

Glucoplex – 60 tablets

NAPPI Code: 887154 006

Composition:

Each tablet contains: Foodstate Vitamin A 667iu, Magnesium 7mg, Chromium 50µg, Vanadium 33µg and Molybdenum 7µg, Phaseolus 50mg and Glucosol™ 8mg.

Classification: Nutritional Supplement

Indications: People requiring support for blood sugar imbalances

Contra Indications: Individual sensitivity to a particular ingredient

Warnings: None

Dosage and directions for use: One tablet twice a day or as directed

Side Effects: See individual ingredients

Interactions: Glucoplex assists in the regulation of blood sugar and therefore sugar levels should be monitored if used in conjunction with hypoglycemic agents.

Identification: Light brown and white speckled, oval shaped tablet with no markings.

Presentation: Plastic white bottle with a clear plastic cap and a "SEALED FOR YOUR PROTECTION" seal. The bottle contains 60 tablets, sponge and dessicant.

Storage Instructions: Store at room temperature not exceeding 25°C in tightly closed containers. Protect from light.
KEEP OUT OF REACH OF CHILDREN

Name and address of supplier:

Sportron International (Pty) Ltd
6 Cambridge Park
22 Witkoppen Road
Paulshof
Sandton
SOUTH AFRICA

Date of publication:

June 2001

Contents

	<i>Page</i>
FoodState defined	3
Vitamin A	5
Chromium GTF	6
Magnesium	9
Molybdenum	11
Vanadium	12
Phaseolus	13
Glucosol™	14
References	21

FOODSTATE NUTRIENTS DEFINED

Foodstate nutrients for high efficiency absorption, retention and utilization

Foodstate nutrients are the most important advance in nutrition today. They are a unique new generation of vitamins and minerals molecularly bonded to proteins, carbohydrates and lipids in a complex food matrix. This is how they are found in natural foods and this is the form in which they can be best utilized by the body.

These nutrients are up to 5 times more bioavailable than commercially available vitamins and inorganic mineral salts, and are retained up to 16 times longer by the body. In addition, their food form targets them for specific metabolic processes and so increases their utility. Because foodstate nutrients are absorbed as readily as food and remain in the body far longer than commercially available vitamins and minerals, they need only be taken in conservative amounts.

Foodstate nutrients are closer to natural foods

In the natural plant and animal foods we eat, nutrients are absorbed, transported, stored, and utilized as parts of food complexes. Dr Abram Hooper explains: "Components (of food) do not exist free in nature; nature does not lay down pure protein, pure fat or pure carbohydrates. Their molecules are interlaced in a very complex 3-dimensional structure, which even now has not been fully described. Intermingled are the essential nutrients such as vitamins and minerals, not free, but combined in complex molecules."

Vitamins and minerals are never found as isolated pure molecules. They do not function as isolated elements or while attached to other chemicals. In the same way, isolated proteins are insoluble and denatured and their biological activity is reduced. Such "proteins" are no longer able to transport vitamins or minerals efficiently.

Foodstate nutrients are already complexed with the necessary compatible organic materials to make them bioavailable to the human body, which therefore recognizes them as food and not as an inorganic substance. Foodstate nutrients contain no chemicals such as orotates or gluconates.

In a landmark American court case which lasted over 3 years and was completed in 1993 the judge found that:

1. Foodstate nutrients are food.
2. They differ from vitamins and minerals mixed with food.
3. Foodstate nutrients are better absorbed, retained and utilized than isolated nutrients.

“Natural” redefined

All products of Nature can be called natural, but not all natural products are foods. As an example, shells and rocks are natural but they would hardly be considered valuable food sources of nutrition. The key concept is utilization. Merely being “natural” carries no guarantee that a nutrient will be utilized efficiently. A natural source is not good enough.

The countless brands of commercially available vitamins are synthetic – even those that are proclaimed to be natural, or naturally sourced, or naturally based.

Here is the background: scientists isolated molecules responsible for certain effects. Thus, vitamins were born and their chemical structures defined. Pure vitamins molecules were then isolated from a natural source, or the vitamin molecules were constructed from a commercially available intermediate like glucose. In both cases, however, all the constituents that naturally are attached to the vitamin are eliminated and the bioavailability and utility of the vitamin is reduced. It's like discovering that the engine of a car is the active ingredient. But the engine of a car is useless to the driver without petrol, wheels, gearbox, controls and bodywork. Until recently, scientists thought that vitamins were mysteriously detached from their food proteins in the digestive system and were then somehow re-attached to proteins after absorption. We now know that this does not happen and that the proteins remain attached.

Vitamins and minerals must be consumed in a true food form for optimal efficiency and effectiveness. And that's where foodstate nutrients come in.

How are foodstate nutrients processed?

Foodstate nutrients begin with the same commercial molecule of vitamins or minerals. However, through an exclusive process, the nutrients are bonded with non-denatured proteins. The vitamins and minerals are added to a nutritional medium and then fed to living yeasts. The result is a complex protein containing the vitamin or mineral as found in natural foods. That's the healthy difference between foodstate nutrients and synthetic products.

An outstanding breakthrough

Our heavy investment in plant and animal studies have made it possible for us to bring this new generation of advanced nutrients to you. Many published and unpublished studies support the foodstate concept.

