



trumacro™ Ketogenic BHB + MCT

D,L-Beta-Hydroxybutyrate Mineral Salt Blend + Medium-Chain Triglycerides

PRODUCT INFORMATION

trumacro™ Ketogenic BHB + MCT Lemon Creme Flavor, 500g bulk powder

Manufactured in the U.S.A. in a cGMP facility for Disruptive Nutrition, LLC, Durham, North Carolina, U.S.A. www.trumacro.com.

DISPENSE BY PRESCRIPTION OR PHYSICIAN ORDER

trumacro™ Ketogenic BHB + MCT is a medical food for the dietary management of a patient requiring a source of ketone bodies where medium-chain triglycerides are tolerated, and other medical conditions for which the ketogenic diet is indicated. trumacro™ Ketogenic BHB + MCT is not intended to be used as a sole source of nutrition. trumacro™ Ketogenic BHB + MCT is to be used under the supervision of a licensed health care practitioner.

DESCRIPTION AND MEDICAL FOOD STATUS

trumacro™ Ketogenic BHB + MCT is a medical food containing a mixture of *D,L*-Beta-Hydroxybutyrate mineral salts and medium-chain triglycerides. trumacro™ Ketogenic BHB + MCT is used for the dietary management of patients requiring a source of ketone bodies and in support of the ketogenic diet. trumacro™ Ketogenic BHB + MCT is to be used only under medical supervision. trumacro™ Ketogenic BHB + MCT has been developed, labeled and should be used in accordance with the statutory and the Food and Drug Administration's (FDA's) regulatory definition of Medical Foods. The Orphan Drug Act of 1988 defines a medical food as "a food which is formulated to be consumed or administered enterally (or orally) under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation" [1]. Medical foods are specially formulated foods intended for the dietary management of certain medical conditions with distinctive nutritional requirements, which cannot be managed by altering a normal diet. Medical foods must be used under the supervision of a licensed health care practitioner.

trumacro™ Ketogenic BHB + MCT is a ready-to-use flavored powder providing a concentrated source of the ketone body beta-hydroxybutyrate plus a ketogenic fat (MCT). Ketone bodies, including beta-hydroxybutyrate, are naturally occurring fat metabolites used as fuel in the body for muscles, the heart, and the brain. The benefits of using trumacro™ Ketogenic BHB + MCT include a balanced mineral profile, variable dosing, mixability with water and foods, palatability, elevated and sustained nutritional ketosis, and the provision of an alternative energy source to carbohydrates and proteins.

INGREDIENTS

All ingredients in trumacro™ Ketogenic BHB + MCT are Generally Recognized as Safe (GRAS) as defined under the Food and Drug Administration guidance [2]. Ingredients are considered GRAS either because their safety had been established by a long history of use in food or by virtue of the nature of the substances, their conditions of use, and the information generally available to scientists.

Macronutrient Profile

trumacro™ Ketogenic BHB + MCT contains 40g fat, 11g carbohydrates, and 6g protein in addition to 20g ketones per 100g of formula. The formulation provides a unique fuel in the form of beta-hydroxybutyrate, a naturally occurring ketone body used by muscles, the brain, and the heart.

Micronutrient Profile

trumacro™ Ketogenic BHB + MCT contains significant levels of sodium, calcium, and magnesium as bound to the ingredient *D,L*-Beta-Hydroxybutyrate. trumacro™ uses this blend of minerals in order to deliver the maximum amount of beta-hydroxybutyrate while minimizing the total content of any one mineral. These minerals are crucial electrolytes and may be important when a ketogenic diet is used in conjunction with trumacro™ Ketogenic BHB + MCT. Typical intake levels do not exceed the upper tolerable limits for these minerals, but it is important to consider the contribution of these minerals to the overall dietary intake of the patient.

D,L-Beta-Hydroxybutyrate

trumacro™ Ketogenic BHB + MCT contains mineral salt forms of the biologically important ketone body, beta-hydroxybutyrate. The formulation contains a racemic mixture of *D,L*-beta-hydroxybutyrate.

