LeptiCore®
healthy weight management for metabolic wellness

Product Summary

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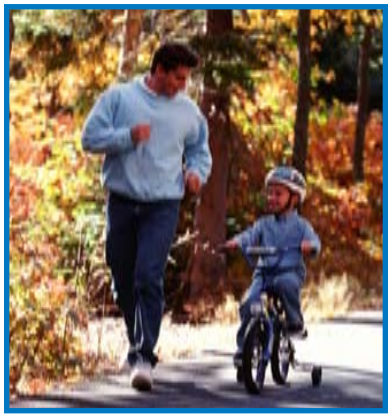
According to recent CDC figures, 68% of American adults and nearly one third of American children are considered overweight or obese. This is particularly troubling because each of these conditions is a primary cause of metabolic syndrome (sometimes called Syndrome X). Metabolic syndrome, which affects 50 million Americans according to data from the American Heart Association and the National Heart, Lung, and Blood Institute, is a cluster of conditions involving abdominal obesity, elevated blood lipid levels and blood pressure, insulin resistance, and inflammation. To date, metabolic syndrome has been managed primarily by treating each risk factor individually with pharmacological or natural agents, with varied success.While there have been some quantifiable benefits from using these agents, the combination of safety concerns, high costs, and the complex nature of the condition has stressed the need for new ingredients with increased efficacy. This has led to the development of LeptiCore®, the most comprehensive, proprietary nutraceutical complex yet developed to address key risk factors associated with Healthy Weight Management and metabolic syndrome.*

Metabolic Wellness Begins with Healthy Weight Management

LeptiCore® is a patent-pending, multifunctional complex of plant-based polysaccharides, esterified fatty acids, pomegranate extract, beta-carotene, and blue-green algae. These complementary ingredients provide multiple mechanisms of action to support Metabolic Wellness and overall health.* Of primary importance is LeptiCore's role in Healthy Weight Management because the risk of developing metabolic syndrome rises dramatically when a person is overweight or obese. To address this key issue, LeptiCore® was formulated to promote Healthy Weight Management through the correction of leptin resistance, which helps support increased satiety, loss of appetite, blood sugar balance, and thermogenesis.* These mechanisms of action led to significant reductions in body weight, stored body fat, and waist and hip size in a randomized, double-blind, placebo-controlled clinical trial involving 92 subjects who took 300 mg of LeptiCore twice daily for 8 weeks.

LeptiCore® Enhances Leptin Function

The primary mechanism utilized in LeptiCore® to support Healthy Weight Management is through enhancement of leptin function.* Leptin is a hormone produced by fat cells that regulates body weight. Normally, in healthy weight individuals, leptin crosses the blood-brain barrier to influence brain activity in the areas of satiety and appetite suppression. Leptin also boosts glycemic control and metabolism. In overweight and obese people, leptin production is high, yet its function is diminished because the body becomes resistant to it. Leptin resistance results in increased appetite, poor blood sugar balance, and slower metabolism. LeptiCore® is clinically proven to lower leptin resistance and improve leptin function.* This is a primary factor in LeptiCore's ability to promote weight and fat reduction.*



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LeptiCore® Addresses Additional Metabolic Risk Factors and Enhances Mood

LeptiCore® contains two antioxidants, pomegranate extract and beta-carotene, that address other risk factors of metabolic syndrome including inflammation and elevated blood lipids.* These risk factors, which also affect cardiovascular health, reach dangerous levels in overweight and obese people. LeptiCore® is clinically proven to reduce C-reactive protein (a marker of systemic inflammation that is inflated in people with metabolic syndrome), lower LDL (bad) cholesterol, and raise HDL (good) cholesterol. In addition, LeptiCore® enhances mood because the blue-green algae it is formulated with contains phenylethylamine (PEA).* Studies have shown that PEA raises levels of serotonin, a neurotransmitter in the brain that is associated with enhanced mood. In a recent clinical trial, serotonin levels rose significantly in subjects who took 300 mg of LeptiCore® twice daily. In addition, serotonin suppresses appetite by a mechanism that is complementary to that of leptin, further contributing to LeptiCore's weight management properties.*

LeptiCore® Substantiated Claims for Dietary Supplements

LeptiCore's clinically proven properties substantiate a diverse range of structure/function claim areas for Healthy Weight Management (Weight Loss/Weight Management, Satiety/Appetite Control, Thermogenesis, Mood Enhancement) and Metabolic Wellness (Cardiovascular Health, Blood Sugar Balance, Metabolic Balance/Metabolic Wellness, Inflammation Response, Antioxidant). These claims are in accordance with the requirements of the Dietary Supplement Health and Education Act of 1994 and have been submitted to the Food and Drug Administration accordingly.