Foodstate nutrients are indeed the nutritional breakthrough for the new millennium

INGREDIENTS

Vitamin A

- Science best understands the role of Vitamin A with regard to its effect on the visual system. Poor adaptation to changes in light and poor vision at night are some of the first signs found with a low Vitamin A status.
- Vitamin A has been included as part of the Glucoplex formula because it is very difficult for a diabetic to convert β -carotene into retinol (Vitamin A) and therefore it is essential to provide Vitamin A in a preformed state.
- **Epithelial Tissue**
The role of Vitamin A in the development and maintenance of epithelial tissue cannot be overstated. Vitamin A status determines whether mucin or keratin is synthesised in epidermal cells; the presence of adequate vitamin A results in mucin production, while a lack results in hyperkeratinization of the skin, cornea, upper respiratory tract or genitourinary tract^(1,2).
- **Immune Function**
Vitamin A affects the immune system because of the essential role it plays in maintaining the epithelial and mucosal surfaces and their secretions. Vitamin A stimulates and or enhances numerous immune processes, including induction of anti-tumour activity, enhancement of white blood cell function and increased antibody response. β -Carotene appears to provide antioxidant protection for the thymus gland which is susceptible to free radical and oxidative change. β -Carotene also appears to enhance thymus gland function and increase interferon's stimulatory action in the immune system⁽³⁾. Interferon is a powerful immune-enhancing compound that plays a central role in protection against antioxidant activity.
- **Antioxidant Activity**
Vitamin A has significant antioxidant properties which is probably the factor responsible for the anti-cancer effects observed in population studies.

Symptoms of deficiency:

- Impaired ability to mount an effective antibody response.
- Decreased levels of helper T-cells.
- Alterations in the mucosal linings of the respiratory and gastrointestinal tracts.
- Increased susceptibility to infections.
- Prolonged deficiency results in follicular hyperkeratosis, night blindness and xerophthalmia.

Nutrient safety :

- Ingestion of large amounts of carrot juice (0.45 – 1,0kg/day of fresh carrots for several years) can cause neutropenia and menstrual disorders.^(4,5)
- According to the DRI report⁽⁶⁾ the recommended intake for vitamin A, as retinol, for males is 900 micrograms per day and for females 700 micrograms per day.

Interactions :

- Vitamin E and zinc are particularly important for the proper function of vitamin A.

Chromium GTF

- Chromium is an essential trace mineral found in concentrations of 20 parts of chromium per 1 billion parts of blood.
- The chromium used in Glucoplex is in the form of Sportron's unique FoodState™ technology, which is the most effective form of chromium. FoodState™ chromium contains chromium as Glucose Tolerance Factor (GTF), which is 50 times more effective than other forms of chromium and 20 times more readily absorbed.
- Organic chromium is an active ingredient of a substance called GTF (glucose tolerance factor).
- Studies indicated that GTF stimulates insulin activity directly by binding to both insulin itself and specific insulin receptors. When chromium is supplemented in the form of GTF and it is active in the human body, it will produce the following results:
 - Control blood glucose by promoting uptake by muscles and organs
 - Stimulates the activity of enzymes involved in the metabolism of glucose for energy and the synthesis of fatty acids and cholesterol.
 - Reduce fat levels in blood
 - Control blood cholesterol levels
 - Increase HDL cholesterol
 - Reduce arteriosclerosis
 - Stimulate production of essential nerve substances
 - Increase resistance to infection
 - Stimulate protein synthesis
 - Suppress hunger symptoms through brain "satiety center"
 - Appears to increase the effectiveness of insulin and the ability of this hormone to metabolise glucose.
 - Involved in the synthesis of protein through its binding action with RNA molecules.

- ***Chromium May Improve Body Composition***

San Antonio, TX (June 23, 1998) – Dietary supplementation with chromium may lead to significant improvements in body composition in moderately overweight subjects,⁽⁸⁾ according to a study reported in Current Therapeutic Research.

The results of new double-blind, placebo controlled clinical study, in which 122 moderately overweight individuals took chromium, showed an average loss of 6.2 pounds of body fat as opposed to only 3.4 pounds in those individuals in the placebo group.

The new research, reported in the June issue of Current Therapeutic Research, reinforces results from an earlier clinical trial and demonstrates that chromium supplementation can play an important role in improving body composition. Body composition is determined by the ratio of fat-free mass versus the amount of fatty tissue in the body.

"The data clearly confirms that supplementation with chromium can lead to significant improvements in body composition resulting from fat loss, particularly for individuals who may not be as aggressive in making lifestyle changes such as reducing caloric intake or increasing their physical activity," says Gilbert Kaats, Ph.D., of the Health and Medical Research Foundation in San Antonio, the leading investigator in the study.

Subjects involved in the study were provided 400 micrograms of chromium or a placebo daily. Changes in body fat, fat-free mass, and weight were measured over a 90-day period. The results of the study demonstrated a statistically significant reduction in body fat (and fat mass) in those individuals who took chromium, without losing any valuable lean body mass.

The authors noted, "It has been proposed that chromium's positive effect on body composition is through its ability to improve insulin utilization, thereby reducing fat deposition and resulting in improving entry of glucose and amino acids into muscle cells. Although this study did not attempt to test this assertion, the findings are consistent with this hypothesis."