Medium-Chain Triglycerides

Medium-chain triglycerides (MCTs) are an easily digestible, well-absorbed fat source which passively diffuse from the gastrointestinal tract into the hepatic portal system without the need for bile salts. "MCT are absorbed and metabolized as rapidly as glucose while having better than twice the caloric density of protein and carbohydrate. They are easily oxidized and utilized as fuel and energy, with little tendency to deposit as body fat. For a quick, high energy source, MCT are outstanding... Also, since MCT readily undergo β -oxidation, ketonemia is usually much more pronounced than with LCT (long chain triglyceride) emulsions [31]." The MCTs in trumacro™ Ketogenic BHB + MCT are a mixture of C8 and C10 fatty acids. The MCT is provided as a powder on a nonfat dry milk carrier. The powdered form may be better tolerated than the oil forms of MCT.

Potassium Citrate

Kidney stones are a potential side effect of the ketogenic diet in children. Consuming citrates has been shown to reduce the likelihood of stone formation. trumacro™ Ketogenic BHB + MCT contains potassium citrate at 32 mEq per 100g.

Silicon Dioxide

Silicon dioxide is used in small amounts to prevent clumping of trumacro™ Ketogenic BHB + MCT due to the humid conditions that can occur during home use.

Flavoring

trumacro™ Ketogenic BHB + MCT Lemon Creme Flavor contains natural flavors and is recommended for oral feeding. These flavors contribute 11g of carbohydrates per 100g of formula.

Sweeteners

trumacro™ Ketogenic BHB + MCT Lemon Creme Flavor contains the sugar alternative, stevia extract, and is recommended for oral feeding.

Colors

trumacro™ Ketogenic BHB + MCT Lemon Creme Flavor contains turmeric, a natural coloring agent.

Allergens

trumacro™ Ketogenic BHB + MCT contains milk. Trace amounts of milk proteins are present in the formula from the nonfat dry milk in MCT powder.

NUTRITION FACTS AND COMPLETE INGREDIENT LISTING

trumacro™ Ketogenic BHB + MCT, Lemon Creme Flavor

NUTRITION INFORMATION PER 100 GRAMS		
NUTRIENT COMPOSITION		AMOUNT
CALORIES	kcal	500
TOTAL FAT	g	40
SATURATED FAT	g	40
TRANS FAT	g	0
CHOLESTEROL	mg	5
SODIUM	mg	2690
TOTAL CARBOHYDRATES	g	11
DIETARY FIBER	g	0
TOTAL SUGARS	g	9
PROTEIN	g	6
CALCIUM	mg	1350
POTASSIUM	mg	1260
MAGNESIUM	mg	340
goBHB® Free D,L-Beta-Hydroxybutyrate	g	20

Ingredients: MCT oil powder (Medium-Chain Triglycerides, Nonfat Dry Milk, Disodium Phosphate, Silicon Dioxide), Sodium *D,L*-Beta-Hydroxybutyrate, Calcium *D,L*-Beta-Hydroxybutyrate, Magnesium *D,L*-Beta-Hydroxybutyrate, Citric Acid, Tripotassium Citrate, Natural Flavors, Malic Acid, Stevia Glycosides (*Stevia rebaudiana*), Silicon Dioxide, Turmeric (natural color).

CLINICAL EXPERIENCE

D,L-Beta-Hydroxybutyrate sodium salt has been used clinically in both healthy subjects and patient populations since the 1980s in an effort to understand both fat and ketone body metabolism [3-16]. More recently, *D,L*-Beta-Hydroxybutyrate sodium, calcium, and magnesium salts have been granted GRAS status and are ingredients in many consumer products and dietary supplements. *D,L*-Beta-Hydroxybutyrate salts are safe both for occasional and long-term use and rapidly induce ketosis upon ingestion. Nutritional intervention with *D,L*-Beta-Hydroxybutyrate in patients with many conditions have been reported [17-30].

trumacro™ Ketogenic BHB + MCT has unique benefits by providing two fuel sources as well as an extended pharmacokinetic profile (below). trumacro™ Ketogenic BHB + MCT is currently in clinical trials as a nutritional intervention for pediatric patients with Angelman syndrome (NCT03644693) and drug-resistant epilepsy (IRB#2020-3267).

