired gastrointestinal function.^{3, 10-12}

Key product features include:

- Specifically formulated to contain free amino acids, partially hydrolyzed carbohydrate and medium chain triglycerides to aid in their absorption from the GI lumen.
- Designed to maintain nutritional sustenance as a sole source of nutrition for up to four weeks.
- Strictly hypoallergenic formula free from intact protein or polypeptides, corn, gluten, soy, and dairy.





PHYSICIANS' ELEMENTAL DIET™ AND PHYSICIANS' ELEMENTAL DIET™ DEXTROSE FREE

Medical Food: Intended for use under medical supervision.

Description

Physicians' Elemental Diet & Physicians' Elemental Diet Dextrose Free are intended for use under medical supervision for the dietary management of patients who have limited or impaired capacity to digest, absorb, or metabolize ordinary foods or certain nutrients. The elemental diet is designed for the dietary management of irritable bowel, Crohn's disease,¹⁻⁶ small intestinal bacterial overgrowth (SIBO)⁷⁻⁹ and moderate to severe impaired gastrointestinal function.^{3,10-12}

Background

Elemental diets have been in use since the 1940's predominantly in hospital settings. More recently, interest in elemental diets has increased for use in various conditions of gastrointestinal/digestive impairment (GDI) under medical supervision in outpatient settings.

Physicians' Elemental Diet and Physicians' Elemental Diet Dextrose Free were created to meet the needs of patients as well as the unique requirements of integrative medicine specialists. Over the course of five years, thought leaders in the naturopathic and integrative medicine community along with product formulation experts provided guidance throughout development at each and every step to ensure these needs were met. According to these expert opinions, the ideal elemental diet formula would be strictly hypoallergenic, contain no intact protein, corn or soy derived micronutrients or macronutrients. The formula must be palatable for patient compliance but contain no artificial flavorings. Finally, it must be cost-effective.

Modified cornstarch and maltodextrin derived from corn are two commonly used ingredients in elemental diets. Both Physicians' Elemental Diet formulas instead contain tapioca maltodextrin and no modified cornstarch. Physicians' Elemental Diet Original contains both maltodextrin and dextrose, while Physicians' Elemental Diet Dextrose Free contains only tapioca maltodextrin. Both formulas deliver medium-chain triglyceride (MCT) oil in powdered formulation without preservatives like potassium sorbate, BHA (butylated hydroxyanisole), or BHT (butylated hydroxytoluene). Physicians' Elemental Diet formulas are strictly hypoallergenic medical foods and further contain neither soybean oil nor soy lecithin. Also, the formulas do not contain yeast, wheat, gluten, dairy products, fructose, sucrose, lactose, disaccharides, sorbitol, mannitol, xylitol, artificial colors, flavors or preservatives.

Physicians' Elemental Diet formulas contain all essential and non-essential amino acids and includes enhanced levels of glutamine. Rather than containing intact proteins or peptides, only free form amino acids are used, the key building blocks of protein. Additionally, Physicians' Elemental Diet and Physicians' Elemental Diet Dextrose Free meet or exceed 100% RDI for 24 micronutrients including active forms of B-vitamins. This balanced approach is crucial as a patient's sole source of nutritional intake, as needed, for up to four weeks. Typical use is 2-3 weeks in duration.

How They Work

Physicians' Elemental Diet formulas are elemental diet medical foods designed for integrative medicine physicians and are intended for adult patients diagnosed with gastrointestinal/digestive impairment (GDI), that are under medical supervision and have distinct nutritional requirements. Elemental diets can be used in a variety of clinical applications.

Elemental diets are used as part of dietary management for SIBO (small intestinal bacterial overgrowth). Physicians' Elemental Diet formulas are intended to provide dietary management for patients with an abnormal hydrogen or methane breath test using either glucose or lactulose challenge material. Lactulose is the only sugar not digested by the body, meaning that it is able to travel all the way through the small intestine. Glucose, on the other hand, is completely absorbed by the body, typically within the first one or two feet of the GI tract. The lactulose breath test thus allows detection of abnormally increased numbers of bacteria located in the distal small intestine. Patients consume lactulose or glucose syrup and samples of their breath are collected over a 3 hour period. The lactulose is taken up by bacteria in the small intestine which digest and ferment it, producing different types of gases such as carbon dioxide, hydrogen, and methane. Similarly, when dietary intake includes fermentable carbohydrates such as lactulose and poorly digested oligosaccharides, it feeds bacteria present in the small intestine producing gases that can be measured in the breath. Elemental diets like Physicians' Elemental Diet and Physicians' Elemental Diet Dextrose Free do not contain such fermentable carbohydrates and provide well-tolerated nutrition for the patient.