Chromium's ability to improve glucose utilization was also the subject of presentations and discussion at the recent International Symposium on the Health Effects of Dietary Chromium sponsored by the Tufts University School of Medicine the US Department of Agriculture, and the Chromium Information Bureau, held in Dedham, Massachusetts

- ***Chromium Supplements Help Control Diabetes***

NEW YORK, NY – November 4, 1997 – The use of chromium supplements significantly drops the level of glycated hemoglobin in type II diabetics⁽⁹⁾ reports a study in this month's journal – *Diabetes* - an official publication of the American Diabetes Association.

This clinical trial was conducted by Dr. Richard Anderson and his coworkers at the Beltsville Human Nutrition Research Center, United States Department of Agriculture (USDA), in Beltsville, Md. and by Dr. Nanzheng Cheng and her colleagues from the Beijing Medical University in Beijing, China.

In this double-blind, placebo-controlled clinical trial, 180 adult patients with the most common form of diabetes (type II or adult-onset) were randomized into one of three equal groups who received either 200µg of chromium, 1,000 µg (one milligram) of chromium or a placebo. All supplements were taken daily for four months, during which time the patients were instructed not to change their customary diets, exercise regimens or medications.

A statistically significant drop in glycated hemoglobin levels occurred at both the low and high levels of chromium. Glycated hemoglobin (hemoglobin molecules with sugar molecules chemically joined together) is a very sensitive indicator of diabetes control, with lower levels indicating better management of the disease. There were no changes in the glycated hemoglobin levels among patients in the placebo group. These data show that supplemental chromium helped to control blood sugar to a clinically important degree.

In addition, both fasting blood sugar and serum insulin levels dropped significantly in the high-level group and fasting insulin levels dropped significantly in the low-level group, as well.

Furthermore, in the group receiving 1,000µg of chromium, serum cholesterol dropped significantly. While beneficial effects on blood sugar have been described for supplementary chromium for more than three decades, the study's authors note chromium's positive effects on serum cholesterol are also consistent with previous results shown by their group and others in clinical trials.

"By supplementing the diets of these patients with chromium, we were able to help them lower blood glucose levels, indicating that their diabetes was under better control," Dr. Anderson said.

The most compelling result of this trial is the magnitude of the glucose-lowering effect seen with chromium," said Jay Skyler, MD former president of the American Diabetes Association and currently a professor of medicine at the University of Miami Medical School. "This is comparable to – or better than – that seen with most medications approved for the treatment of type II diabetes in the U.S.

“Chromium supplementation is easy, effective and safe and ought to be a consideration for most patients with adult-onset diabetes.”

Symptoms of Deficiency :

- The primary sign of chromium deficiency is glucose intolerance characterised by elevated blood glucose and insulin levels.

Nutrient Safety :

- Trivalent chromium, the form used in chromium supplements, is extremely safe.
- According to the DRI report⁽⁶⁾ the recommended intake for chromium for males is 30-35µg per day and for females 20-25 µg per day.

Interactions :

- Refined sugars, white flour products and lack of exercise can deplete chromium levels.
- Calcium carbonate and antacids may reduce chromium absorption.

Magnesium

- The primary function of magnesium is enzyme activation for the metabolism of carbohydrates and amino acids.
- Magnesium plays an important role in neuromuscular contractions.
- It helps regulate the acid/alkaline balance in the body.

- Magnesium helps promote absorption and metabolism of other minerals such as calcium, phosphorus, sodium and potassium.
- It also helps utilise B-complex and vitamins C and E in the body.
- It aids during bone growth and it is necessary for proper functioning of the nerves and muscles, including those of the heart.
- Sufficient amounts of magnesium are needed in the conversion of blood sugar into energy.

Symptoms of Deficiency :

- Magnesium deficiency is common, particularly in the elderly and in women during the premenstrual period.
- It becomes deficient in the body for a number of reasons but these include when there is diabetes, kidney disease or alcoholism. It also appears as if it is depleted when there is a high sugar intake.
- Signs and symptoms of deficiency are:
 - Fatigue
 - Mental confusion
 - Irritability
 - Weakness
 - Heart disturbances
 - Problems in nerve conduction
 - Muscle cramps
 - Loss of appetite
 - Insomnia
 - Predisposition to stress.

Nutrient Safety :

- Individuals with kidney disease or severe heart disease should not take magnesium except under the supervision of a physician.
- Magnesium is very well tolerated, however magnesium supplementation (particularly magnesium sulphate, hydroxide or chloride) may cause diarrhoea.
- According to the DRI report⁽⁶⁾ the recommended intake for magnesium for males is 420mg per day and for females 320mg per day.
- The upper safe level for supplemental magnesium is 320mg per day⁽¹⁰⁾.

Interactions :

- Magnesium, calcium, potassium and other minerals interact extensively.
- Vitamin B₆ works together with magnesium in many enzyme systems and increases the intracellular accumulation of magnesium.
- A high calcium intake and a high intake of dairy foods fortified with vitamin D result in decreased magnesium absorption.
- There are many drugs that adversely effect magnesium status, particularly many diuretics, insulin and digitalis.

Molybdenum

- Molybdenum is a trace mineral found in practically all tissue.
- High intakes of refined and processed foods lead to deficiency, and hence the inclusion of this mineral into Glucoplex.
- It functions as a component in several enzymes including those involved in alcohol detoxification, uric acid formulation and sulphur metabolism.
- Molybdenum is a factor in copper metabolism.

Signs of Deficiency :

- Molybdenum deficiency manifests as an inability to detoxify sulphites because the enzyme that detoxifies sulphites (sulphite oxidase) is molybdenum dependent.
- Symptoms of deficiency are increased heart rate, shortness of breath, headache, nausea and vomiting.

