NUTRITIONAL SUPPLEMENTATION FOR WEIGHT MANAGEMENT

DaVinci® BENEFITS line™

SIMPLY FORMULATED
TO DELIVER MORE

INTRODUCTION

Obesity and overweight have reached epidemic proportions the world over. Perhaps more complex than the "calories in, calories out" model, a number of factors can influence the accumulation of excess fat tissue:[1] stress, hormonal imbalance, gastrointestinal dysfunction, neurochemical imbalances, sedentary lifestyle, and a poor diet high in refined and processed foods (malnutrition). Surgical and pharmaceutical interventions exist but a safer, long-term solution would be to treat obesity and overweight by targeting internal factors as well as external factors with a program of nutrition, activity, and supplementation based on an individual's unique needs. African mango, white kidney bean, green tea, and green coffee bean show promise as antiobesity agents. In human, animal, and cell studies they decrease body weight, fat mass, and fat cell development. *Laminaria japonica* is a marine vegetable that has also shown potential as a weight loss agent. Together these natural products contain a variety of ingredients that act via different mechanisms in the body and can work synergistically in an adjunctive treatment to a comprehensive weight loss program.

OVERWEIGHT AND OBESITY

Approximately 78 million adults in the United States are obese.[1] In children, obesity rates are nearly 17% and this is more pronounced in minority groups. The prevalence of obesity and overweight has increased dramatically in the last few decades, going from 15% in 1976 to 32.9% in 2003. Overweight and obesity have been associated with one in five deaths.[1] On the international stage, 2.3 billion adults were estimated to be overweight and 700 million adults were estimated to be obese in 2015.[2] Less than half of American adults meet the federal Physical Activity Guidelines and more than seven out of ten school children get less than 60 minutes of physical activity each day.[1]

Obesity is a nutritional and metabolic disorder characterized by high numbers of large fat cells. A body mass index greater than 30 kg/m2 puts a person into the obese classification. Overweight is defined as excess body weight for height and a BMI of 25-29.9 kg/m2.[1] Overweight characterized by a high fat mass and elevated lipid concentration in blood.[3] It is a risk factor for developing type 2 diabetes and cardiovascular disease, due to the underlying metabolic changes that are collectively called, "metabolic syndrome:" hyperglycemia, dyslipidemia, hypertension, inflammation, and oxidative stress.[2] Obesity is also associated with coronary artery disease and certain cancers.[3]

The causes of obesity are complex and go beyond a simple equation of energy intake and energy output. Factors affecting fat mass include:[1]

Metabolism	Race	Psychological health
Genetics	Sex	Lactation history in mothers
Physical activity	Age	History of gestational diabetes
Hormones	Diet	
Socioeconomic status	Smoking cessation	
Ethnicity and culture	Pregnancy and menopause	

WEIGHT LOSS MECHANISMS OF ACTION

No longer simply an organ of storage, adipose tissue is now recognized as an endocrine organ.[4] Fat tissue produces a number of hormones and adipokines that can affect whole-body metabolism. Examples are: leptin, adiponectin, resistin, tumor necrosis factor-alpha, and interleukin 6 (IL-6).[5] Adiponectin is made by fat cells and improves insulin sensitivity, modulates the inflammatory response, and regulates energy metabolism.[6] Adiponectin increases with weight loss.[5] Leptin is a hormone that has a major influence on energy balance in the body. It suppresses food intake and causes weight loss.[7] Leptin is made by fat cells and levels are closely correlated with adipose tissue mass.[5]

FAT TISSUE PRODUCES A NUMBER OF HORMONES AND ADIPOKINES THAT CAN AFFECT WHOLE-BODY METABOLISM.