Not all patients that could benefit from nutritional ketosis are able to digest/metabolize fats, so trumacro™ Ketogenic BHB + MCT is only suitable for patients that can tolerate MCT.

SERVING SIZE DETERMINATION

trumacro™ Ketogenic BHB+MCT is to be used under medical supervision. The health care practitioner will need to consider patient body weight, medical conditions, medications, and dietary intake when determining the amount of formula to consume each day, as well as how often. Full nutrition information can be incorporated into a dietary plan using the Keto Diet Calculator app available at the Charlie Foundation website: <https://www.ketodietcalculator.org>.

The formula can be weighed out for each serving, or the common household measure equivalent can be used, based on HCP recommendation. All measures are “leveled,” i.e. “one level teaspoon.” The equivalents are shown below:

Formula in Grams	Household Measure
0.35	1/8 teaspoon
0.7	1/4 teaspoon
1.4	1/2 teaspoon
2.8	1 teaspoon
5.6	2 teaspoons
9	1 tablespoon
35	1/4 cup
70	1/2 cup
140	1 cup

The chart below is used to determine the amount of *D,L*-beta-hydroxybutyrate consumed per day based on desired target consumption and patient body weight. For example, if the HCP determines that the patient should consume 250mg of *D,L*-beta-hydroxybutyrate per kg of body weight per day, and the patient weighs 40kg, then 50g of formula should be consumed. If it is determined that three servings spread across the day is desired, then this would correlate to about 13g per serving.

Product administration guidelines based on patient body weight:

QUICK REFERENCE GUIDE FOR MILLIGRAMS OF BHB PER KG PER DAY BASED ON AMOUNT OF FORMULA CONSUMED

		Grams of formula per day									
		5	10	15	20	25	30	40	50	75	90
Body weight in kilograms	5	200	400	600	800	1000	1200	1600	2000	3000	3600
	10	100	200	300	400	500	600	800	1000	1500	1800
	15	67	133	200	267	333	400	533	667	1000	1200
	20	50	100	150	200	250	300	400	500	750	900
	25	40	80	120	160	200	240	320	400	600	720
	30	33	67	100	133	167	200	267	333	500	600
	35	29	57	86	114	143	171	229	286	429	514
	40	25	50	75	100	125	150	200	250	375	450
	45	22	44	67	89	111	133	178	222	333	400
	50	20	40	60	80	100	120	160	200	300	360
	55	18	36	55	73	91	109	145	182	273	327
	60	17	33	50	67	83	100	133	167	250	300
	65	15	31	46	62	77	92	123	154	231	277
	70	14	29	43	57	71	86	114	143	214	257
	75	13	27	40	53	67	80	107	133	200	240
	80	13	25	38	50	63	75	100	125	188	225

Calculation to determine the amount of formula to consume each day based on a target amount of free BHB:

$$\text{grams of formula per day} = \frac{(\text{grams/kg/day of free BHB desired}) \times (\text{kg body weight}) \times 100 \text{ grams of formula}}{20 \text{ Grams of free BHB in formula}}$$

For example: $\frac{(0.125\text{g/kg/day BHB})(83\text{kg})(100\text{g})}{20\text{g}}$ = 52g of formula per day (17g three times per day, approximately 2 tablespoons each serving)

PHARMACOKINETICS

Beta-hydroxybutyrate mineral salts when dissolved in an aqueous environment dissociate into free beta-hydroxybutyric acid and the corresponding mineral ion; both of which are rapidly absorbed by the small intestine. When consumed as a single ingredient, beta-hydroxybutyrate blood levels rise rapidly and peak between 30-90 minutes, declining back to baseline by 3 hours post ingestion [35]. The degree and duration of ketosis are directly related to the amount consumed and is affected by dietary habits, whether or not the subject is fed or fasted when ingesting the material, and genetic predisposition. Blood ketone levels typically increase by about 0.5-1 mMol [35]. Beta-hydroxybutyrate blood levels will decline back to basal levels by about four hours. Concurrently, urine acetoacetate levels will start to rise by 30 minutes post ingestion and taper off slowly by 3-4 hours.