Nutrient Safety :

- According to the DRI report⁽⁶⁾ the recommended intake for molybdenum for both males and females is 45µg per day.

Interactions :

- Besides the interaction with copper and fluoride, there are no known interactions between molybdenum and other drugs or nutrients.

Vanadium

- Vanadium, named after the Scandinavian goddess of beauty, youth and luster, was established as an essential mineral based on data from four different laboratories on two different species⁽¹¹⁾.
- Vanadium inhibits some of the enzymes that hydrolyze phosphate ester bonds.
- Vanadate exhibits many insulin effects such as increasing glucose transport and metabolism in skeletal muscle, adipocytes and mouse fibroblasts⁽¹²⁾.
- Vanadate has been shown to stimulate glycogen synthesis, activate glycolysis, and inhibit glucose-6-phosphatase activity.
- In diabetic animals, vanadate treatment results in an increase in the number of cellular glucose transporters

Nutrient requirements:

- Intakes of vanadium range from 3µg per day for infants to 11µg per day for adults⁽¹¹⁾.
- Neither an adequate intake or an upper safe level for this nutrient have been established.

Phaseolus vulgaris

- Phaseolus vulgaris is derived from the extract of the northern white kidney bean.
- When we ingest an excessive amount of carbohydrates in our diets, and particularly refined carbohydrates, then these carbohydrates are converted to glucose. The glucose is converted to glycogen which supplies body energy. Excessive amounts of glycogen are converted into glycerol which becomes body fat. The white kidney bean has the ability to inhibit the actions of the enzyme α -amylase. This enzyme is involved in converting starch to glucose. Because the starch is not broken down, it is excreted from the body, thus preventing extra amounts of glycogen which would otherwise be turned to fat.
- A number of studies have demonstrated this inhibition of α -amylase

Nutrient Safety :

- Phaseolus has no known toxicity.

Interactions :

- None known

Glucosol

A Clinical Study was done to show that Glucosol™ is Effective in Reducing Blood Glucose Levels:-

Study Objective

In 1999 a clinical study was conducted by Dr William V. Judy at the Southeastern Institute of Biomedical Research, Bradenton, Florida, to confirm Corosolic acid's effect in lowering blood glucose levels and to evaluate dose-response relationship.

Study Subjects

This randomized, double-blind, cross-over trial was conducted with 12 subjects (6 men and 6 women) over 22 weeks. An initial dose-response trial was conducted on a group of 10 subjects (5 men and 5 women).

The criteria for including subjects in this study were mild case insulin independent diabetes (Type II), inability to tolerate glucose levels of more than 150mg/deciliter (fasting level) and subjects older than 46 years of age with an informed consent. The clinical reference value of normal blood glucose ranges from 65 to 110mg/deciliter.

Dose-Response Relationship

To evaluate the response of the patients to different dose levels and different formulations of Glucosol™ it was given orally according to the following regimen:

The ten subjects were divided into two groups of five. Both groups were given orally a placebo for two weeks. Following the placebo period, one group was given orally an oil-based soft gelatin capsule and another group was given a powder-based two-piece hard gelatin capsule. Each capsule (two-piece or soft gelatin capsule) contained 8mg Glucosol™. The initial dosage regimen was 16mg Glucosol™ daily for two weeks. Fasting glucose levels were measured in venous blood at 15 and 30 days of Glucosol™ supplementation. The dose of Corosolic acid, the active ingredient of Glucosol™, was 1,0% or 0.16mg/day. A (placebo) washout period of 2 weeks was allowed before the last dosage regimen. The last dosage was 48mg Glucosol™ per day.

The average fasting blood glucose level in both groups during placebo treatment was 167.7mg/deciliter.

Glucosol™ formulated in an oil base in soft gelatin capsules were given to each group of five people at 16 or 32 or 48mg Glucosol™ per day for 2 weeks. The average blood glucose level dropped 4.9% at 16mg Glucosol™ while the decrease was 10.7% at 32mg Glucosol™ and a drop of 31.9% was noted at 48mg Glucosol™ dose per day (Figure 1).

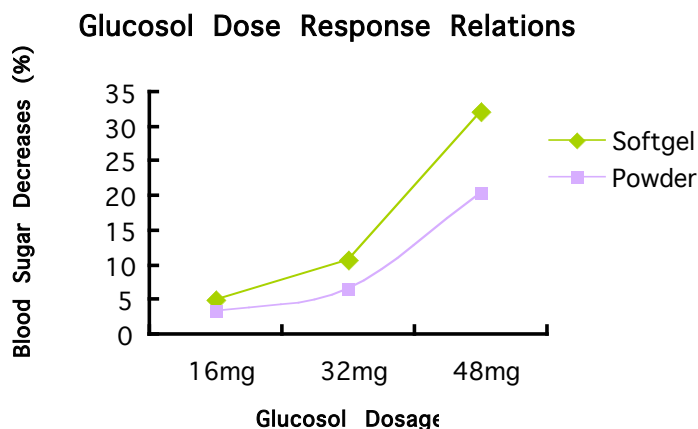


FIG1: Relative changes in blood sugar content with different dosages of Glucosol. Note that changes for the softgel formulation is significantly ($p>0.001$) greater than that for the hardgel formulation. Again, softgel formulation with Glucosol extract has a significantly greater effect on blood sugar reduction at a dose of 48mg than does that for the hardgel formulation.