Diet-based therapies and herbal supplements are the most common complementary and alternative medicine treatments employed for weight loss. They are generally safe with few to no side effects.[2] Most pharmacological therapies for obesity have had safety concerns and have fallen out of use or have been withdrawn from the market.[8] Thus, there is great interest in finding safe, effective treatments for obesity from natural sources.[8]

Plant products target a variety of mechanisms of action that enhance weight loss. They may influence hormonal balance, by affecting leptin, adiponectin, or insulin. They can affect appetite, satiety, or insulin sensitivity. Natural agents often have beneficial effects on glucose levels. They may interfere with digestion and absorption of glucose or alter enzymatic conversion of glycogen into glucose. Treatments for weight loss can increase thermogenesis, that is, they can increase the energy released from fat tissue in the form of heat9 or they can increase beta-oxidation of fatty acids. They may suppress inflammation or oxidation. Certain plants can prevent fat cell development (adipogenesis) or encourage the break-down of fats (lipolysis).

Nutritional supplements can shift the balance of hormones and chemical signals that may underlie metabolic disorders. Clinicians can support a patient's internal physiology to get successful weight loss using safe, natural agents in conjunction with a program that addresses lifestyle factors.

WELLTRIM® IG (IGOB131®) AFRICAN MANGO SEED EXTRACT

Irvingia gabonensis (African mango seed extract) is a traditional food eaten in Nigeria and Cameroon and has medicinal properties. The active ingredients in African mango appear to be: ellagic acid, mono-, di-, tri-O-methyl-ellagic and certain long-chain glucosides.[10] African mango supports body weight and waist circumference, blood lipids, adiponectin, and can lower C-reactive protein.

Irvingia's beneficial effects on metabolism were attributed to its high fiber content early on. The fiber content of I. gabonensis seeds act as a "bulk-forming" laxative. This action may help to delay gastric emptying and thereby slow the absorption of glucose after a meal, leading to better insulin sensitivity.[11] Some authors suggest that seed fiber may bind bile acids in the gut for excretion. This could explain how Irvingia lowers blood lipids.[10] [11]

However, further studies have shown it influences metabolism more directly.[5] In 102 overweight or obese subjects, 150 mg of *Irvingia gabonensis* was given twice daily over the course of 10 weeks. Results were dramatic. Patients taking the African mango seed showed decreases in blood glucose (22.5%), body weight (12.8%), body fat, and waist circumference (16.2%). Body fat was reduced by 6.3% in the treatment group but only 0.05% in the placebo group. Total cholesterol and LDL cholesterol were decreased. C-reactive protein was lowered by 52% (compared to 1.2% in the placebo group). Adiponectin levels increased by 159.8% (compared to 23.4% in the placebo group) and leptin levels improved in the treatment group.[5]

In 40 obese subjects, approximately three grams of I. gabonensis per day resulted in an average decrease in body weight of 5.25 kg as well as lowered cholesterol, triglycerides, LDL-C, and an increase in HDL-C.[11] Three randomized controlled trials reported decreased body weight, waist circumference, and reductions in blood lipids after treatment with *I. gabonensis*. Two of the trials reported significant reductions in body fat. However, because of flaws in design, these trials do not constitute strong evidence of the clinical effects of African mango and further studies are needed.[12]

> THREE RANDOMIZED CONTROLLED TRIALS REPORTED DECREASED BODY WEIGHT, WA IST CIRCUMFERENCE, AND REDUCTIONS IN BLOOD LIPIDS AFTER TREATMENT WITH I. GABONENSIS (AFRICAN MANGO SEED EXTRACT).[12]

Animal studies seem promising. Diabetic rats were given I. gabonensis seeds for three weeks and decreased glucose and glucose-6-phosphatase levels. Rabbits given the extract of the bark showed decreases in glucose and body weight.[10]

In a cell study of adipocytes, Irvingia extract suppressed cell development (adipogenesis) through its suppressive actions on PPAR gamma and leptin. It also appeared to raise adiponectin.[5]