HEALTHY WEIGHT MANAGEMENT

Weight Loss/Weight Management Claims

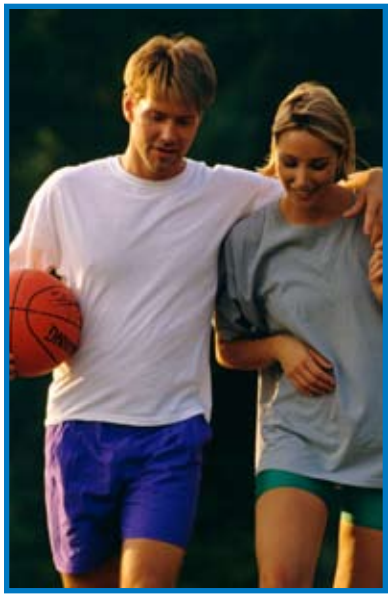
- Helps provide effective multifunctional weight loss activity*
- Promotes healthy weight management *
- Clinically proven to promote weight loss activity*

Satiety/Appetite Control Claims

- Helps you feel fuller longer*
- Helps support a feeling of fullness and satiety*
- Fullness and satiety promoter*

Thermogenesis Claims

- Promotes thermogenesis*
- Boosts metabolism*



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Mood Enhancement Claims

- Helps promote a positive mind and mood*
- Enhances feelings of emotional well-being*
- Helps promote a peaceful state of mind*

METABOLIC WELLNESS

Cardiovascular Health Claims

- Supports healthy cardiovascular function*
- Helps support cholesterol levels which are already within the normal range*

Blood Sugar Balance Claims

- Helps support blood sugar levels which are already within the normal range*

Metabolic Balance/Metabolic Wellness Claims

- Supports weight management and metabolic balance/wellness*
- Helps to regulate and balance healthy metabolic function*

Inflammation Response Claims

- Maintains a healthy inflammatory response*
- Promotes a healthy response to inflammation*

Antioxidant Claims

- Provides antioxidant protection*
- Helps to protect cellular and tissue health*
- Helps retard the aging effects from pro-oxidative cellular damage*

Product Summary

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Features & Benefits

- Patent-Pending
- Clinically Proven in Double-Blind, Placebo-Controlled Clinical Trials
- Substantiated Structure/Function Claims
- Well-Defined Chemical Composition
- Safe and Effective
- Experiential
- Stable- Two-Year Shelf Life
- Vegetarian

LeptiCore® multifunctional nutraceutical may be utilized as either a stand-alone or complementary ingredient in various formulations. Due to the breadth and strength of the claims support for LeptiCore®, the ingredient can serve as "the active" in multiple-ingredient formulations.

LeptiCore® heightens the proprietary status of a wide variety of product applications including:

Weight management, metabolic wellness/balance, blood sugar balance, cardiovascular health, and gender-specific formulas

Safety & Stability

LeptiCore® has an exceptional safety and stability profile. In an 8 week long human clinical trial involving 92 subjects, LeptiCore® was well tolerated with no dropouts. Additionally, LeptiCore® is supported by both sub-acute and LD_{50} oral toxicity studies confirming its safety. Accelerated stability studies confirm that LeptiCore® has a shelf life of two years.

Product Application & Dosage

Suitable for encapsulation, tableting, drink mixes, and liquid preparations. Suggested dosage: 300 mg twice a day taken before meals

LeptiCore®
healthy weight management
for metabolic wellness

Product Profile

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LeptiCore® is the first patent-pending, clinically-proven complex of complementary natural ingredients that supports Healthy Weight Management as well as the key risk factors associated with metabolic syndrome in an effective, multifunctional manner.* Plant-based polysaccharides and esterified fatty acids act in concert to help improve leptin function, which promotes weight loss.* Pomegranate extract and beta-carotene antioxidants help reduce inflammation and improve blood lipid levels.* High-phenylethylamine (PEA) blue-green algae supports Healthy Weight Management by helping to enhance mood and increase satiety.*