Medium-chain triglycerides are absorbed by the gut and into the portal vein and rapidly β -oxidized in the liver to acetyl-CoA, the substrate for ketogenesis [33]. When consumed as a single ingredient, MCT oil has been shown to increase blood ketone levels by 0.2-0.5 mMol starting at 30 minutes, peaking after about an hour, then declining back to baseline after less than 2 hours [32]. Similarly, the degree and duration of ketosis are directly related to the amount consumed and is affected by basal dietary habits, whether or not the subject is fed or fasted when ingesting the material, and genetic predisposition.

The combination of beta-hydroxybutyrate with MCT provides an elevated and sustained ketosis that is superior to either ingredient alone. Blood ketone levels rise by 1.0 mMol and peak around 60 minutes, and remain significantly elevated up to 6 hours later [34]. There is the potential for blood glucose to dip slightly depending on background dietary habits, and whether or not the subject is fed or fasted when ingesting the material. Therefore, close monitoring is important if a patient is susceptible to hypoglycemia.

PRECAUTIONS and CONTRAINDICATIONS

trumacro™ Ketogenic BHB + MCT contains significant amounts of the electrolytes sodium, calcium, magnesium, and potassium, and therefore, should only be used under medical supervision. trumacro™ Ketogenic BHB + MCT may not be suitable for individuals that are sodium sensitive. There are certain conditions in which a ketogenic diet may be contraindicated, and therefore, the use of ketone-containing formulations may also be contraindicated, such as:

- Beta-oxidation defects
- Carnitine deficiency (primary)
- Carnitine palmitoyltransferase I or II deficiency
- Carnitine translocase deficiency
- Porphyria
- Pyruvate carboxylase deficiency
- Long-chain 3-hydroxyacyl-CoA deficiency
- Medium-chain 3-hydroxyacyl-CoA deficiency
- Long-chain acyl dehydrogenase deficiency
- Medium-chain acyl dehydrogenase deficiency
- Short-chain acyl dehydrogenase deficiency
- Long-chain 3-hydroxyacyl-CoA deficiency

SPECIAL POPULATIONS

trumacro™ Ketogenic BHB + MCT is appropriate for consumption by patients that require a dietary source of beta-hydroxybutyrate. trumacro™ Ketogenic BHB + MCT Lemon Creme Flavor is suitable for oral feeding. Always check with your physician for proper use recommendations.

ADMINISTRATION

Use as directed by your physician. Must be administered under medical supervision only. Dry powder should be stored in a cool, dry place. Powder can be mixed in water where it readily dissolves, or mixed with food. Once reconstituted, any unused mixture should be refrigerated and consumed within 24 hours.

HOW SUPPLIED

trumacro™ Ketogenic BHB + MCT is supplied as a bulk powder, 500 grams per container. Store in a cool, dry place.

ADVERSE REACTIONS

There are no known incremental adverse reactions for the use of trumacro™ Ketogenic BHB + MCT as a part of dietary intervention. Consumption of MCT and *D,L*-Beta-Hydroxybutyrate mineral salts are well tolerated. Reported side effects include gastrointestinal discomfort, dehydration, metabolic alkalosis, and renal stone formation [20-21]. Close medical supervision is required.

DRUG INTERACTIONS

trumacro™ Ketogenic BHB + MCT, when used as a medical food for supplemental nutrition, may impact how some drugs are metabolized. All medications should be discussed with a physician or pharmacist. Medical supervision by a physician is required.

REFERENCES

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