The second group of five people were given Glucosol™ formulated in a dry powder base in two-piece hard gelatin capsule, at 16, 32 or 48 mg Glucosol™ per day. In this group, compared to the placebo, the average blood glucose level dropped by 3.18% at 16mg Glucosol™, 6.5% at 32mg Glucosol™ and 20.2% at 48mg daily dose of Glucosol™ (Figure 1).

These results indicate that the higher the daily dose of Glucosol™ the greater the drop in blood glucose levels.

Further, an oil-based soft gelatin capsule formulation of Glucosol™ seems to be more potent than a comparable dry-powder formulation of Glucosol™ in a two-piece hard gelatin capsule over the same dose range. These results suggest differences in absorption with significantly greater blood glucose level drop at 48mg daily dose of Glucosol™ in an oil-based soft gelatin formulation (Figure 2).

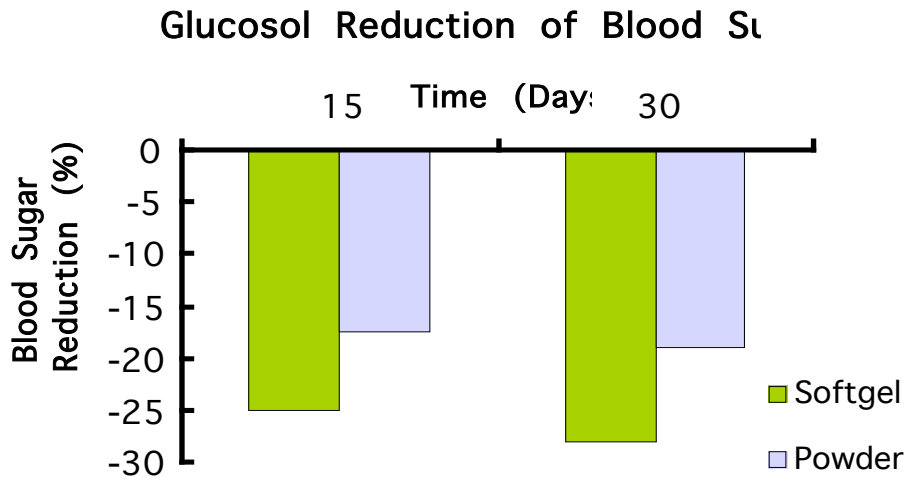


FIG2:Relative changes in blood sugars during softgel and powder Glucosol supplementation. Both forms significantly reduced blood sugars. Changes with the softgel form were significantly ($p > 0.001$) greater than those for the powder form at 15 and 30 days).

Measurement

The subjects were monitored for the following parameters: Blood glucose, blood pressure, body weight, temperature, heart rate, and general health and comfort in response to the supplement. Patient feed-back was also noted.

Cross-over Study

In the cross-over study design, a group of 12 subjects were given placebos for two weeks and their fasting blood glucose levels were monitored. The same group was given an oral daily dose of 48mg Glucosol™ (two capsules of 8mg Glucosol™ after each meal or a total of 6 capsules a day) in an oil-based soft gelatin formulation for 30 days. A (placebo) washout period of 45 days was allowed. After the initial washout period, the same group was crossed over to a daily 48mg Glucosol™ treatment (two capsules of 8mg Glucosol™ after each meal or a total of 6 capsules a day) in a dry-powder hard gelatin formulation for a period of 30 days. Following the hard gelatin Glucosol™ treatment, a second washout period of 45 days was allowed. The blood glucose levels were monitored at 15-day intervals, during the dosing and washout periods.

The Outcome

The results of this cross-over study demonstrate that an oral dose of Glucosol™ is effective in reducing blood glucose levels, with no signs of adverse effects. The average blood glucose level in the control group was 168.3 ± 10.3 mg/deciliter and the soft gelatin formulation caused a rapid drop to an average value of 127.2, and 115.1 mg/deciliter at the 15th and the 30th day of Glucosol™ treatment, respectively. During the washout period, the recovery of the blood glucose level was slow (131.7, 153.2 and 168.2 mg/deciliter at 15, 30 and 45 day of washout period). The washout period blood glucose levels suggest a memory effect of Glucosol™ treatment is notable in the slow recovery of blood glucose levels (Figure 3).

