



Code: 9236 Size: 1404 g Powder

ElementAll® Biological Diet

Nutritionally Complete Formula
100% Free Form Amino Acids · Chocolate

- Provides a hypoallergenic formula, with 100% of protein supplied from free-form amino acids, particularly L-glutamine, a key fuel for intestinal cells
- Contains easily assimilated and tolerated carbohydrates
- All nutrient requirements met, while needing little-to-no digestive functionality for macronutrient breakdown
- Excellent taste for improved compliance

PRODUCT SUMMARY

ElementAll Biological Diet is an elemental diet formula that provides comprehensive, hypoallergenic, easily digestible stand-alone nutrition for individuals with impaired digestive function. The therapeutic efficacy of elemental diets has partly been attributed to the elimination of all allergens (while providing nutrients requiring minimal digestion). This promotes gastrointestinal mucosal healing, normalization of intestinal permeability, and improved clinical symptoms among participants with Crohn’s disease (as determined by the lactulose/L-rhamnose permeability ratio). Among people with newly diagnosed Crohn’s disease, complete elemental nutrition induces remission in over 80% of patients, while a “half elemental diet” significantly lowered relapse rates when followed longer term.

Elemental diets target gut microbiota as well as inflammation; in addition to suppressing NF-κB levels (a critical regulator of inflammation), they significantly lower the population of *Bacteroides fragilis*, a species linked to inflammatory bowel disease (IBD) as well as colorectal cancer. Among individuals with irritable bowel syndrome (IBS) and abnormal lactulose breath tests (indicative of small intestinal bacterial overgrowth [SIBO]), 85% had normalized breath values as well as improved symptoms after following an elemental diet. Elemental diets have also led to similar improvement when compared to corticosteroid therapy among rheumatoid arthritis participants, and both immunopathologic and clinical improvement among participants with refractory celiac disease.

ElementalAll Biological Diet provides all the essential micro- and macronutrients optimized for easy assimilation and is designed to be the sole source of nutrition for individuals with impaired digestive function.



ELEMENTAL[®] BIOLOGICAL DIET

NUTRITIONALLY COMPLETE FORMULA · 100% FREE FORM AMINO ACIDS · CHOCOLATE

Serving Size: 4 Scoops (156 g)

Servings Per Container: 9

Nutritional Information	Per 100 g	Per 1 Mixed Serving
		Ready to Serve Formula*:
Calories (Energy)	395 Cal	616 Cal
Protein	**	***
Fat	8.2 g	13 g
Linoleic Acid	1.0 g	1.5 g
Carbohydrate	58 g	90 g
Dietary Fibre	2.3 g	3.6 g
Vitamin A	1795 IU	2800 IU
Vitamin D	147 IU	230 IU
Vitamin E	26 IU	40 IU
Ascorbic Acid	51 mg	80 mg
Thiamine	1.3 mg	2.0 mg
Riboflavin	1.3 mg	2.0 mg
Niacin	8.3 mg	13 mg
Vitamin B6	1.7 mg	2.6 mg
Vitamin B12	184 mcg	287 mcg
Folic Acid	172 mcg	268 mcg
<i>d</i> -Pantothenic Acid	8.3 mg	13 mg
Biotin	128 mcg	200 mcg
Vitamin K2	26 mcg	40 mcg
Choline	85 mg	133 mg
Calcium	256 mg	400 mg
Phosphorus	199 mg	311 mg
Iron	3.8 mg	6.0 mg
Iodine	44 mcg	68 mcg
Magnesium	85 mg	133 mg
Copper	0.428 mg	0.668 mg
Zinc	5.3 mg	8.3 mg
Sodium	224 mg	349 mg
Potassium	785 mg	1225 mg
Manganese	0.833 mg	1.3 mg
Selenium	56 mcg	88 mcg
Molybdenum	21 mcg	32 mcg
Chromium	44 mcg	68 mcg
Boron	0.641 mg	1.0 mg

*1 mixed serving equals 4 scoops (approx. 156 g) mixed with 500 mL water.