Elemental Diet and Clinical Research

Pimentel and his team at Cedars-Sinai Medical Center provided patients with gastrointestinal symptoms and an abnormal lactulose breath test with an elemental diet formula (Vivonex[®] Plus[†]) as a sole source of nutrition based on individualized caloric needs for two weeks, at which point the subjects were retested. Those subjects who still had abnormal tests were provided an additional week of the elemental diet. Of the 93 patients assessed, 85% normalized the breath test and this correlated with symptom improvement.⁹ This same group previously found in a double-blind randomized controlled clinical trial that normalizing lactulose breath tests improved symptom status in patients with irritable bowel.¹³ Much of the clinical research on elemental diets was performed on the elemental diet product Vivonex[®] Plus. Vivonex[®] Plus differs from both Physicians' Elemental Diet formulas in macronutrient ratios. All formulas are considered elemental diet products.

Macronutrients	Physicians' Elemental Diet™	Physicians' Elemental Diet™ Dextrose Free	Vivonex [®] Plus
Protein:	14%	20%	17%
Fats:	18%	20%	6%
Carbohydrates:	68%	60%	77%

[†] Vivonex[®] is a registered trademark of Société des Produits Nestlé S.A., Vevey, Switzerland.

Another group provided an elemental diet as a sole source of nutrition to 28 consecutive patients with active Crohn's disease. Mucosal biopsies were obtained from the distal small intestine and colon and compared against a control group. Seventy-one percent of patients were reclassified in regards to disease status after four weeks.⁵

A half elemental diet was found to be a promising dietary management approach to Crohn's disease. A half elemental diet is one in which half of the patient's caloric needs are met with an elemental diet formula and the remaining are met with tolerated foods. In one clinical trial patients were recommended a half elemental diet for, on average, 11.9 months and found to be better managed than those who ate typical foods.¹⁴

The duration for typical dietary management using an elemental diet formula is 2 weeks for most patients and 3-4 weeks for some potentially more complex cases. Some patients with less severe gastrointestinal/digestive impairment may report benefit with shorter duration than 2 weeks. An elemental diet can be used as an initial dietary management tool or used periodically¹⁵ or when the physician deems the patient may benefit from easily digestible sources of nutrients. A half-elemental diet for longer periods of time, up to a year in some cases, may be prudent.

Conclusion

Physicians' Elemental Diet formulas are intended for adult patients who have been instructed how to use the products properly. It is formulated to provide dietary management for patients with gastrointestinal/digestive impairment who require easy assimilated nutrition through the delivery of free amino acids and partially-digested carbohydrate.

REQUEST A SAMPLE TODAY FROM YOUR MEDICAL SALES MANAGER
OR OUR CUSTOMER CARE TEAM AT 800.931.1709

PHYSICIANS' ELEMENTAL DIET™ DEXTROSE FREE

Medical Food: Intended for use under medical supervision.

NUTRITION INFORMATION

Serving Size 1.23 oz (35 g)

Amount per Serving

Calories	150
Calories from Fat	30
Total Fat	3 g
Saturated Fat	1.5 g
Total Carbohydrate	23 g
Sugars	<1 g
Sodium	90 mg
Potassium	150 mg
Protein	**
Vitamin A (Beta Carotene)	833 IU
Vitamin C	20 mg
Calcium	85 mg
Iron	1.5 mg
Vitamin D3	66 IU
Vitamin E	10 IU
Vitamin K	10 mcg
Thiamin	0.5 mg
Riboflavin (Riboflavin-5-phosphate)	0.56 mg
Niacin	3.3 mg
Vitamin B6 (Pyridoxal-5-phosphate)	667 mcg
Folate (as Quatrefolic® brand (6S)-5-methyltetrahydrofolate glucosamine salt)	33 mcg
Vitamin B12 (Methylcobalamin)	0.5 mcg
Biotin	50 mcg
Pantothenic Acid	3.3 mg
Phosphorus	82.8 mg
Iodine	16.5 mcg
Magnesium	33.5 mg
Zinc	2 mg
Selenium	18 mcg
Copper	167 mcg
Manganese	332 mcg
Molybdenum	8.25 mcg
Chloride	164.6 mg
Choline	33.35 mg