LeptiCore® - Clinically Proven to Promote Weight Loss and Improve Body Size

Promoting Healthy Weight Management is vital to achieving Metabolic Wellness because overweight and obese individuals are much more likely to develop metabolic syndrome compared to those with normal weight according to the Third National Health and Nutrition Examination Survey. Indeed, a wide body of scientific research has shown that weight loss leads to a significant reduction in risk factors for metabolic syndrome. With this in mind, developers of LeptiCore® created a unique complex of ingredients that, when taken as directed, leads to a significant reduction in weight and improvement in body size. In a randomized, double-blind, placebo-controlled clinical trial, 92 subjects who were suffering from metabolic syndrome (as defined by American Heart Association criteria) and who maintained their normal diet took 300 mg of LeptiCore® twice daily before meals for 8 weeks and lost 5.24 kg ($p \leq 0.001$ compared to placebo), which represents a 5.4% reduction in weight compared to baseline (Figure 1). This was accompanied by significant reductions in body fat (2.8%; Figure 2), waist size (4.6 cm), and hip size (4.4 cm) over the same period ($p \leq 0.05$ compared to placebo).

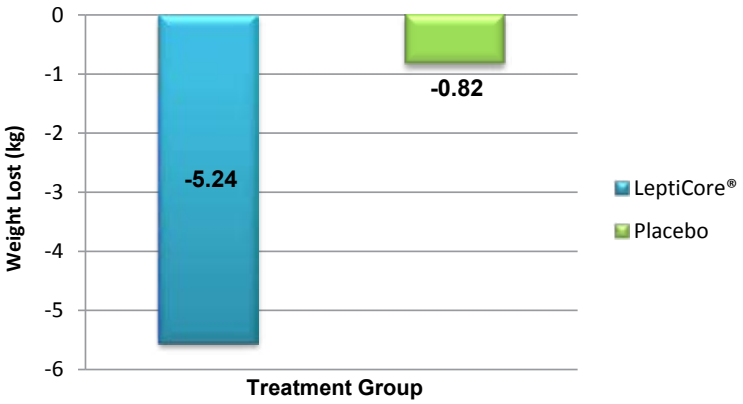

Figure 1. Amount of Weight Lost by Subjects Receiving LeptiCore® Compared to a Placebo after 8 Weeks.

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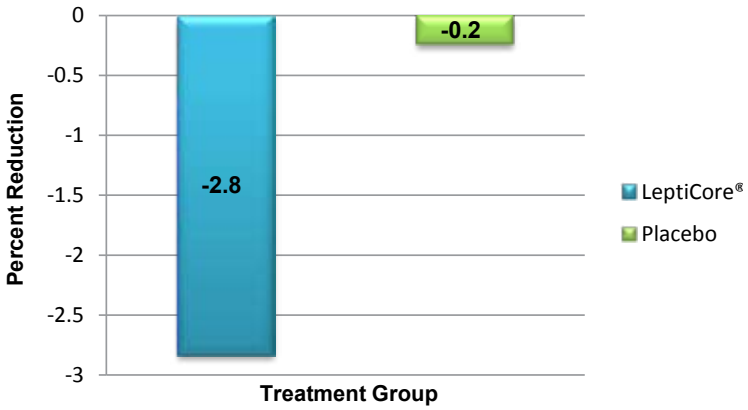


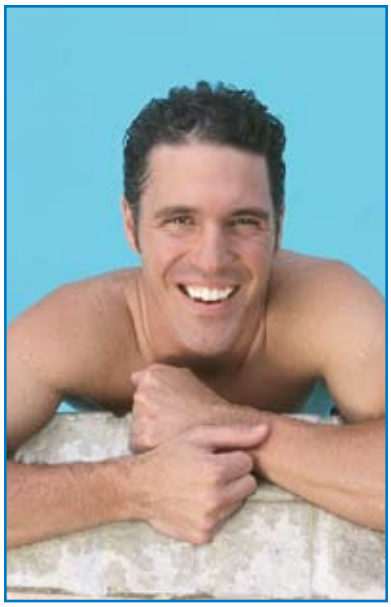
Figure 2. Percent Reduction in Body Fat in Subjects Receiving LeptiCore® Compared to a Placebo after 8 Weeks.

LeptiCore® Enhances Leptin Function

LeptiCore® utilizes a proprietary formulation that was created specifically to stimulate multiple mechanisms of action that support healthy weight loss. A primary mechanism is the improvement of leptin function. This has wide ranging effects in the body because, as extensive scientific research has confirmed, leptin is a hormone produced by fat cells that controls satiety, appetite, blood sugar balance, and thermogenesis while reducing abdominal obesity. Leptin acts as a lipostat to regulate body weight; the more fat a person carries, the more leptin that is produced. Under normal conditions, leptin exists in a free state in the blood, which allows it to cross the blood-brain barrier and produces its effects by binding to receptors on the surface of neurons in a region of the brain called the hypothalamus.

