

Episulin

World's first natural insulin mimetic

Diabetes is a major leading cause of death in the world. It is a disease in which the body does not produce or properly use insulin necessary for the body to metabolize glucose (sugar). The glucose stays in your blood instead and its level then gets too high, causing you to have diabetes. Diabetes affects a large population in the world including India and it is growing phenomenally. Globally the statistics are staggering.

Once diabetes is diagnosed the first stop is usually to visit the family doctor for instruction on lifestyle changes, medications, and daily blood tests for life since there is no cure, only treatments to control it and delay its devastating affects! Over time, complications from diabetes can lead to blindness, kidney failure, heart disease, nerve damage, and limb amputations. Current medications can have serious side-effects including nausea, diarrhea, skin rash, weight gain, respiratory infections, liver damage, hypertension, neuropathy and headaches.

People with diabetes -whether Type 1 or 2 - have an increased risk of severe complications if the disease goes undiagnosed and untreated, or if it is poorly managed. The high blood glucose levels that occur make it easier for blockages to form in the body's arteries and for nerve damage, causing numbness and tingling, especially in the legs and feet. Most people with diabetes have health problems such as high blood pressure and cholesterol that increase one's risk of heart disease and stroke. In fact 65% of diabetics die from it. Signs of diabetes are:

- § Being very thirsty
- § Urinating often
- § Feeling very hungry or tired
- § Losing weight without trying
- § Having slowly healing sores
- § Dry itchy skin
- § Losing feeling or tingling sensations in limbs
- § Having blurry eyesight

There are two common forms of diabetes:

Type 1 diabetes, or insulin-dependent diabetes, is usually first diagnosed in children, teenagers or young adults. In this form of diabetes, the beta cells of the pancreas no longer make insulin because the body's immune system has attacked and destroyed them.

Type 2 diabetes, or non-insulin-dependent diabetes, is the most common form. People can develop Type 2 at any age and is where the pancreas does not make enough insulin and the body does not use it properly due to insulin resistance.

Treatment for diabetes includes insulin shots, medications, wise food choices, exercise, and controlling blood pressure and cholesterol."

As one can see, there are no prescription drugs without serious side effects. These drugs often cause severe fluctuation in blood sugar levels causing hypoglycaemia. These fluctuations cause more damage to the health of the patient. Episulin™ and Prepeptone™ are clinically proven to have no side effects and are guaranteed to be 100% effective.

It has been felt world wide that a diabetes patient needs an integrated approach towards management of the overall health condition associated with diabetes viz. blood sugar level, cholesterol, blood urea, constipation, sluggish liver, BMI, indigestion, neuropathy and obesity.

The key to Episulin effectiveness lies in researched blend of botanical ingredients combined from over four years of laboratory trials and immuno-pharmacological research. Every ingredient plays its particular role and the botanical blend as a whole represents a powerful tool to normalize your blood sugar levels. Episulin is a breakthrough in scientific research and works at the cellular level in stages as follows:

Episulin

Pharmacology and actions:

Episulin is a combination of herbs that has been proven to be synergistically beneficial to a diabetic patient. This combination is based on nine active scientifically proven herbs for their action in diabetes. This formulation contains an active principle "Epicatechin" derived from the bark of *Pterocarpus marsupium* which has been proven to be a natural insulin mimetic. This formula contains optimum concentrations of each and every ingredient to have a better, balanced, complementary and beneficial medicine.

The formulation offers a synergistic action of active principle with other natural ingredients in controlling Diabetes Mellitus as a whole which has been proven experimentally.

This combination has not only the potent anti-diabetic action but also prevents and cures different complications of diabetes like neuropathy, nephropathy and vasculopathy which are the main complications and side effects of diabetic patients which has been proved by clinical trial amongst NIDDM patients. Thus along with correcting the blood sugar level and body resistance it also corrects the metabolic derangements and hence prevents the man from the side effects and other complications of modern synthetic anti-diabetic drug.

