

GlucoHelp™

*A fast-acting, clinically proven way
to control blood glucose levels*

Balance.

Banaba Leaf Extract standardized to 18% corosolic acid



SOFT GEL
TECHNOLOGIES, INC.

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The Threat:

Insulin Resistance

One of the biggest health threats to the American public today is insulin resistance, a key factor in the development of metabolic syndrome and diabetes.

People who are insulin-resistant produce adequate amounts of the hormone insulin, which is responsible for transporting glucose out of the bloodstream and into the cells — however, their bodies simply don't respond to it anymore. That's a problem for two reasons. First, it means that glucose stays in the bloodstream, where it can cause damage to the nerves, blood vessels and organs. Second, it means that cells don't get enough glucose, which is their major source of fuel.

The Insulin Resistance Statistics Are Grim:

- 23.6 million American adults and children — or 8% of the population — have diabetes.¹
- Another 57 million — or 19% of the population — have pre-diabetes.²
- One in three children born in 2000 will develop diabetes in his or her lifetime.³
- 35% of U.S. adults age 20 or over have metabolic syndrome, a cluster of metabolic abnormalities that include insulin resistance, high blood pressure, excess abdominal fat, abnormal blood lipids and elevated inflammatory markers.⁴

People with pre-diabetes, diabetes and metabolic syndrome are all at increased risk for heart disease and stroke. In fact, diabetes is the sixth-leading cause of death in the United States.⁵

The Opportunity:

Sales of Diabetes Supplements Rising

With so many Americans facing insulin resistance and its accompanying health problems, consumer demand for dietary supplements that can help control blood glucose is increasing. In 2006, the market for diabetes supplements in natural supermarkets and conventional food, drug and mass stores was estimated to be nearly \$70 million.⁶ And according to the Natural Marketing Institute's 2007 Health & Wellness Trends Survey, diabetes is one of the top health categories for dietary supplements.⁷

Manufacturers have a unique opportunity to formulate supplements that can help on two fronts: preventing metabolic syndrome and diabetes in those at risk, and controlling the disorders in those who already have them. That's exactly the potential of GlucoHelp™ from Soft Gel Technologies.

The Answer:

GlucoHelp™ Banaba Leaf Extract

GlucoHelp™ is a proprietary banaba leaf extract, manufactured in Japan and standardized to 18% corosolic acid — a key bioactive constituent. The subject of two original human clinical studies, GlucoHelp™ has been shown to:

- Significantly lower fasting blood glucose levels
- Significantly lower blood glucose levels following a starchy meal
- Improve clinical symptoms of diabetes

Because of its high concentration of corosolic acid, GlucoHelp™ works *quickly*, causing greater than 10% decreases in blood glucose levels after just *one week* of supplementation — without producing symptoms of hypoglycemia. In fact, both clinical trials on GlucoHelp™ showed a complete lack of adverse events.

Clinical Research on GlucoHelp™

Two human clinical studies were conducted to evaluate the effect of GlucoHelp™ on two types of blood glucose readings: **fasting blood glucose**, which measures blood sugar levels after eight hours of refraining from eating and drinking, and **post-prandial blood glucose**, which measures blood sugar levels following a meal. Both are important measures of blood glucose control:

- Fasting blood glucose measures the amount of glucose in the blood independent of dietary influences, and is often used in the diagnosis of diabetes. Levels between 70-99 mg/dL are considered normal, 100-125 mg/dL pre-diabetic and 126 mg/dL and above diabetic.
- Post-prandial blood glucose measures how high blood sugar spikes after a meal, and how effectively the body is able to clear the blood of glucose after eating. For 2-hour post-prandial blood glucose, levels lower than 140 mg/dL are considered normal.

Both of the clinical studies conducted on GlucoHelp™ revealed remarkably consistent results.

Clinical Study #1

In the first study, 12 non-diabetic adults (average age 58, average body mass index 25) were enrolled.⁸ The subjects' baseline blood glucose levels were established by measuring fasting blood glucose, as well as post-prandial blood glucose 30, 60 and 120 minutes after eating a starchy meal. For two weeks, each participant then took one soft gel of GlucoHelp™ daily, providing 10 mg of corosolic acid, the main active constituent.