**Contains 7.5 g free form amino acids per 35 g serving.

Ingredients: tapioca maltodextrin, medium chain triglycerides, l-glutamine, l-proline, natural flavor, l-aspartic acid, l-serine, l-arginine hydrochloride, l-alanine, potassium citrate, l-leucine, l-lysine hydrochloride, disodium phosphate, l-valine, l-glycine, l-isoleucine, l-threonine, tricalcium phosphate, l-tyrosine, dimagnesium malate, dicalcium malate, l-phenylalanine, choline bitartrate, l-methionine, l-histidine, l-cysteine hydrochloride, potassium malate, magnesium citrate, l-tryptophan, l-carnitine, l-tartrate, sodium ascorbate, d-alpha tocopheryl acetate, iron gluconate, l-taurine, zinc sulfate, calcium d-pantothenate, beta cartene, niacinamide, sodium chloride, sodium selenite, manganese citrate, phytonadione, pyridoxyl-5'-phosphate, cholecalciferol, riboflavin-5'-phosphate, thiamine hydrochloride, copper sulfate, Quatrefolic® ((6S)-5-methyltetrahydrofolate glucosamine salt), d-biotin, sodium molybdenate, potassium iodide, methylcobalamin.

MEDICAL FOOD INTENDED FOR USE UNDER MEDICAL SUPERVISION

Not intended for use in children.

Physicians' Elemental Diet Dextrose Free contains 100% free form amino acid-based formula intended for distinctive nutritional requirements. Physicians' Elemental Diet Dextrose Free requires minimal digestive functionality for assimilation.

Physicians' Elemental Diet Dextrose Free formula provides 150 calories per serving, distributed as approximately 20% protein, 60% carbohydrate, and 20% fat.

For more information, please visit integrativepro.com.

Recommended Use: Thoroughly mix each level scoop (35 g) in 4-8 oz. (118-327 mL) chilled or room temperature water. Additional water may be added to the mixture slowly over a period of 15 to 60 minutes or more, dependent upon individual comfort. Once mixed, any product that is not consumed after 60 minutes should be refrigerated for a maximum of 24 hours, then shaken or stirred prior to consumption

The contents are based upon the weight of product, and may settle during shipping and handling.

Keep out of reach of children. Safety sealed for your protection. Do not use if pouch is torn or open.

Contains No: corn, yeast, wheat, gluten, soy, dairy products, dextrose, fructose, sucrose, lactose, sorbitol, mannitol, xylitol, artificial colors, flavors, or preservatives.

Quatrefolic® is a registered trademark of Gnosis S.p.A.

Integrative Therapeutics™

1,260 G (44.44 OZ) 36 SERVINGS - 12264

References

- Gorard, DA, Hunt, JB, Payne-James, JJ, et al. 1993. *Gut*. 34:1198-202.
- O'Morain, C, Segal, AW, Levi, AJ. 1984. *Br Med J (Clin Res Ed)*. 288:1859-62.
- Ueno, F, Matsui, T, Matsumoto, T, et al. 2013. *J Gastroenterol*. 48:31-72.
- Verma, S, Kirkwood, B, Brown, S, Giaffer, MH 2000. *Dig Liver Dis*. 32:769-74.
- Yamamoto, T, et al. 2005. *Inflamm Bowel Dis*. 11:580-8.
- Zoli, G, Carè, M, Parazza, M, et al. 1997. *Aliment Pharmacol Ther*. 11:735-40.
- Van Citters, GW, Lin, HC. 2005. *Curr Gastroenterol Rep*. 7:317-20.
- Bures, J, et al. 2010. *World J Gastroenterol*. 16:2978-90.
- Pimentel, M, et al. 2004. *Dig Dis Sci*. 49:73-7.
- Eiden, KA. 2003. *Pract. Gastroenterol*. 2003, 33-43, 47-54
- Fisher, RL 1999. *J Nutr*. 129:252S-5S.
- Devlin, J, David, TJ, Stanton, RH. 1991. *Arch Dis Child*. 66:93-9
- Pimentel M, Chow EJ, Lin HC. *Am J Gastroenterol* 2003;98:412-9.
- Takagi S, Utsunomiya K, Kuriyama S, et al. *Aliment Pharmacol Ther*. 2006 Nov 1;24(9):1333-40.
- Tanaka M, Kawakami A, Iwao Y, Fukushima T, Yamamoto-Mitani N. *Gastroenterol Nurs*. 2016 Jan-Feb;39(1):42-7.