Mechanism of action:

The active principle of Episulin is Epicatechin, which is extracted from the bark of *P. marsupium* in a highly scientific manner.

The active principle controls diabetes in the following manner:

- § Epicatechin increases the cAMP content of the islet which is associated with increased insulin release.
- § Epicatechin plays a role in the conversion of proinsulin to insulin by increasing cathepsin β activity.
- § Epicatechin plays an insulin-mimetic effect on osmotic fragility of human erythrocytes.
- § Epicatechin inhibits Na/K ATPase activity on patient erythrocytes, an effect similar to that of insulin.

Pharmacokinetics:

Ingredient	Action & Role
<i>Pterocarpus marsupium</i>	Regenerates beta cells, mimics insulin, checks blood sugar level.
<i>Momordica charantia</i> Linn	Astringent, controls blood sugar level
<i>Cinnamomum tamala</i>	Diuretic, increases blood insulin, stimulates Pancreas
<i>Trigonella foenum graecum</i>	Diuretic, decrease blood sugar level, stimulates appetite
<i>Eugenia jambolana</i>	Diuretic, antidiabetic. It diminishes the quantity of sugar in urine; allays the unquenchable thirst of urine
<i>Melia azadirachta</i>	Checks basal metabolism and body sugar level
<i>Picororrhiza kurrooa</i>	Checks basal metabolism, bitter tonic, corrects the function of liver and kidney

Ocimum sanctum	Diaphoretic, stimulant, anti-stress, adaptogenic
Gymnema sylvestre	Hypoglycemic agent, diuretic, have an oxidase action on glucose solution and shows glycolysis

The whole formulation of Episulin is researched around the active principle 'Epicatechin' which is at the core of the total product. Other ingredients are added to prevent and cure the different complications of diabetes. It controls the metabolic derangements rather than mere control of blood sugar level.

Clinical Information:

A clinical trial has been conducted to evaluate the efficacy of Episulin in the treatment of Non Insulin Dependant Diabetes Mellitus (NIDDM) at Sir Sunder Lal Hospital by DR. K. N. Dwivedi, Consultant-Diabetic Clinic (I. M.), Institute of Medical Sciences, Benaras Hindu University, Varanasi. Dr. K. N. Dwivedi is a member of Diabetic Association of India (DAI), Research Society of Study of Diabetes in India (RSSDI) and Indian Society of Wound Management (ISWM).

A number of diagnosed patients of Non Insulin Dependant Diabetes Mellitus (NIDDM) were selected for present study from the Out Patient Department (OPD) and in-door of the diabetes clinic, Indian Medicine, Sir Sunderlal Hospital, Institute of Medical Sciences, Benaras Hindu University, Varanasi. All the patients were examined clinically for the signs and symptoms of Diabetes Mellitus and subjected for routine biochemical investigations as per clinical protocol. Self control method was used in this clinical trial.

Parameters of objective assessment were:

- § Reduction in fasting and post-prandial blood sugar level
- § Desirable change in the status of body mass index (BMI)
- § Changes in hemoglobin level
- § Changes in levels of serum cholesterol
- § Changes in levels of blood urea and serum creatinine

Parameters of subjective assessment were:

The presence or absence of symptoms at the end of three months treatment.

Effect of Episulin on Objective Parameters of assessment

Sl No.	Objective Parameters	Before Treatment	Three Months after Treatment	P Value
1	Body Mass Index (BMI) (Mean Value)	25.96	24.88	< 0.01
2	Fasting Blood Sugar (Mean Value in mg%)	170.37	109.80	< 0.001
3	Post-Prandial Blood Sugar (Mean Value in mg%)	243.93	164.77	< 0.001
4	Hemoglobin (Mean Value in gm%)	11.58	13.27	< 0.001
5	Serum Cholesterol (Mean Value in mg%)	229.90	194.03	< 0.001
6	Blood Urea (Mean Value in mg%)	38.23	33.23	< 0.001
7	Serum Creatinine (Mean Value in mg%)	1.57	1.32	< 0.001