Results

The results were remarkable. After just one week of GlucoHelp™ administration, all four measurements of blood glucose had dropped significantly. After two weeks, they had declined even more — along with weight and BMI. In fact, the average subject lost three pounds in two weeks.

While none of the subjects in the trial had diabetes, some of them did have pre-diabetes, as evidenced by baseline fasting blood glucose levels of 110 mg/dL or above. Interestingly, the greatest decreases in blood glucose were seen in pre-diabetics — 15% after one week and 21% after two weeks — indicating that GlucoHelp™ has the most dramatic impact on those with the greatest need. The researchers concluded that GlucoHelp™ “can be expected to control blood glucose level[s]...in a short period of time.”

Importantly, no adverse effects were observed with GlucoHelp™ treatment.

Blood Glucose Measurement	Baseline	1 week after administration	% drop from baseline	2 weeks after administration	% drop from baseline
Fasting	104.25±10.02 mg/dL	94.25±15.74 mg/dL	10%	91.91±10.02 mg/dL	12%
30-minute post-prandial	178.16±30.10 mg/dL	168.33±25.90 mg/dL	6%	164.58±26.45 mg/dL	8%
60-minute post-prandial	194.41±35.59 mg/dL	181.58±27.97 mg/dL	7%	171.16±34.27 mg/dL	12%
120-minute post-prandial	141.75±32.05 mg/dL	138.08±26.89 mg/dL	3%	128.33±20.31 mg/dL	9%

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Clinical Research on GlucoHelp™

Clinical Study #2

In the second study, a randomized, placebo-controlled clinical trial, 100 adults with either Type II diabetes or high blood glucose were enrolled.⁹ All subjects were required to strictly follow a special diet; however, those taking drugs to control their diabetes were allowed to continue doing so. Baseline blood glucose levels were established by measuring fasting blood glucose, as well as post-prandial blood glucose two hours after eating a starchy meal.

Study subjects were then divided into two groups: half were administered one daily soft gel of GlucoHelp™, providing 10 mg of corosolic acid, for 30 days, while the other half were given a similar-looking placebo.

Results

The results were similar to those seen in the first study. After 30 days, both fasting and 2-hour post-prandial blood glucose levels had declined significantly in the GlucoHelp™ group compared to the control (placebo) group. In addition, GlucoHelp™ treatment caused an obvious improvement in symptoms of diabetes, including thirstiness, somnolence (drowsiness), polyphagia (excessive hunger or eating) and hypodynamia (diminished strength or movement) compared to control.

Again, no adverse effects were observed with GlucoHelp™ treatment, and there were no changes in blood pressure, blood cell count, hemoglobin or liver or kidney function.

Changes in fasting blood glucose level

Group	Baseline	30 days after administration	Lowering rate
Control	166.25±61.92 mg/dL	162.54±59.22 mg/dL	2%
GlucoHelp™	164.52±59.76 mg/dL	141.84±43.02 mg/dL	12%

Changes in 2-hour post-prandial blood glucose level

Group	Baseline	30 days after administration	Lowering rate
Control	272.16±102.78 mg/dL	267.66±101.52 mg/dL	1%
GlucoHelp™	266.22±79.56 mg/dL	232.56±63.36 mg/dL	11%

Supporting Research

Dose-dependence Study

The two human clinical trials conducted on GlucoHelp™ add to the body of research on proprietary banaba leaf extracts developed by Soft Gel Technologies. Previously, our GlucoFit™ banaba leaf extract, standardized to 1% corosolic acid, was the subject of a randomized trial among ten Type II diabetics.¹⁰

For two weeks, subjects were administered one soft gel or one hard gelatin capsule of GlucoFit™ daily, providing 0.16, 0.32 or 0.48 mg of corosolic acid. At daily dosages of 0.32 and 0.48 mg of corosolic acid, subjects experienced a significant drop in fasting blood glucose levels compared to baseline. Interestingly, the soft gel formulation yielded greater decreases in fasting blood glucose levels than the hard gelatin capsule, suggesting it has greater bioavailability.