GREEN COFFEE BEAN EXTRACT

Green coffee bean's (GCB) principal phenolic constituent is chlorogenic acid, which has thermogenic activity and has been suggested as a weight loss aid.[13] In epidemiological studies, coffee consumption seems to reduce the risk of developing diabetes. Chlorogenic acid in coffee has been shown to reduce body weight and blood glucose in overweight and obese subjects.[13] Decaffeinated green coffee bean provides a low-caffeine product that is rich in chlorogenic acid.[14]

> EGCG HAS BEEN SHOWN TO INHIBIT FAT CELL SYNTHESIS AND GROWTH, CAUSE FAT CELL DEATH, INHIBIT FAT ACCUMULATION IN CELLS, AND PROMOTE THE BREAK-DOWN OF FATS BY BETA-OXIDATION.[14]

GCB for 60 days at 400 mg/day led to weight loss in a clinical trial of overweight subjects.[14] GCB also has a hypotensive effects in those with mild hypertension[15] [17] In mice, GCB extract counteracted the effects of a high fat diet by decreasing visceral fat mass and improving insulin resistance,[14] probably by altering the expression of genes involved in inflammation and adipogenesis.[14] In fat cells, chlorogenic acid increases lipolysis.[13]

Coffee has strong antioxidant capacity.[17] [18] In animal studies, GCB increased glutathione, decreased oxidative damage, decreased fat mass, decreased fat absorption, and stimulated fat metabolism in the liver.[17] [18] GCB also may stimulate the Nrf-2 pathway, which promotes endogenous antioxidant defenses.[19]

> CHLOROGENIC ACID IN COFFEE HAS BEEN SHOWN TO REDUCE BODY WEIGHT AND BLOOD GLUCOSE IN OVERWEIGHT AND OBESE SUBJECTS.[13]

Chlorogenic acids inhibits the glucose-6-phosphatase enzyme, which may explain its role in balancing blood glucose.[13] Glucose-6-phosphatase is a rate-limiting enzyme involved in gluconeogenesis.[17] It converts glycogen into glucose. Some experts say GCB decreases intestinal glucose absorption while inhibiting glucose-6-phosphatase enzymes, which stimulate glucose release into the blood stream. In this scenario, the liver releases less glucose so that fat is used as a preferred energy source.[20]

GREENSELECT® GREEN TEA PHYTOSOME™

GreenSelect® Phytosome™ is a novel delivery method of green tea, found in both Lean Benefits and Adipo-Leptin Benefits™. Unlike liposomal delivery, phytosomal delivery disperses the ingredients throughout a lipid bilayer instead of putting the ingredients inside of the lipid bilayer. As soon as the phytosomal membrane makes contact with gastrointestinal mucosa, the ingredients are absorbed. This bypasses the extra work necessary to break down a capsule or liposome to access the active ingredients and improves bioavailability.

Green tea, rich in catechins (especially epigallocatechin gallate, EGCG) and caffeine, has garnered tremendous interest as an antiobesity agent. Green tea has thermogenic,[21]

antioxidant,[22] and lipolytic properties.[23] It interferes with lipid digestion and absorption,[24 25] decreases cortisol,[26] decreases blood pressure,[27] and improves insulin sensitivity.[28] Mechanisms of action underlying the antiobesity effects of green tea include inhibition of pancreatic lipase, appetite suppression, thermogenesis, lipid metabolism, and decreased fat cell development.[2]

In animal and cell studies, evidence is very strong for the antiobesity effects of green tea.[24] EGCG has been shown to inhibit fat cell synthesis and growth, cause fat cell death, inhibit fat accumulation in cells, and promote the break-down of fats by beta-oxidation.[29] In animal studies, these effects were replicated. EGCG or green tea extract decreased body weight, fat mass, lipids, cholesterol and triglycerides. It also improved blood sugar balance by decreasing serum glucose and insulin resistance.[29] Green tea increases gene expression related to adiponectin (DiPierro, Alt Med Rev 2009).