PHYSICIANS' ELEMENTAL DIET™

Medical Food: Intended for use under medical supervision.

NUTRITION INFORMATION

Serving Size 36 g

Amount per Serving

Calories	150
Calories from Fat	25
Total Fat	3 g
Saturated Fat	1.5 g
Total Carbohydrate	25 g
Sugars	11 g
Sodium	95 mg
Potassium	150 mg
Protein	**
Vitamin A (Beta Carotene)	833 IU
Vitamin C	20 mg
Calcium	83 mg
Iron	1.5 mg
Vitamin D3	66 IU
Vitamin E	10 IU
Vitamin K	10 mcg
Thiamin	0.5 mg
Riboflavin (Riboflavin-5-phosphate)	0.56 mg
Niacin	3.3 mg
Vitamin B6 (Pyridoxal-5-phosphate)	667 mcg
Folate (as Quatrefolic® brand (6S)-5-methyltetrahydrofolate glucosamine salt)	33 mcg
Vitamin B12 (Methylcobalamin)	0.5 mcg
Biotin	50 mcg
Pantothenic Acid	3.3 mg
Phosphorus	116 mg
Iodine	16 mcg
Magnesium	33 mg
Zinc	2 mg
Selenium	18 mcg
Copper	167 mcg
Manganese	332 mcg
Molybdenum	8 mcg
Chloride	142 mg
Choline	33 mg

**Contains 5 g free form amino acids per 36 g serving.

Ingredients: dextrose, tapioca maltodextrin, medium chain triglycerides, natural flavor, l-glutamine, l-proline, l-aspartic acid, l-serine, potassium citrate, l-arginine hydrochloride, l-alanine, disodium phosphate, l-leucine, l-lysine hydrochloride, l-valine, l-glycine, calcium glycerophosphate, tricalcium phosphate, l-isoleucine, choline bitartrate, l-threonine, l-tyrosine, magnesium citrate, l-phenylalanine, l-methionine, l-histidine, magnesium glycerophosphate, l-cysteine hydrochloride, potassium chloride, l-tryptophan, sodium ascorbate, l-carnitine l-tartrate, sodium chloride, d-alpha tocopheryl acetate, ferrous gluconate, l-taurine, zinc sulfate, calcium d-pantothenate, beta carotene, niacinamide, sodium selenite, manganese citrate, phytonadione, pyridoxal-5-phosphate, cholecalciferol, riboflavin-5-phosphate, thiamine hydrochloride, copper sulfate, Quatrefolic® (6S)-5-methyltetrahydrofolate glucosamine salt, d-biotin, sodium molybdate, potassium iodide, methylcobalamin

MEDICAL FOOD INTENDED FOR USE UNDER MEDICAL SUPERVISION

Not intended for use in children.

Physicians' Elemental Diet contains 100% free form amino acids in a powdered elemental formula intended for distinctive nutritional requirements.

Physicians' Elemental Diet formula provides 150 calories per serving, consisting of 68% carbohydrate, 18% fat and amino acids equivalent to 14% protein.

For more information, please visit integrativepro.com.

Recommended Use: Thoroughly mix each level scoop (36 g) in 3-4 oz. (89-118 mL) cold water. Consume the mixture slowly over a period of 15 to 60 minutes or more, dependent upon individual comfort. Once mixed, any product that is not consumed after 60 minutes should be refrigerated for a maximum of 24 hours, then shaken or stirred prior to consumption. After opening, store remaining powder in a dry place at room temperature.

The contents are based upon the weight of product, and may settle during shipping and handling. Due to variations in product handling, there may be slight variations between each scoop.

Contains No: Corn, yeast, wheat, gluten, soy, dairy products, fructose, sucrose, lactose, disaccharides, sorbitol, mannitol, xylitol, artificial colors, flavors or preservatives.

Quatrefolic® is a registered trademark of Gnosis S.p.A.

Integrative Therapeutics™

432 G (15.238 OZ) 12 SERVINGS - 11306
1,296 G (45.715 OZ) 36 SERVINGS - 11307