Constituent Research

In addition to these human clinical trials, there is a growing body of scientific literature pointing to corosolic acid and ellagitannins as the active constituents responsible for banaba leaf's glucose-lowering activity.

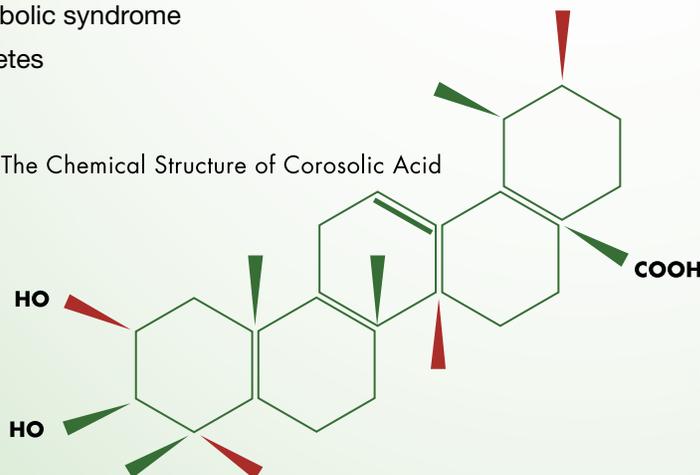
- Corosolic acid was shown to **activate glucose uptake** of Erlich tumor cells.¹¹
- Corosolic acid markedly **decreased glycosuria** (the amount of glucose in the urine) in diabetic mice in a dose-dependent manner, meaning the higher the dose, the more pronounced the effect.¹²
- Corosolic acid **facilitated the transport of glucose into muscle tissue** in diabetic mice.¹³
- Lagerstroemin, an ellagitannin from banaba leaf, **increased the rate of glucose uptake** in rat fat cells, showing that, similar to corosolic acid, it has an insulin-like action.^{14, 15}

GlucoHelp™ contains a high concentration of corosolic acid, as well as naturally occurring levels of ellagitannins — the two classes of bioactive constituents considered responsible for banaba leaf's glucose-lowering effect.

GlucoHelp™ Indications

- Insulin resistance/pre-diabetes
- Metabolic syndrome
- Diabetes

The Chemical Structure of Corosolic Acid



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Mechanism of Action

Banaba, also known as crepe myrtle, grows widely in tropical areas throughout India and Southeast Asia. For centuries, residents of the Philippines have brewed a tea from banaba leaves as a treatment for diabetes. They may not have known why banaba was effective, but modern research has elucidated a probable mechanism of action.

Stored within the cells of the body are specialized carrier proteins known as glucose transporter proteins, or GLUT. As the name suggests, glucose transporter proteins transport glucose from the blood into the cells.

One type of GLUT transporter, known as GLUT4, is present in fat cells, skeletal muscle cells and cardio-muscle cells. GLUT4 migrates; it can either “hide” inside the cell, or it can be out in the open on the cell membrane. Exactly where GLUT4 happens to be determines how much glucose can enter the cell. If a lot of GLUT4 transporters are waiting at the cell membrane “doors,” they can let glucose in. But if most of them are sequestered away in the inner part of the cell, glucose gets locked out.

So what determines where GLUT4 migrates in the cell? Insulin.

In a healthy body, when the hormone insulin is present, GLUT4 moves to the cell membrane. When it’s not present, GLUT4 retreats to the inner cell. In a nutshell, insulin is the “key” that unlocks the cell doors, allowing glucose to enter.

In cases of insulin resistance, GLUT4 transporters don’t respond properly to insulin. Even if the hormone is present, they may stay sequestered in the inner part of the cell, leaving the doors locked. As a result, glucose is unable to enter, and blood sugar levels stay elevated.

What is unique about banaba leaf is that two of its bioactive compounds — corosolic acid and ellagitannins — “pinch hit” for insulin. Both constituents direct GLUT4 to move to the cell membrane and activate it to incorporate glucose into the cell. Specifically, corosolic acid has been shown to activate GLUT4 in skeletal muscle cells,¹⁶ while ellagitannins have been shown to activate GLUT4 in fat cells.¹⁷ The net effect is that more glucose enters the cells, reducing the level of sugar in the blood.