**Contains 19 g of amino acids – key building blocks of protein.

***Contains 30 g of amino acids – key building blocks of protein.

Ingredients: Organic tapioca dextrose, Organic tapioca maltodextrin, L-glutamine, Natural flavours, L-leucine, Safflower oil, Modified palm oil (medium chain triglycerides), L-arginine hydrochloride, Organic alkalized cocoa powder, Sunflower lecithin, L-lysine hydrochloride, Calcium glycerophosphate, L-isoleucine, L-valine, Potassium citrate monohydrate, Sodium citrate dihydrate, Silica, L-cysteine hydrochloride, L-phenylalanine, L-threonine, L-histidine hydrochloride, Magnesium citrate, L-tyrosine, L-methionine, L-aspartic acid, L-proline, Choline dihydrogen citrate, Tricalcium phosphate, Magnesium glycerophosphate, L-tryptophan, Methylcobalamin, Sodium molybdate, L-alanine, Glycine, L-serine, Sodium ascorbate, L-carnitine tartrate, *d*l-Alpha tocopheryl acetate [fish], Taurine, Ferrous fumarate, Menaquinone MK-7 [soy], Zinc sulfate monohydrate, Biotin, Selenomethionine, Calcium *d*-pantothenate, Niacin, Sodium borate decahydrate, Vitamin A palmitate, Copper sulfate, Manganese citrate, Pyridoxal 5'-phosphate, Riboflavin 5'-phosphate, Thiamine hydrochloride, Cholecalciferol, Potassium iodide, Folate (from (6S)-5-methyltetrahydrofolic acid (MTHF), glucosamine salt, Quatrefolic[®]), Chromium picolinate.

Suggested Use: Mix one serving (4 scoops) in 500 mL of water or as directed by a health care practitioner. You can adjust by adding more water if desired. To be consumed promptly. Take 3 servings per day or as directed by a health care practitioner. 3 servings (12 scoops) provide 1848 calories.

Note: This product is a food for special dietary and intended for use only under the direction of a qualified health care practitioner. It is not intended to diagnose, treat, cure, or prevent a disease.

Caution: Keep out of reach of children.

Contraindications: Avoid if persistent nausea/vomiting and/or mechanical obstruction occurs. Safety during pregnancy/lactation is not established, and diabetics should monitor blood sugar closely.

Drug Interactions: May impair absorption of quinolones, e.g., ciprofloxacin.

Contains no artificial colours, preservatives, or sweeteners; no dairy, wheat, gluten, yeast, egg, shellfish, tree nuts, or GMOs. Sealed for your protection. Do not use if seal is broken. For freshness, store in a cool, dry place.

References available at bioclinicnaturals.com



· GUARANTEED ·

Bioclinic Naturals[®] products are manufactured to meet or exceed current Good Manufacturing Practices (cGMP) of the U.S. Food and Drug Administration (FDA), Health Canada, and the Therapeutic Goods Administration (TGA) of Australia.



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bioclinicnaturals.com

FOR PROFESSIONAL USE ONLY. This product is not intended to diagnose, treat, cure or prevent any disease.

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ElementAll™ Biological Diet

About ElementAll™ Biological Diet

- An elemental diet (ED) provides complete and balanced nutrition for people with impaired digestive function. The easily digested and hypo-allergenic form promotes healing of the gastrointestinal tract.
- ElementAll Biological Diet contains all macronutrients (proteins, carbohydrates, and fats) broken down into their basic building blocks, and all essential vitamins and minerals required to be the sole source of nutrition.
- EDs have been shown to reduce inflammation and intestinal permeability (leaky gut), favourably shift the type and amount of bacteria in the gastrointestinal tract, and provide bowel rest, giving the gut a chance to heal while avoiding allergens and correcting underlying malnutrition.
- A full ED, in which all other sources of calories are avoided for at least two weeks, has been clinically shown to improve symptoms and signs of digestive health in individuals with Crohn's disease, irritable bowel syndrome, small intestinal bacterial overgrowth, rheumatoid arthritis, and celiac disease.
- A half ED, in which half of the daily calories are supplied by whole foods, has been shown to reduce relapse rates among individuals with Crohn's disease when used for a longer duration. Half EDs are also used to ease in and out of full EDs. The full or half ED protocol will be at the discretion of your health care practitioner.