Overweight and obese people produce high levels of leptin from excessive quantities of fat, yet at these levels leptin function decreases because of widespread, systemic inflammation. This leptin resistance makes it difficult for people to lose weight because it leads to increased appetite, poor blood sugar balance, and slower metabolism.

Researchers at the University of Pittsburgh School of Medicine have demonstrated that elevated levels of C-reactive protein (CRP), a marker of systemic inflammation, inhibit leptin's role in controlling appetite and boosting metabolism by preventing its transit across the blood-brain barrier. In a published study involving both *in vivo* and *in vitro* research, Dr. Zhao and his colleagues found that when CRP levels are high in the blood, as is the case in overweight and obese people, CRP binds to and forms a complex with leptin. This complex limits the ability of leptin to cross the blood-brain barrier, bind receptors in the hypothalamus, and carry out its function.



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LeptiCore® - Clinically Proven to Reduce Serum C-Reactive Protein and Leptin Levels

LeptiCore® reduces leptin resistance by modulating the primary inflammatory components hindering leptin function, namely C-reactive protein.* In the same double-blind, placebo-controlled clinical trial mentioned previously, subjects taking LeptiCore® experienced a 15.1% reduction in CRP after 8 weeks ($p \leq 0.05$ versus placebo; Figure 3). At the same time, leptin function improved in these subjects as indicated by a 46.95% drop in serum leptin levels ($p \leq 0.05$ versus placebo; Figure 4). With less CRP available to form complexes with leptin, increased passage of leptin across the blood-brain barrier occurred (resulting in lower serum leptin levels). Additionally, when leptin freely enters the brain, the brain signals fat cells to slow leptin production via a negative feedback loop involving the sympathetic nervous system. This results in sustained reductions in serum leptin levels. Improved leptin function in LeptiCore® helps support satiety, appetite control, blood sugar balance, and thermogenesis as well as a reduction in abdominal obesity.*

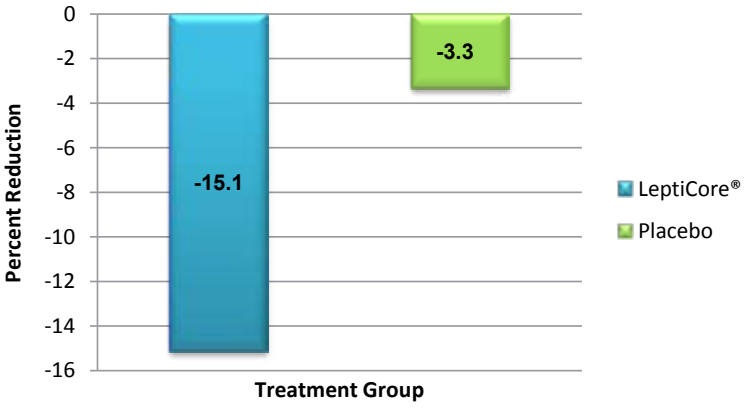

Figure 3. Percent Reduction in C-Reactive Protein in Subjects Receiving LeptiCore® Compared to a Placebo after 8 Weeks.

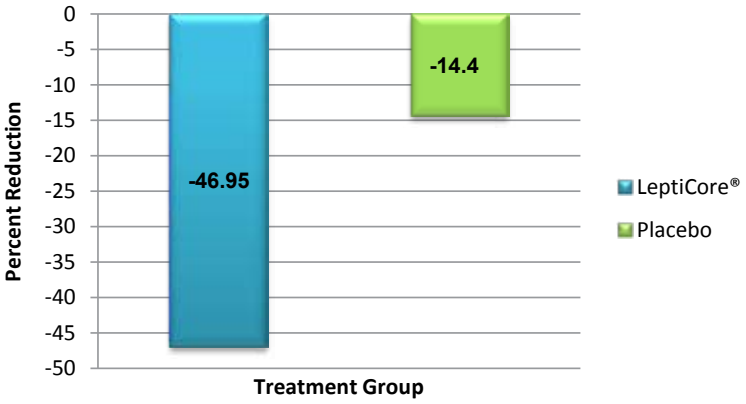

Figure 4. Percent Reduction in Leptin in Subjects Receiving LeptiCore® Compared to a Placebo after 8 Weeks.