Figure -1

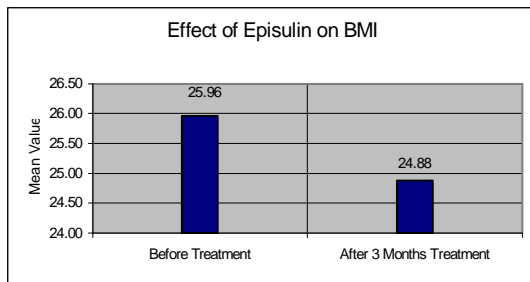


Figure – 2

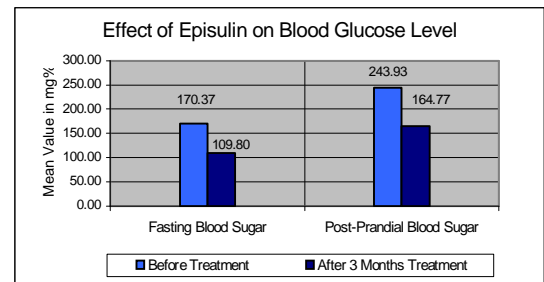


Figure – 3

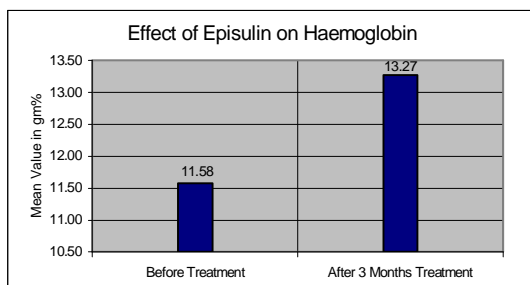


Figure – 4

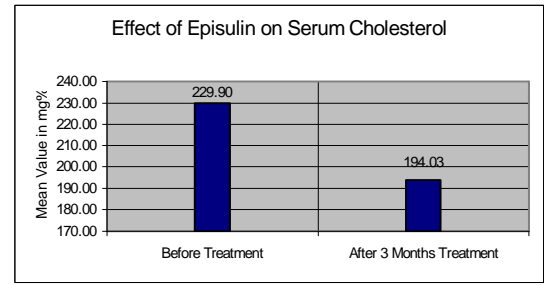


Figure – 5

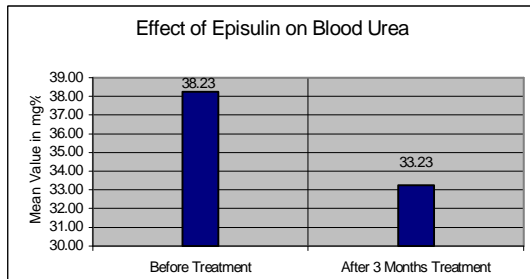


Figure - 6

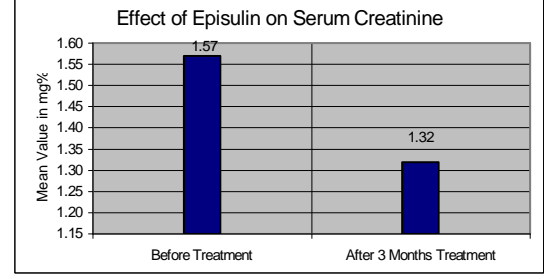


Figure – 1 to 6 shows that:

Mean BMI of the patients was 25.96 indicating that majority of the patients were overweight. Episulin reduced their BMI up to a mean of 24.88 indicating a reduction in BMI value towards normal range. P value (< 0.01) depicts that drug is statistically significant in reducing BMI.

Mean Fasting Blood Sugar level was reduced by the Episulin from the beginning value of 170.37 mg% to the level of 109.80 mg% at the end of three months therapy. P value (< 0.001) shows the statistically promising significance of the drug in the reduction of Fasting Blood Sugar level.