How to Use ElementAll Biological Diet

- Mix one serving (4 scoops) in 500 mL of water or as directed by a health care practitioner. You can adjust by adding more water if desired. To be consumed promptly. Take 3 servings per day or as directed by a health care practitioner. Three servings (12 scoops) provide 1872 calories.
- Your dose is determined by your basal metabolic rate (determined by your height, weight, age, and gender), as well as your activity level, and should be determined by your health care practitioner. Most adults will likely need three servings per day while following a full ED.
- A full ED typically lasts two weeks but may be extended with your practitioner's recommendation. For a half-elemental diet, your daily dose of ElementAll Biological Diet is cut in half, with the other half of your caloric intake coming from low-allergenic whole foods.

PATIENT NAME: _____

PRACTITIONER NOTES:

Cautions and Contraindications

- This product is designed for dietary support and intended for use under the direction of a qualified health care practitioner. Keep out of the reach of children.
- Avoid if persistent nausea/vomiting and/or mechanical obstruction occur. Safety during pregnancy/lactation is not established, and diabetics should monitor blood sugar closely.

Drug Interactions

- May impair absorption of quinolones (e.g., ciprofloxacin).

Quick Tips for Optimal Health

- An ED can also be used as an "elimination" diet. By avoiding all allergenic foods, underlying food allergies can be unmasked as symptoms improve. After following a full ED, selectively reintroduce food back in during a "challenge" phase.
- Keep track of your weight during the ED as some weight loss may occur – be sure to communicate your progress with your health care practitioner.
- You can add ice cubes to the product and blend up for a smoothie-like texture. You can also pre-mix and store in the refrigerator for a cool drink.
- Drinking through a lid with a straw can also be helpful for variety, especially if you are sensitive to smells.
- You may find a full serving to be too much at one time – you can half the dose and have more frequent meals. You can also add additional water to the mix.
- Take advantage of the extra time not spent in food preparation by taking a walk, reading a book, etc.
- Be sure to stay well hydrated and maintain your regular intake of water during the ED.
- When finishing a full ED, you may find it easier to transition slowly back to a healthy diet by following a partial ED. To do this, add back low-allergenic whole foods while still supplementing with ElementAll Biological Diet for some of your nutritional needs.

PRACTITIONER CONTACT INFORMATION:

Elemental Diet Protocol

Introduction

An elemental diet (ED) offers significant clinical benefit for patients with digestive dysfunction, including those with Crohn's disease, rheumatoid arthritis, celiac disease, irritable bowel syndrome (IBS), and small intestinal bacterial overgrowth (SIBO). An ED provides complete nutrition, including amino acids, mono and disaccharides (organically sourced), medium chain triglycerides, as well as vitamins and minerals. By providing all needed nutrients in a pre-digested hypoallergenic form, an ED allows for healing of the GI mucosa, and potentially a shift in the GI microbiota.

Assessment

Depending on the patient's condition, various means of assessment may be applied. For example, clinical trials for participants with Crohn's disease typically monitor the frequency of remission, though one trial assessed small bowel permeability with sugar markers of permeability. All children enrolled in this trial had an elevated lactulose/rhamnose ratio before beginning dietary therapy, and by six weeks of an ED all had significant improvement, with 50% achieving normal values.¹ For individuals with increased intestinal permeability, sugar ratios may be one simple method of monitoring progress.

For individuals with suspected SIBO, a common non-invasive test is the lactulose breath test (LBT). Among participants with IBS and SIBO, after two weeks of an ED, 80% had normal LBTs, while 85% achieved normal results after an additional week of dietary therapy. Normalization of LBTs also correlated closely with clinical improvement in bowel symptoms.²

For those with rheumatoid arthritis, standard clinical measures can be used for assessment, such as early morning stiffness, pain on a visual analog scale, etc.³

General Recommendations

With any dietary supplement or medical food, administration and dosing are important components in achieving desired outcomes, and EDs are no different. Understanding these protocols can help the health care practitioner achieve the treatment objectives. An important factor in the administration and selection of an ED protocol is the health care practitioner's assessment and purpose for using it. These considerations will be important in calculating the proper protocol for each patient.