GlucoHelp™ Delivery System

GlucoHelp™ banaba leaf extract is available as an off-the-shelf formulation in a soft gelatin capsule. Research has suggested that the main active ingredient in banaba leaf, corosolic acid, is lipophilic (fat-loving) and therefore better absorbed in an oil-based soft gel.





GlucoHelp™ Highlights

Available exclusively from Soft Gel Technologies, GlucoHelp™ is a proprietary banaba leaf extract standardized to 18% corosolic acid — a key bioactive constituent — that has been clinically proven to help control blood glucose levels in pre-diabetic and diabetic adults, without causing hypoglycemia.

Original human clinical trials have shown that GlucoHelp™:

- Lowers fasting blood glucose levels
- Lowers post-prandial blood glucose levels
- Improves clinical symptoms of diabetes, such as thirstiness, drowsiness, excessive hunger and diminished strength

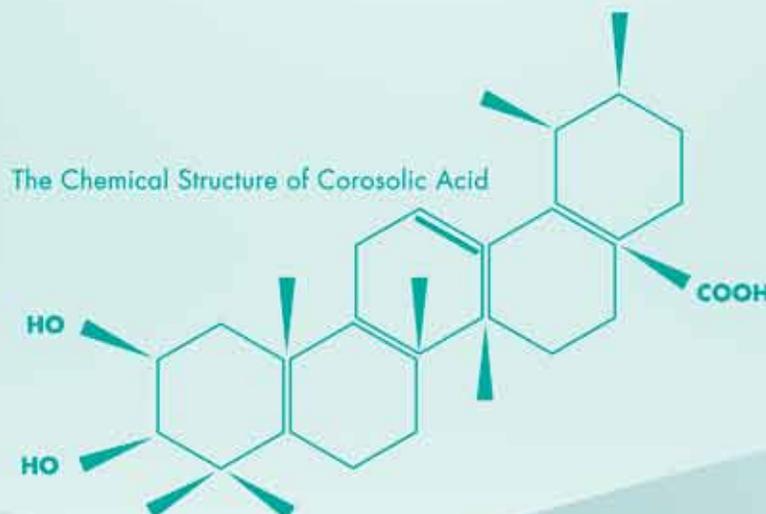
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Why Choose GlucoHelp™?

- **Clinically proven.** Increasingly, consumers are demanding that the supplements they buy be supported by sound science — in other words, not generic research on the ingredients in a product, but original research on the product itself. GlucoHelp™ is one of the few nutraceutical ingredients aimed at blood sugar control that is backed by original human clinical studies, showing 10%+ drops in fasting and post-prandial blood glucose levels.
- **Fast-acting.** The authors of the first clinical study on GlucoHelp™ noted that, based on previous research, a blood glucose-lowering effect “can be expected when taking 0.16-0.48 mg of corosolic acid per day for a long period of 4-48 weeks.” However, because of the high concentration of corosolic acid found in GlucoHelp™ — 10 mg per 56-mg soft gel — significant decreases in fasting and post-prandial blood glucose were seen in just one week.
- **Versatile.** GlucoHelp™ has proven benefits for both diabetics, in that it lowers blood glucose levels and improves clinical symptoms of diabetes, and pre-diabetics, in that it may reverse insulin resistance by facilitating the effective utilization of glucose.
- **Need-based results.** GlucoHelp™ does not have an across-the-board blood glucose-lowering effect; rather, it works best in those with the greatest need. The first clinical trial showed that examinees with a fasting blood glucose level of 110 mg/dL (pre-diabetes) experienced the most dramatic blood glucose-lowering effect — 15% after one week and 21% after two weeks.
- **Safe:** Banaba leaf extracts have a proven record of safety, and no adverse events were observed in either of the clinical trials performed using GlucoHelp™. Additionally, there were no changes in blood pressure, blood cell count, hemoglobin or liver or kidney function.
- **Made in Japan.** GlucoHelp™ is manufactured in a state-of-the-art cGMP-certified facility in Chiba, Japan.



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