Mean Post-Prandial Sugar level which was 243.93 mg% (before treatment) was reduced by Episulin to 164.77 mg% at the end of three months therapy which falls within normal range. The statistically significant efficacy of the drug is evident by its p value (< 0.001).

Hemoglobin level was improved by Episulin from a mean value of 11.58 gm% to 13.27 gm% during three months therapy which indicates restoration of positive health of the patient.

Serum Cholesterol level was reduced by Episulin in three months from a mean value of 229.90 mg% to 194.03 mg% thus it also reduces the chance of ischemic heart disease among diabetic patients.

Mean Blood Urea level 38.23 mg% which was towards external limit of normal range was reduced significantly up to the level of 33.23 mg% at the end of three months. This is indicative of Episulin efficiency to improve the functions of kidney as well as its Reno-protective action.

Reduction of mean Serum Creatinine value from a value of 1.57 mg% to 1.32 mg% again depicts Episulin's role in Reno-protection and in the improvement of renal function.

Effect of Episulin on Subjective Symptoms

Symptoms	No. of Cases			Percentage Improved
	Before Treatment	After Treatment	Improved	
Polyurea	24	0	24	100
Polydipsia	29	0	29	100
Increased Appetite	14	0	14	100
Weakness	30	3	27	90
Fatigue	30	3	27	90
Feeling of cold in Hand and Feet	4	0	4	100
Burning Sensation	18	2	16	89
Numbness	9	0	9	100
Paraesthesia	5	1	4	80
Muscular Pain	30	0	30	100

Above table shows that there was marked improvement in subjective symptoms. Besides this a better sense of well being was observed in all the patients.

Marked improvement in symptoms along with a better sense of well being was experienced by all the patients. This may be due to better glycaemic control exerted by the drug or we may say that these are the specific ayurvedic natural constituents of Episulin which in addition to adequate glycaemic control, induces a better sense of well being.

Indication and Usage:

- § Episulin is a herbal product for diabetes II (NIDDM)
- § Episulin is a good adjuvant for IDDM, in order to reduce the amount of needed Insulin.
- § Episulin can be advised along with other modern / synthetic oral hypoglycemic drugs.
- § Episulin is preventive as well as curative for diabetic complications.
- § Episulin is advised along with appropriate diet and exercise.
- § Episulin can be advised along with any integrated diabetes control program.
- § Active principles of Episulin stimulate the body for its hypoglycemic activity and has been studied that it induces no risk of hypoglycemia even at very high dosage.

Contraindications: None

Precautions:

Avoid Sweets, Creams, Butter, Cheese, Jams, Pastry and Jellies. Avoid taking fatty and fried food stuff with excessive spices. Regular morning walk and mild exercise like yoga helps in effective control of diabetes. Blood sugar level should be monitored periodically.

Warning

If the patient is on insulin or any other type of treatment with modern medicines or others Episulin should be started concurrently and other medications may be gradually tapered off on weekly or fortnightly monitoring of blood sugar level and general feeling of well being by the patient himself.

Adverse effects / Toxicity

Acute oral toxicity study of Episulin has been conducted at Institute of Toxicological Research Centre (I.T.R.C.), Lucknow.

Dosage (mg/kg)	Dead/Dosed	Death	Signs of Toxicity
5000	0/5	Nil	Nil

Episulin at a limit dose of 5000 mg/kg has not produced any signs of poisoning or death of animals. Autopsy of the surviving animal at the end of the observation period did not indicate any gross pathological changes.

The very high test dose (equivalent to 40-80 gms per day by a person of normal weight range) and the observation that there was no residual effect in the critical organs of the animal and no toxicity confirms that Episulin is very safe and since it is 100% of plant origin it gets fully metabolized by the body's own digestive system without leaving any residual or accumulated load on the critical organs of the body.

Drug Interactions:

No adverse drug interaction has been reported so far when Episulin is taken with other medications during trials and since the Episulin is in the market. However patients are requested to stop Episulin and report any adverse effect due to interaction of the drug.