The most clinically studied of the EDs is the full elemental diet (full ED), with most clinical trials employing 100% of calories from an ED for a two-week period, though some have extended it for 4–6 weeks. This type of ED was first used in patients with limited or impaired capacity to digest, absorb, and/or metabolize foods. As mentioned earlier, an exclusive ED is implemented in inflammatory bowel disease (IBD) and those conditions that go hand in hand with IBD, such as SIBO and even IBS. Continued research into the microbiome and the relationship between gut health and systemic health, including the brain-gut connection, has also led to the development and use of shorter EDs, which may help jump-start gut healing.

In addition to use as a short-term therapy, a half elemental diet (half ED) may extend the benefits achieved with a full ED. In clinical practice, once the ED has produced the required effects, a half ED can be implemented. In this type of diet, half of the human physiological caloric requirements are met with the ED formula and the other half through whole, hypoallergenic foods. Clinical studies have shown that patients have better overall long-term effects when they employ a half ED immediately following a full ED in the management of conditions such as CD.^{4,5}

Protocols

Part A: Calculating nutritional requirements

1. First calculate the patient's basal metabolic rate (BMR):
 - a. Women: $BMR = 655 + (4.35 \times \text{weight in pounds}) + (4.7 \times \text{height in inches}) - (4.7 \times \text{age in years})$ **OR**
 - b. Women: $BMR = 655.1 + (9.563 \times \text{weight in kg}) + (1.850 \times \text{height in cm}) - (4.676 \times \text{age in years})$
 - c. Men: $BMR = 66 + (6.23 \times \text{weight in pounds}) + (12.7 \times \text{height in inches}) - (6.8 \times \text{age in years})$ **OR**
 - d. Men: $BMR = 66.5 + (13.75 \times \text{weight in kg}) + (5.003 \times \text{height in cm}) - (6.755 \times \text{age in years})$ ⁶⁻⁸
2. Final calculation with the Harris-Benedict Equation. This formula uses the calculated BMR and then applies an activity factor to determine the patient's actual total daily energy expenditure in calories. The more active a person is, the more calories they will use. Harris-Benedict Factors are the following:
 - a. Little-to-no exercise: $BMR \times 1.2 = \text{total daily calories}$
 - b. Light exercise/sports 1–3 days/week: $BMR \times 1.375 = \text{total daily calories}$
 - c. Moderate (moderate exercise/sports 3–5 days/week): $BMR \times 1.55 = \text{total daily calories}$
 - d. Very active (hard exercise/sports 6–7 days/week): $BMR \times 1.725 = \text{total daily calories}$
 - e. Extra active (very hard exercise/sports 6–7 days/week): $BMR \times 1.9 = \text{total daily calories}$.⁶⁻⁸

PART B: Different forms of the ED

1. Full ED

The patient consumes 100% of caloric requirements using the ED. This becomes the patient's sole source of nutrition for the designated time period, which normally spans 14 days (as evidenced by clinical trials).⁹⁻¹⁹

Application: CD, SIBO, and IBS.^{11,18}

Dosage: To accurately calculate the patient's total caloric needs, determine their BMR and then use the Harris-Benedict equation above to calculate total caloric requirements (approximately 1,800 calories per day). Advise the patient to take the calories in divided doses during the day: approximately 200–300 calorie servings every 2–3 hours over a 30-minute period until the caloric requirements are met.

Duration: Two weeks has been clinically validated. This time period can be extended at the sole discretion of the health care practitioner, if necessary.