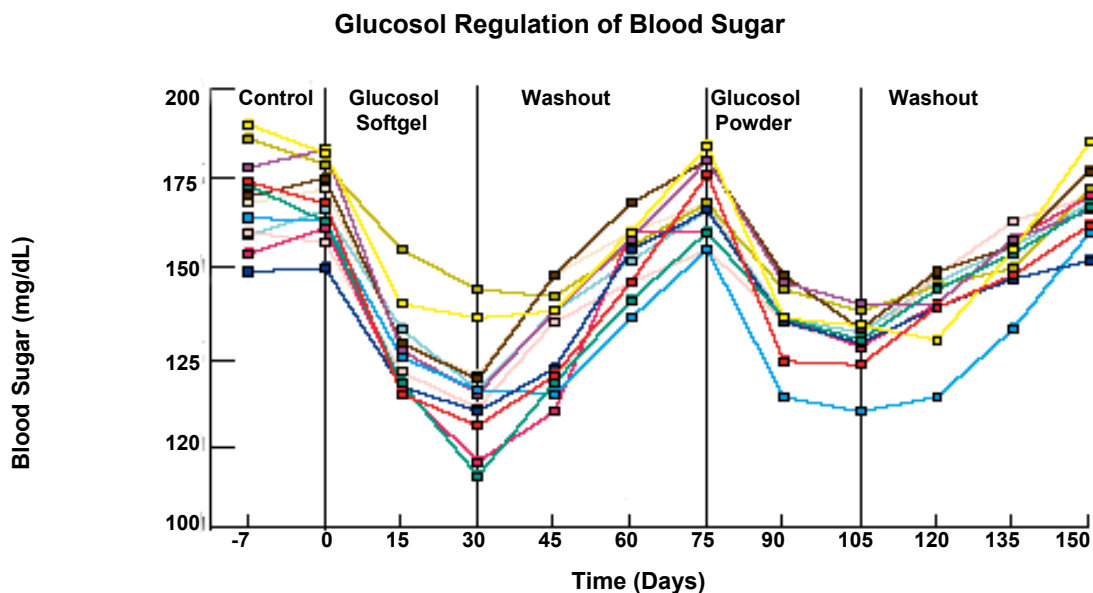


FIG3: Influence of Glucosol softgel and dry powder formulations on blood sugar regulation in Type II Diabetic patients. Glucosol was given at a dose of 48mg/day (16mg after each meal). Individual patient responses are present. Controls were from -7 to 0 days. Crossover was at 75 days. The active supplementation period was from 0 to 30 days (softgel) and 75 to 105 days (dry powder). The first washout period was from 30 to 75 days, and the second at 105 days. All volunteers responded to Glucosol supplementation with various rates and magnitudes of fasting blood sugar reduction. During the washout interval, the recovery of blood sugar was delayed in all volunteers for 45 days.

Compared to the dry-powder formulation treatment, a significantly greater drop in the average blood glucose level is observed with the soft gelatin formulation of Glucosol™.

Furthermore, these results indicate that both formulations, at 48mg Glucosol™ per day show continued blood glucose reduction until the end of the 30-day period. However, the soft gelatin formulation demonstrates a comparatively rapid and significantly greater blood glucose level drop at both 15 and 30 day period compared to the hard gelatin formulation. Furthermore, the greatest decrease of blood glucose to Glucosol™ treatment seem to occur in the first 15 days in both formulations (Figure 4).

Glucosol Regulation of Blood Sugar

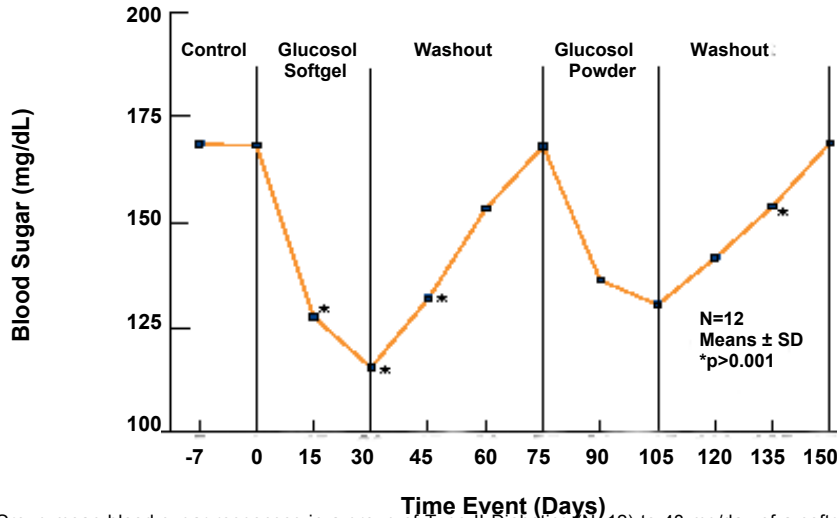


FIG4: Group mean blood sugar responses in a group of Type II Diabetics (N=12) to 48 mg/day of a softgel and a dry powder Glucosol formulation. Note the rapid Blood sugar reduction in the initial 15 days of supplementation and a gradual change thereafter for both Glucosol formulations. Significant blood sugar reductions occurred for both formulations, however the 30 day group response was significantly ($p > 0.001$) greater for the softgel Glucosol formulation.

Regaining Blood Glucose Balance

Glucosol™ supplementation seems to help in regaining blood glucose balance in adult onset diabetes (Type II) compared to pre-treatment control. Steeper decline in blood glucose levels and maintenance of lower blood glucose levels are evident in Glucosol™ supplementation compared to control conditions (Figure 5).