Green tea supports lowering body weight, fat mass, and triglycerides. It increases energy expenditure, fat utilization, and balances glucose metabolism.[29] However, human studies have been mixed.[30 32] Some report decreased BMI, decreased waist circumference, and increased lipid metabolism.[33] Yet one meta-analysis did not find significant changes on body weight or fat percent[34] and another reported only small, statistically nonsignificant weight loss in obese or overweight patients.[29] This may be due to differing dosages, bioavailability, genetics, ethnicity, age, gender, length of treatment, caffeine content, physical activity, diet, body composition, or study design.[24 29 35]

BROWN SEAWEED

Laminaria japonica is a brown seaweed that is a popular dietary marine vegetable in Korea and is used medicinally in maternal health and in weight loss formulas.[3] Animal studies suggest that Laminaria may have potential as a weight loss aid. Seaweeds are also nutritious: They are rich in vitamins, minerals, fiber, polyunsaturated fatty acids, polyphenols, and iodine.[9 36]

A GREAT DEAL OF INTEREST HAS BEEN FOCUSED ON PHASEOLUS VULGARIS, ALSO KNOWN AS WHITE KIDNEY BEAN, FOR ITS ROLE AS A "STARCH BLOCKER" AND A POTENTIAL WEIGHT LOSS AID.

Fucoxanthin is an antioxidant carotenoid found in edible seaweeds such as Laminaria. Fucoxanthin has antiobesity effects and influences mitochondrial function, promoting beta-oxidation of fatty acids and thermogenesis in fat tissue.[3 9]

In mice, Laminaria increased insulin sensitivity, decreased blood glucose, and led to slight reductions in body weight.[36] Laminaria also has anti-inflammatory, anti-tumor, anti-diabetic, and anti-atherosclerotic activities. It is known to reduce the intestinal absorption

of glucose.[3 36] Rats treated with Laminaria extract showed decreased weight gain, lipid levels,

leptin levels, and tumor necrosis factor-alpha levels. It lowered fat accumulation and increased fat burning.[3] When mice were given Laminaria, they showed improved insulin sensitivity and lower inflammatory cytokines from fat tissue.[36] Human studies are still needed to reproduce the effects of fucoxanthin and Laminaria that have been seen in animal models.[9]

IN HUMANS, WHITE BEAN EXTRACT CAN LOWER POST-PRANDIAL BLOOD GLUCOSE, INSULIN, CHOLESTEROL, BODY WEIGHT, WAIST CIRCUMFERENCE, AND FAT MASS.[37]

BEANBLOCK® (*PHASEOLUS VULARIS L.*)

BeanBlock® is a patented purified bean (*Phaseolus vulgaris L.*) extract obtained from a single and specific Italian bean variety. A great deal of interest has been focused on *Phaseolus vulgaris*, also known as white kidney bean, for its role as a "starch blocker" and a potential weight loss aid. A starch blocker interferes with digestion of complex carbohydrates. It reduces or delays digestion so that less energy is extracted, or less glucose is absorbed, from carbohydrates.[37]

White bean contains three isoforms of an a-amylase inhibitor,[37] which interferes with digestion of complex carbohydrates, lowers post-prandial glucose, and promotes weight loss.[38] P. vulgaris effectively prevents starch digestion by completely blocking access to the active site of the a-amylase enzyme. Likewise, researchers have shown that levels of amylase activity in the lumen of the gut are decreased after ingesting the a-amylase inhibitor from white bean extract.[37] When starch is taken together with the amylase inhibitor, blood glucose levels are lowered.[37] White bean extract also lowers post-prandial plasma insulin and C-peptide.[37]

A number of clinical trials have been carried out with white bean extract. In humans, white bean extract can lower post-prandial blood glucose, insulin, cholesterol, body weight, waist circumference, and fat mass.[8] [39] [40] White bean extract has a good safety profile, making it a desirable option for a natural weight loss aid.[37] However, meta-analyses have found study design limitations of randomized controlled trials. Thus, further studies are needed to confirm the weight loss effects of white bean extract in humans.[41]

