



# ULTRAMEAL®

Medical Food in Powdered Beverage Form

## INDICATIONS AND USAGE

UltraMeal is indicated for individuals with conditions associated with altered body composition (excess body fat), such as:

- Hypertension
- Metabolic syndrome
- Dyslipidemia
- Estrogen imbalance

UltraMeal is specifically formulated to nutritionally support the management of these conditions while promoting a healthy, lean body composition.

## DESCRIPTION

UltraMeal is a nutritionally fortified, soy-based, powdered medical food designed for those who want to improve their body composition. UltraMeal mixes easily with water for a balanced meal or healthy snack, and is available in a variety of delicious flavors for greater patient compliance. UltraMeal has been clinically tested and shown to have a low glycemic index, making it an appropriate form of nutritional support for those with insulin and blood glucose dysregulation. To meet other dietary restrictions, UltraMeal is also free of dairy, wheat, gluten, egg, yeast, and artificial colors, flavors, and sweeteners. For added convenience, the ready-to-eat UltraMeal® Bar is available in Chocolate Raspberry.

## Nutritional Information Per Serving:

Serving Size	2 Scoops (47 g)
Servings Per Container	14
Calories	160
Fat	2 g
Cholesterol	0 mg
Sodium*	170-180 mg
Potassium*	510-660 mg
Total Protein	15 g
Total Carbohydrate	24 g
Simple	5 g
Complex	10 g
Dietary Fiber*	4-5 g
Soy Isoflavones	17 mg
Vitamin A (as retinyl palmitate)	1750 IU
Vitamin D (as cholecalciferol)	200 IU
Vitamin C (as ascorbic acid)	60 mg
Vitamin E (as d-alpha tocopheryl acetate)	11 IU
Thiamin (as thiamin hydrochloride)	750 mcg
Riboflavin	850 mcg
Niacin (as niacinamide)	10 mg
Pantothenic Acid (as D-calcium pantothenate)	5 mg
Vitamin B <sub>6</sub> (as pyridoxine hydrochloride)	25 mg
Vitamin B <sub>12</sub> (as methylcobalamin and cyanocobalamin)	30 mcg
Biotin	150 mcg
Folate <sup>†</sup> (as folic acid, L-5-methyl tetrahydrofolate <sup>††</sup> , and 5-formyl tetrahydrofolate)	500 mcg
Vitamin K	40 mcg
Calcium (as calcium phosphate)	600 mg
Iron (as ferrous fumarate)	3 mg
Phosphorus	460 mg
Iodine (as potassium iodide)	75 mcg
Magnesium (as magnesium citrate)*	180-190 mg
Zinc (as zinc citrate)	9 mg
Copper (as copper gluconate)	1 mg
Manganese (as manganese gluconate)	1 mg
Molybdenum (as molybdenum amino acid chelate)	75 mcg
Chromium (as chromium polynicotinate)	100 mcg
Selenium (as selenomethionine)	35 mcg

**Other Ingredients (Vanilla):** Soy protein isolate (PharmaSoy®), fructose, maltodextrin, soy fiber, corn bran, natural flavors, lecithin, olive oil, xanthan, carrageenan, and cellulose gum.

\*Content varies according to flavor.

†Featuring ActiFolate™, a proprietary blend of active folates.

††As Metafolin® U.S. Patent Nos. 5,997,915; 6,254,904.

## METHOD OF ACTION

### Controlled Calorie Program

UltraMeal provides a meal option of only 160 calories as an ideal part of a proactive body composition program that includes a lowfat diet and moderate exercise.

### Low Glycemic Index

Glycemic index (GI) is a value assigned to a food based on its postprandial glycemic response—defined as the rise in blood glucose after ingestion. This is compared to the rise generated by the ingestion of a standard test food. In clinical testing, UltraMeal was shown to have a GI of 44 (when referenced against white bread) and 31 (when referenced against glucose), which classifies it as a low GI food.<sup>1</sup> Because low GI foods have a lower potential for raising blood glucose levels, UltraMeal is considered to be beneficial for individuals with dysglycemia.<sup>2</sup>

## Soy Protein and Isoflavones

Soy protein may help improve body composition by promoting a healthy lean muscle mass. In particular, research suggests that soy isoflavones—such as genistin and daidzin—enhance weight control in animals and humans. This is presumably due to their effects on pancreatic insulin secretion, antioxidative actions, or estrogen receptor-mediated mechanisms.<sup>3,4</sup> Isoflavones have also been shown to support breast health in women and prostate health in men, possibly by providing antioxidant activity and targeting estrogen and androgen-mediated signaling pathways.<sup>5</sup> Furthermore, diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease.<sup>6</sup> (UltraMeal provides 15 grams of soy protein per serving.)