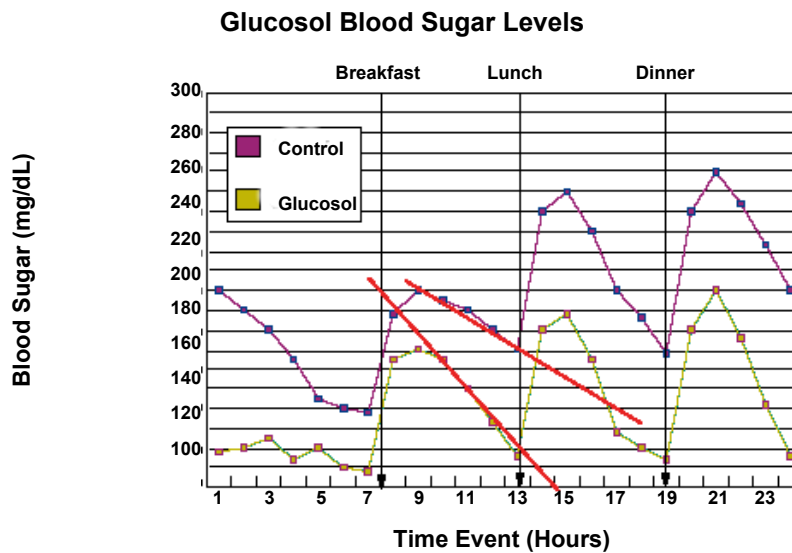


FIG5: Hourly blood sugar levels in Type II Diabetic patients before and after 30 days of 48mg/day Glucosol supplementation. Note the apparent steeper decline and the lower minimal blood sugar level during Glucosol supplementation compared to the control study. These differences (20 vs 11 mg/dL/hour) between Glucosol and the control conditions shows that the rate of sugar transport during Glucosol supplementation is twice that for the control condition.

Furthermore, Glucosol™ treatment shows sharper decline in blood glucose level after a meal resembling normoglycemic profile compared to the slow decline observed in (diabetic) untreated control condition (Figure 6). Subjects under Glucosol™ supplementation report disappearance of conditions associated with adult onset diabetes, such as frequent thirst and urination.

Blood sugar Variations Before and During Glucosol Supplementation

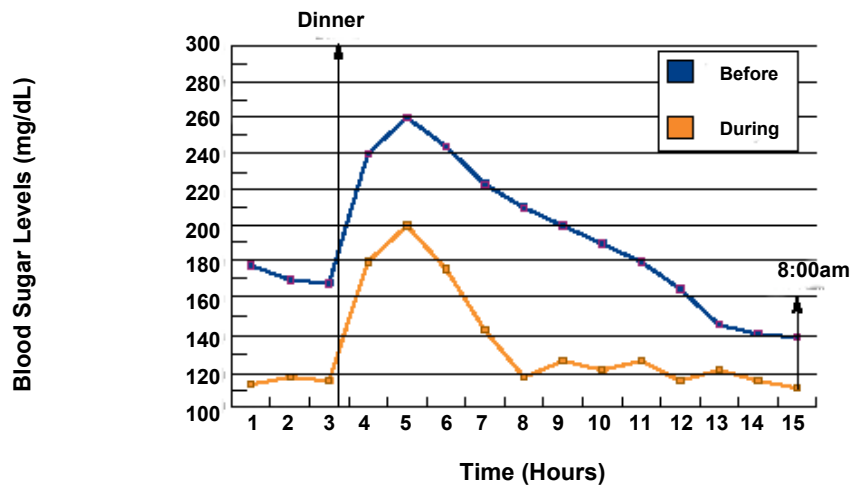


FIG6: Hourly blood sugar levels in a Type II diabetic patient before and during (30 days) Glucosol supplementation. Note the similar rise in blood sugar after the evening meal, but the slow decline in blood sugar before, compared to that during Glucosol supplementation. The 15 hr data points are the fasting glucose levels. The blood sugar profile during Glucosol is more representative of that found in normal sugar regulation, whereas the slow sugar decrease after a meal is the characteristic of a Type II Diabetic

Weight Loss

Subjects receiving the oil-based Glucosol™ formulation on a soft gelatin capsule seem to show an increased tendency of weight loss (an average weight loss of 3.2 pounds) than a dry-powder based Glucosol™ formulation (an average weight loss of 2.6 pounds) (Figure 7).

Glucosol and Body Weight Change

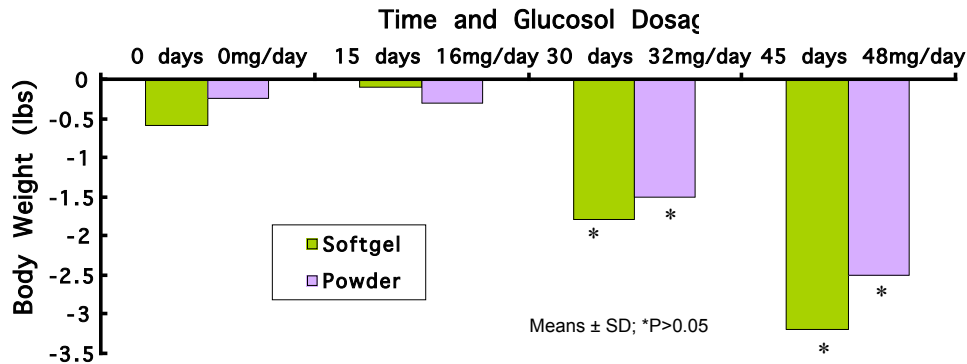


FIG7: Body weight change in Type II Diabetes during supplementation with 16, 32 and 48 mg/day Glucosol. Supplementation time for each dose was 15 days. Both the softgel and powder forms of Glucosol decreased body weight significantly at the 32 and 48mg/day dosages. The difference between Glucosol forms was not statistically different.

Mechanism of Action

Several types of glucose transporters are known in cell membranes of mammalian tissues. A glucose transporter is important in regulating the level of intracellular glucose. Glucose transport is one of the most important functions of all cells to acquire energy.