2. Half ED

The patient consumes 50% of their daily caloric needs from the ED and the other 50% from a whole food diet. The scientific literature has found that half EDs (sometimes called partial EDs) help with maintaining remission of CD.²⁰ They can also be used when compliance becomes difficult for patients on full EDs for SIBO and IBS. In addition, half EDs can be used as starting and exiting conduits to full EDs, easing the patient's experience and possibly improving compliance.⁵

Application: Maintaining remission of CD after completion of the full ED, used as conduits to full EDs and in place of full EDs for patients having difficulty with compliance. This will be at the discretion of the health care practitioner.⁵

Dosage: The dose supplied by the half ED is 50% of the daily total calories divided into 200–300 calorie servings, consumed every 2 hours (use either first or second half of day). Whatever part of the day where the half ED is not used, the patient consumes a whole food diet.

To accurately calculate the patient's total needs, determine their BMR and then use the Harris-Benedict equation (see above) to calculate total caloric requirement (divide this by half to give the calories needed from the half ED, which should be approximately 900 calories per day).⁵

Duration: There are no published reports specifically demonstrating the optimal duration of a half ED, however, 4–6 weeks can be a good starting point. The duration would be calculated at the discretion of the health care practitioner, considering patient symptomatology and other markers deemed important.

3. Short ED

This can be used to give the gastrointestinal tract a "rest" by avoiding all the complex processes involved in digestion, including allergen and by-product exposure created through digestive and absorption processes. This can be useful in helping support gut mucosal healing processes. Due to the short duration, compliance is usually very good and may be used as a "bridge" to introduce the full ED.

Dosage: In a short ED, dosing can follow either the full-ED or half-ED directives and calculations can be made accordingly.

Duration: There are no published data regarding the duration of a short ED, however 1–3 days is generally the accepted time frame.

4. Intermittent ED

Although intermittent EDs have no clinical research, some health care practitioners believe that some benefit could be gained from giving the gastrointestinal tract a period of “rest” during parts of the day. In particular, the possible restoration of the migrating motor complex and, in turn, overall gastrointestinal health may benefit from an intermittent ED acting as a type of fast without compromising nutritional status.

Dosage: Intermittent EDs will entail consuming 300 calories over a 15-minute period.

Duration: There are no published studies on this type of use of the ED, but much like intermittent fasting, it can go on for several months. It is important to always be under the guidance of a health care practitioner during this time.

Note: No food or beverages should be consumed during the ED (water is unrestricted), however in specific cases there can be continued observable therapeutic effects with the addition of chicken or steak (no fat), herbal or black tea, or black coffee.

Part C: After the ED

Upon completion of the ED, a transition diet is recommended along with prokinetics with meals to prevent bloating and help with motility.

- Prokinetics with meals:
 - Ginger: 500 mg with each meal
 - Prescription medication at night
- Transition diet:
 1. Days 1–2: No fibre, meats, eggs, lactose
 2. Days 2–3: Add cooked pureed low FODMAP/fibre vegetables (e.g., carrots, zucchini)
 3. Day 4: Back to whole foods diet

Part D: Patient monitoring

Elemental diets are completed under the supervision of a health care practitioner, where several markers are monitored:

1. Compliance – Ensure that patients report the correct number of calories being consumed per day, according to directives.²¹
2. Weight – Monitoring weight is important as there will be some weight reduction in the first week of treatment on the full ED. Monitoring this marker also ensures that caloric consumption needs are being met during the diet.²¹
3. Symptoms – Monitor symptoms throughout the program, such as cramping and diarrhea due to osmolality, constipation, and nausea. The patient should report all of these symptoms as the diet may need to be adjusted as a result.²¹
4. Lactulose breath test (LBT) – This test helps diagnose SIBO, a condition that often goes hand in hand with IBS and IBD. Lactulose is a large sugar that is not digested by the body and thus has the ability to travel through the entire small intestine. During the test, patients are given a bolus of lactulose and then they collect breath over a period of time. Bacteria will take the lactulose and produce gases that include hydrogen and methane, depending on the type and quantity of bacteria. If certain percentages of gases are found in the breath, a diagnosis of SIBO is given.²² As noted previously, the vast majority of individuals with IBS and abnormal lactulose breath tests had normal values after three weeks of following an ED diet. Repeat testing may be considered if symptoms return, particularly if the ED diet has been discontinued.

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PRACTITIONER NOTES:

Cautions and Contraindications

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