## Fiber

As part of a healthy diet, fiber supports healthy body composition management due to its unique properties that enhance or prolong signals of satiety. Increased fiber intake is also associated with improved gastrointestinal function and reduced risk of cardiovascular disease and certain forms of cancer.<sup>7,9</sup>

## Chromium

Preliminary evidence suggests that chromium may help reduce excess body fat and increase lean muscle mass. This is most likely due to its beneficial effects on glucose, insulin, and lipid metabolism.<sup>10,11</sup>

## Dairy-Free Calcium

Numerous studies have shown that calcium promotes optimal bone health in individuals of all ages. Recent research suggests that calcium, combined with a moderate exercise program, improves body composition management in animals and humans.<sup>12-14</sup>

## ActiFolate™

ActiFolate is a proprietary blend of active folates that provides folic acid, 5-formyl tetrahydrofolate, and L-5-methyl tetrahydrofolate to enhance folate status—even in individuals with genetic variations in folate metabolism.

### Folate (Folic acid)

Folate provides the one-carbon units necessary for methylation of a wide variety of biological substances, including DNA, homocysteine, neurotransmitters, catechol estrogens, phospholipids, and proteins. Thus, healthy folate status is critical to maintaining the health of the cardiovascular, skeletal, and nervous systems as well as normal growth and development, mental function, and breast health.<sup>15,16</sup>

### 5-formyl tetrahydrofolate (5-formyl THF)

As an intermediate form of folate, 5-formyl THF is a highly efficient and bioavailable source of folate. Through direct supplementation of 5-formyl THF, numerous enzymatic steps in folate metabolism can be bypassed.

### Metafolin®: L-5-methyl tetrahydrofolate (L-5-MTHF)

Due to genetic variation in the activity of the folate metabolizing enzyme methylenetetrahydrofolate reductase (MTHFR), up to 40% of the population may not receive all the vital benefits expected from dietary folate or folate supplementation. That is, folate may not be converted efficiently into one of its biologically active forms—L-5-MTHF. Because L-5-MTHF is the form most used by the body, it may be preferred for this large segment of the population.<sup>17</sup>

## B Vitamins

Along with folate, vitamins B<sub>6</sub> and B<sub>12</sub> function as important cofactors for methylation and estrogen metabolism. In addition, vitamin B<sub>6</sub> metabolites are involved in the biosynthesis of serotonin, suggesting it may positively impact mood and the ability to cope with stress.<sup>18-20</sup>

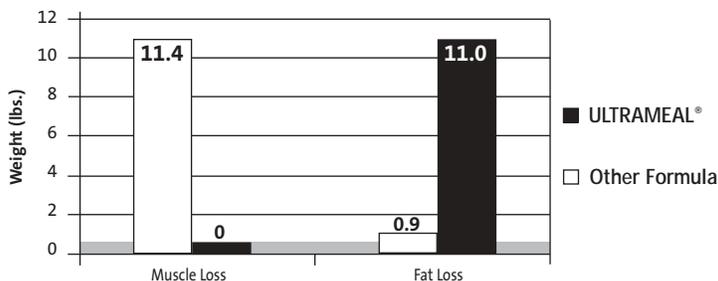
## Other Vitamins and Minerals

UltraMeal contains other important vitamins and minerals such as high potency B vitamins, iron, selenium, etc. that act as important cofactors and coenzymes required for normal metabolic functioning and overall health.