Glucosol™ and the Body Weight Change

Modifications of the activity of glucose-transport would cause several physiological effects, such as lowering glucose level. Only a few compounds have been known to affect glucose transport activity. For example, forskolin is a known glucose transport inhibitor and is useful as a control for *in vitro* test of glucose uptake. Therefore, finding an activator of glucose transport is more beneficial. Ehrlich ascites tumor cells are known to contain a glucose transporter and they can be easily propagated and are thus useful as a simple experimental system for screening glucose transport activity of natural products and extracts.

The time course of 2-deoxy-D-glucose (2-DG) uptake by Ehrlich cells was measured and the rate of uptake was linear up to 2 minutes at concentrations of 0.2 to 1.0mM. In this system, Forskolin inhibited 2-DG uptake by 51%, at a concentration of 20 μ M, and used as a control.

Corosolic acid, the active ingredients in Glucosol™, showed a significant glucose transport-stimulation activity, at a concentration of 1 μ M, (Figure 8). A recent report indicates that oral administration of Corosolic acid in normoglycemic rats resulted in hypoglycemic effect and this result correlates *in vitro* the above glucose uptake *in vitro* assay.

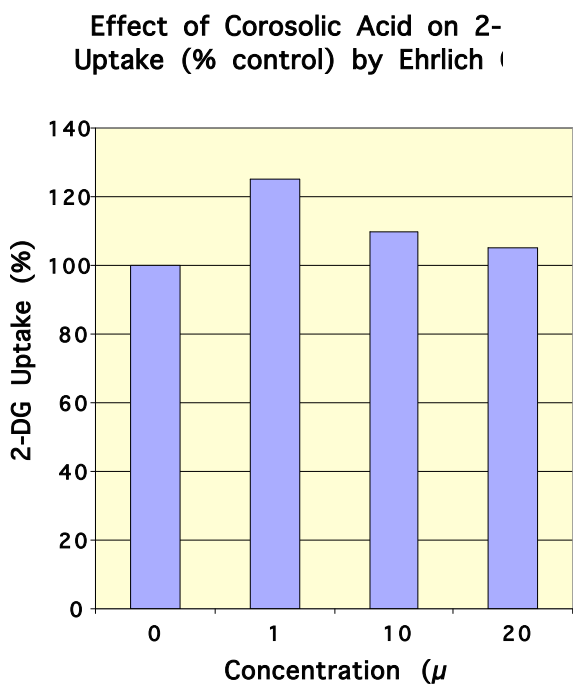


FIG8: Corosolic acid, the active ingredient in Glucosol, showed a significant glucose transport-stimulating activity at a concentration of 1 μ M.

Glucosol™ is Different from Insulin

Glucose transporters are important in regulating the level of intracellular glucose and, as notes above, insulin increased this glucose transporter activity.

Insulin, however, is temperature sensitive while Glucosol™ is temperature insensitive. Oral administration of insulin does not produce hypoglycemic effect, or drop in blood sugar level, whereas Glucosol™ does show hypoglycemic effect. Large doses of insulin injected parenterally, produces convulsions or death, while oral dose of Glucosol™ does not have any side effects.

Hence Glucosol™ is called phyto-insulin or insulin or insulin-like principle.

Conclusion

Glucosol™ is a clinically proven potent natural product for formulations to activate cell glucose-transporter “shuttles” and thus help balance blood glucose levels. Glucosol™ shows a memory effect of blood glucose lowering even after the treatment is stopped. An oil-based Glucosol™ formulation in a soft gelatin capsule seems to be relatively more efficient in lowering blood glucose levels naturally in Type II diabetics.

Glucosol™ also delivers a strong anti-oxidant activity to scavenge free radicals and to prevent cell membrane lipid peroxidation. In addition, Glucosol™ helps maintain low blood pressure and normal kidney function.

REFERENCES:

1. Olson R.; Present Knowledge in Nutrition, Nutrition Reviews' 6th Edition. Nutrition Foundation, Washington D C 1989 pp. 96-107.
2. Folman Y.; et al., The effect of dietary climatic factors in fertility, and in plasma progesterone and oestradiol – 17b levels in dairy cows. J Steroid Biochem 19 863-868 1983.
3. Kemmann E.; Pasquate S.A.; Skaf R.; Amenorrhea associated with carotenemia. JAMA 249 926-929 1983.
4. Dunne L.J.; Nutrition Almanac 3rd Edition. Mc Graw – Hill New York 1990 pp.25, pp.42.
5. Murray M.T.; Encyclopedia of Nutritional Supplements. Prima Publishing. Rocklin 1996, pp. 100, 809, 128, 125, 191, 193, 149, 221, 222.
6. Trumbo, P.; Yates A.A.; Schlicker, M.P.; Dietary Reference Intakes. Journal of the American Dietetics Association 101 294-301 2001
7. Okawa M.; et al., Vitamin B₁₂ treatment for sleep-wake rhythm disorders. Sleep 13 1-23, 1990.
8. Kaats G.; Current Therapeutic Research. June 1998.
9. Anderson R.; et al., Diabetes. November 1997.
10. Standing Committee on the Scientific Evaluation of Dietary Reference Intakes; Dietary Reference Intakes for calcium, phosphorus, magnesium, vitamin D, and fluoride. National Academy Press Washington, D. C. 1997.
11. Mahan L.K.; Escott-Stump S.; Food Nutrition and Diet Therapy. W.B Saunders Company. Philadelphia 1996.
12. Meyerovich J.; et al., Vanadate normalizes hyperglycaemia in two mouse models of non-insulin dependant diabetes mellitus. J Clin Invest 87 1286 1991