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LeptiCore® Enhances Mood and Increases Satiety by Raising Serotonin Levels

A person who is overweight or obese and has difficulty losing weight is often irritable with a negative mood. LeptiCore® has additional properties that address these mood issues which can make Healthy Weight Management more achievable.* Blue-green algae in LeptiCore® contains high phenylethylamine (PEA), a neuromodulating factor that research has shown increases serotonin concentration in the body. Serotonin (5-HT) is a vital neurotransmitter involved in a wide range of behavioral functions in the body, including mood enhancement (PEA is the compound found in dark chocolate that provides feeling of well-being). LeptiCore® supports an enhanced mood by increasing serotonin levels.* In the same double-blind, placebo-controlled clinical trial mentioned previously, serotonin levels increased by 28.5% in subjects taking LeptiCore® ($p \leq 0.05$ versus placebo; Figure 5). Increased serotonin also controls satiety through a physiological pathway that is complementary to the one utilized by leptin, providing LeptiCore® with additional satiety properties.*

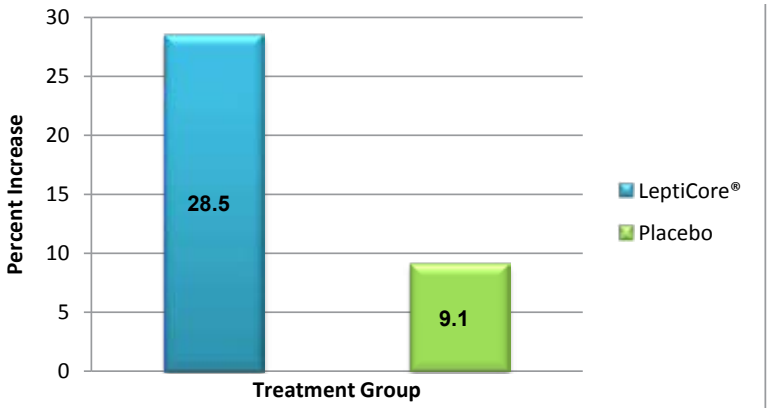
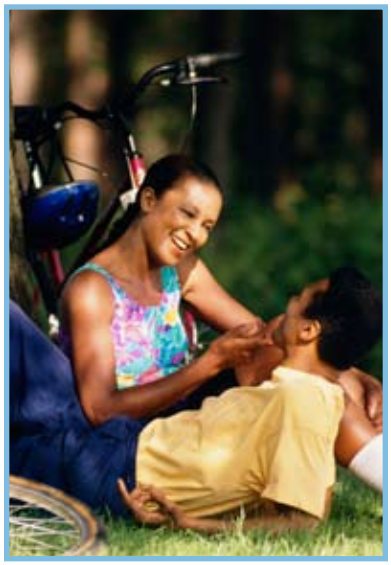


Figure 5. Percent Increase in Serotonin in Subjects Receiving LeptiCore® Compared to a Placebo after 8 Weeks.

LeptiCore® - Clinically Proven to Improve Blood Lipid Levels

LeptiCore® addresses additional risk factors of metabolic syndrome by improving blood lipids levels.* In the previously described clinical trial, the group taking LeptiCore® experienced significant reductions in LDL (-14.6%) and triglycerides (-7.1%) and a significant increase in HDL (13.6%) after 8 weeks ($p \leq 0.05$ versus placebo). This is further evidence that LeptiCore® promotes Metabolic Wellness and Balance by addressing key risk factors of metabolic syndrome in a comprehensive manner.*



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LeptiCore® is a Superior Choice

Clinically proven LeptiCore® has the scientific support and regulatory substantiation to excel in today's demanding marketplace. LeptiCore® is a patent-pending, safe, all natural nutraceutical ingredient with clinically-proven efficacy for reducing obesity and other risk factors contributing to metabolic syndrome.* Those concerned about reducing these risk factors will find that supplementation with LeptiCore® in combination with a healthy diet and exercise regimen is particularly effective. LeptiCore® offers a superior choice to marketers looking to develop new dietary supplement products in the areas of Healthy Weight Management and Metabolic Wellness. Call us today to learn more about LeptiCore® and how it can add substantial value to your product line.

About Us

Located in the Connecticut River Valley area of Southern Vermont, Icon Group is a diversified nutraceutical product marketing company dedicated to the development and commercialization of proprietary, scientifically researched, health-promoting ingredients. Icon Group strives to develop strong, mutually beneficial strategic alliances with its customers by providing proprietary nutraceutical products addressing today's most pressing health issues.

ICON GROUP

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* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

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