## CLINICAL STUDIES

At the University of Oregon School of Human Performance, 18 subjects were instructed to take UltraMeal on a daily basis (2-3 times a day). All subjects followed a reduced calorie diet and participated in a moderate exercise program 3 times a week. Body weight, body mass index (BMI), waist-to-hip ratio, and skinfold caliper measurements were monitored throughout the 7-week study. At the end of the study, subjects not only lost weight but also had lowered their percentage of body fat and increased their percentage of lean muscle. Magnetic resonance spectroscopy offered evidence that mitochondrial energy dynamics had improved, suggesting that muscle energy function was preserved over the course of the study.<sup>21,22</sup>

In another study, 34 subjects were assigned to one of two 10-week dietary intervention programs. Twenty-two subjects followed a doctor-supervised program utilizing UltraMeal. The remaining 12 subjects were placed on an unsupervised, over-the-counter beverage program. All subjects were instructed to follow the same dietary regimen and exercise routine. Laboratory assessment, fitness evaluation, body composition analysis, and anthropometric measurements were made at weeks 0, 2, 6, and 10. Upon completion of the study, subjects in both groups lost weight, but only the UltraMeal subjects lost predominantly body fat as assessed by body composition analysis. Subjects taking the unsupervised, over-the-counter beverage lost the majority of their weight as lean muscle, rather than as body fat.<sup>23</sup>



## CAUTIONS

### General

While calorie reduction is an important component of any body composition program, dietary plans that provide less than 800 calories a day are not recommended. Individuals with a hypersensitivity to ingredients in UltraMeal should avoid use. Individuals with soy hypersensitivities may wish to try UltraMeal® RICE.

### Vitamin A

Chronic high vitamin A (retinyl acetate or palmitate) intake has been associated with an increased risk of bone fracture in epidemiological studies. These findings remain controversial and are not applicable to beta-carotene/mixed carotenoids. Low dose vitamin A (1,250 IU or less) is generally thought to be safe for adults.

### Vitamin B<sub>6</sub>

Taking high doses (200 mg per day or greater) of vitamin B<sub>6</sub> for prolonged periods of time may cause temporary, reversible neurological symptoms. If these symptoms occur, decrease vitamin B<sub>6</sub> intake until symptoms diminish.

### Soy and Thyroid Function

Some individuals who have an underactive thyroid or who may be predisposed to thyroid problems may want to limit their intake of soy. Although the mechanism(s) is (are) unclear, an effect on thyroid peroxidase has been demonstrated in animal studies. Individuals who are taking thyroid medication may want to refrain from simultaneous ingestion of soy products as soy may limit the absorption of the medication. A rice-based, functional food alternative for those who may be sensitive to soy is available in Natural Chocolate.

### Pregnancy and Nursing

Due to lack of testing in these individuals, UltraMeal is not recommended for pregnant or nursing women.

### Children

The nutritional content of UltraMeal is based on adult RDIs (Reference Daily Intakes), and no testing in children has been done thus far. For these reasons, UltraMeal is not recommended for use in infants or children under the age of 12.

## POTENTIAL DRUG/NUTRIENT INTERACTIONS

### Hormone Replacement Therapy/Oral Contraceptives

Although no adverse effects have been reported, the isoflavones in UltraMeal may interact with hormone replacement therapy or oral contraceptives by competing for estrogen receptor sites.<sup>26</sup>

### Warfarin

UltraMeal contains a low dose of vitamin K. At higher doses, vitamin K can compete with warfarin and increase clotting activity.

## WARNINGS

### Vitamin A

Excess vitamin A may be toxic and may increase the risk of birth defects. Pregnant women and women who may become pregnant should not exceed 5,000 IU of preformed vitamin A (retinyl acetate or palmitate) per day.

### STORAGE

Keep tightly closed in a cool, dry place.

### DOSAGE AND ADMINISTRATION

Blend, shake, or briskly stir two level scoops into eight ounces of chilled water.

### HOW SUPPLIED

23.2 oz. (658 g) powder container.