Animal studies show that the addition of white bean extract decreases food intake, appetite,[42] body weight, and lipids in genetically obese animals.[43] [45] White bean extract is particularly interesting because it suppresses food intake, even of highly palatable foods like butter cookies.[42] This leads authors to suggest that white bean extract interrupts central mechanisms involved in appetite, satiety, and the food-reward system.[42] White bean extract has been suggested as a promising potential therapy for the treatment of overeating not only for its glucose- and insulin-lowering effects but because it lowers ghrelin secretion, increases satiety, and decreases the desire to eat.[42] The starch may also feed gut bacteria, which could also affect metabolism.[37]

CONCLUSIONS

Certain nutritional ingredients have been shown to balance leptin and adiponectin levels, promote thermogenesis, alter appetite, reduce post-prandial glucose spikes by slowing the release of glucose into the bloodstream, and increase beta-oxidation of fatty acids. Ultimately these biochemical activities help to reduce body weight, fat mass, and waist circumference in human clinical studies and animal models.

Adipo-Leptin Benefits™ and Lean Benefits™ are both designed to support weight management efforts, but their clinical applications differ.* Adipo-Leptin Benefits™ supports hormonal balance, appetite control, and satiety.* This product may be ideal for the patient who has already made many successful changes to their life but who still struggles with excess weight due to underlying hormonal imbalance. Lean Benefits™ is designed to counteract the effects of poor lifestyle choices (such as high dietary refined carbohydrates and starches) while patients learn to implement healthier behaviors.

While nutritional supplementation holds promise for mediating the effects of a poor diet and sedentary lifestyle, the most effective weight loss strategy is to balance underlying biochemical issues, promote a lifestyle of activity, low-stress, restorative sleep, and a nutritious diet rich in whole foods. Weight loss formulas, with safe, with naturally-sourced ingredients, are an excellent addition to (and can even jump start) a comprehensive program designed to address the underlying causes of obesity and overweight.

ADIPO-LEPTIN BENEFITS™

SUPPLEMENT FACTS

Serving Size 2 Capsules
Servings Per Container 30

Amount Per Serving		% Daily Value
Green Coffee Bean Extract	300 mg	*
Brown Seaweed (Laminaria japonica) Whole Plant Extract	200 mg	*
WellTrim® iG (IGOB131®) African Mango (Irvingia gabonensis) Seed Extract	150 mg	*
GreenSelect® Green Tea Phytosome™ (Camellia sinensis Leaf Extract/ Phosphatidylcholine complex)	150 mg	*

*Daily Value not established.

Other ingredients: hypromellose (capsule), microcrystalline cellulose, vegetarian leucine.

GSP GREEN SELECT PHYTOSOME · PHYTOSOME™ MORE BIOAVAILABLE · WellTrim® iG PATENTED AFRICAN MANGO • IGOB131® · MADE WITH NON GMO INGREDIENTS

GreenSelect® Phytosome™ is a registered trademark of Indena S.p.A.

WellTrim® iG is a trademark of Icon Group, LLC. IGOB131® is a trademark of Gateway Health Alliances, Inc. and is protected under U.S. Patent 7,537,790.

LEAN BENEFITS™

SUPPLEMENT FACTS

Serving Size 1 Capsule
Servings Per Container 60

Amount Per Serving		% Daily Value
GreenSelect® Green Tea Phytosome™ (Camellia sinensis Leaf Extract/ Phosphatidylcholine complex)	150 mg	*
Beanblock® (standardized dry extract of Phaseolus vulgaris)	100 mg	*

*Daily Value not established.

Other ingredients: hypromellose (capsule), microcrystalline cellulose, vegetarian leucine.

GSP GREEN SELECT PHYTOSOME · PHYTOSOME™ MORE BIOAVAILABLE · BEANBLOCK™ · MADE WITH NON GMO INGREDIENTS

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