## REFERENCES

1. Brand-Miller J, Wolever TMS, Colaguri S, et al. *The Glucose Revolution*. 1st ed. New York: Marlowe & Co;1999:28.
2. Willett W, Manson J, Liu S. Glycemic index, glycemic load, and risk of type 2 diabetes. *Am J Clin Nutr* 2002;76(1):274S-80S.
3. Goodman-Gruen D, Kritz-Silverstein D. Usual dietary isoflavone intake is associated with cardiovascular disease risk factors in postmenopausal women. *J Nutr* 2001;131(4):1202-06.
4. Bhatena SJ, Velasquez MT. Beneficial role of dietary phytoestrogens in obesity and diabetes. *Am J Clin Nutr* 2002;76(6):1191-201.
5. Sarkar FH, Li Y. Mechanisms of cancer chemoprevention by soy isoflavone genistein. *Cancer Metastasis* 2002;21(3-4):265-80.
6. U.S. Department of Health and Human Services. (1999). *FDA approves new health claim for soy protein and coronary heart disease* (FDA Talk Paper No. T99-48). Rockville, MD.
7. Anderson JW, Gustafson NJ, Bryant CA, et al. Dietary fiber and diabetes: a comprehensive review and practical application. *J Am Diet Assoc* 1987;87(9):1189-97.
8. Anderson JW, Bryant CA. Dietary fiber: diabetes and obesity. *Am J Gastroenterol* 1986;81(10):898-906.
9. Howarth NC, Saltzman E, Roberts SB. Dietary fiber and weight regulation. *Nutr Rev* 2001;59(5):129-39.
10. McCarty MF. Exploiting complementary therapeutic strategies for the treatment of type II diabetes and prevention of its complications. *Med Hypotheses* 1997;49(2):143-52.
11. Anderson RA, Cheng N, Bryden NA, et al. Elevated intakes of supplemental chromium improve glucose and insulin variables in individuals with type 2 diabetes. *Diabetes* 1997;46(11):1786-91.
12. Teegarden D. Calcium intake and reduction in weight or fat mass. *J Nutr* 2003;133(1):249S-51S.
13. Papakonstantinou E, Flatt WP, Huth PJ, et al. High dietary calcium reduces body fat content, digestibility of fat, and serum vitamin D in rats. *Obes Res* 2003;11(3):387-94.
14. Parikh SJ, Yanovski JA. Calcium intake and adiposity. *Am J Clin Nutr* 2003;77(2):281-87.
15. Jacob R. Folate, DNA methylation, and gene expression: factors of nature and nurture. *Am J Clin Nutr* 2000;72:903-04.
16. Shils M, Olson J, Shike M, et al. *Modern Nutrition in Health and Disease* 9th ed. Williams & Wilkins: Baltimore, MD: 1999.
17. Fohr IP, Prinz-Langenohl R, Bronstrup A, et al. 5,10-Methylenetetrahydrofolate reductase genotype determines the plasma homocysteine-lowering effect of supplementation with 5-methyltetrahydrofolate or folic acid in healthy young women. *Am J Clin Nutr* 2002;75(2):275-82.
18. Fafouti M, Paparrigopoulos T, Liappas J, et al. Mood disorder with mixed features due to vitamin B(12) and folate deficiency. *Gen Hosp Psychiatry* 2002;24(2):106-09.
19. McCarty MF. High-dose pyridoxine as an 'anti-stress' strategy. *Med Hypotheses* 2000;54(5):803-07.
20. Bender D. Oestrogens and vitamin B<sub>6</sub>—actions and interactions. *Wild Rev Nutr Diet* 1987;51:140-88.
21. Hackman RM, Ellis BK, Brown RL. Phosphorous magnetic resonance spectra and changes in body composition during weight loss. *J Am Coll Nutr* 1994;13(3):243-50.
22. Hackman RM, Ellis BK. Increased lean body mass in conjunction with fat loss during a comprehensive weight management programme. *Int Clin Nutr Rev* 1991;11(4):184-89.
23. Bland JS, DiBase F, Ronzio R. Physiological effects of a doctor-supervised versus an unsupervised over-the-counter weight-loss program. *J Nutr Med* 1992;3:285-93.
24. Divi RL, Chang HC, Doerge DR. Anti-thyroid isoflavones from soybean: isolation, characterization, and mechanisms of action. *Biochem Pharmacol* 1997;54(10):1087-96.
25. Persky VW, Turyk ME, Wang L, et al. Effect of soy protein on endogenous hormones in postmenopausal women. *Am J Clin Nutr* 2002;75(1):145-53.
26. Morito K, Hirose T, Kinjo J, et al. Interaction of phytoestrogens with estrogen receptors alpha and beta. *Biol Pharm Bull* 2001;24(4):351-56.