Dosage and administration:

One capsule twice daily half an hour before principal meals for the newly diagnosed NIDDM patients. If the patient is suffering from chronic or severe diabetes Episulin may be included in the treatment at a higher dose 2-3 capsules twice to thrice daily minimum half an hour before meals without stopping the modern / synthetic drugs. These synthetic drugs may be gradually tapered down with the regular monitoring of blood sugar level and patients own feeling of well being. Effect of Episulin may reach to a level when gradually synthetic drug s may not be required then gradually high dose of Episulin is brought down to the maintenance dose of 2 capsules BD before meals. Effect of Episulin differs from patient to patient due to difference in physiological, physical, social, familial and dietary conditions.

Although so far no adverse reaction or result has been reported, chronic and severe diabetic patients are advised to consult their physician for dose management and treatment method.

FAQ

Q: How Episulin™ controls blood sugar level?

A: Episulin has insulin mimetic action which helps in regulating blood sugar level. The other actions of Episulin help the body system by increasing conversion of pro-insulin in to insulin and by increasing glucose up take by the cells.

Q: Does Episulin™ cause hypoglycaemia?

A: Unlike synthetic oral hypoglycaemic drugs Episulin does not cause hypoglycaemia.

Q: Is there any report regarding toxicity of Episulin™?

A: Yes. Episulin has been evaluated at Industrial Toxicological Research Centre, Lucknow, a Government of India's institute for Toxicological research at a 66 times higher dose in mice with excellent tolerance and no side effects, no changes in system.

Q: In which cases of diabetes use of Episulin is recommended?

A: Episulin is useful in Non Insulin Dependent Diabetes Mellitus also known as type 2 or maturity onset diabetes.

Q: Can Episulin be taken with other allopathic antidiabetic drugs?

A: The allopathic antidiabetic drugs are known as Oral Hypoglycaemic Agents (OHAs). Episulin can be co-administered with OHAs which helps in cutting down the dose of OHAs. The dose of OHAs should be tapered down gradually.

Q: Is there any side effect of Episulin?

A: No side effect has been reported with use of Episulin. It is a safe herbal preparation.

Q: Should I take any caution while using Episulin?

A: There is no caution with Episulin as such. The cautions advised by the physician for the management of diabetes must be followed viz. avoiding sugar products, fats etc. Regular exercise as told by the physician is always beneficial for keeping good health.

Q: How long can I take Episulin?

A: Episulin can be taken as long as required. It is a safe product and is completely metabolized.

Q: How much time it takes to see normal blood glucose level with the use of Episulin?

A: Normally it takes 6 to 12 weeks to experience the benefits of Episulin. In certain individuals it may take little longer.

Q: Does Episulin cause hypoglycaemia?

A: No. Episulin does not cause hypoglycaemia. There was no reporting of hypoglycaemia when Episulin was evaluated clinically. None of the users has reported hypoglycaemia. However when patient is taking other OHAs alongwith Episulin proper dose adjustment is required of OHAs with the help of monitoring of blood sugar level and patients own feeling. With the use of Episulin requirement of other OHAs gradually comes down.

Q: What should I do when a dose of Episulin is missed before meals?

A: You can take Episulin after meals if a dose is missed before meals. But it is advisable to take it 30 minutes before meals.

Q: Does Episulin contain any metal or mineral?

A: No metal or mineral has been used in the formulation of Episulin. Episulin is 100% plant material based product.

Q: My weight is 90 Kg. Shall I take more than 2 capsules a day?

A: Some overweight people take 3 or 4 capsules a day without any side effects. But if you are taking OHAs also, monitor blood sugar levels regularly. This will help in tapering down the dose of OHAs.

Q: Why Episulin shows slow on set of action in certain cases?

A: It is a natural process that damaged parts take time to restore normal functioning. Episulin aims to restore the damaged body function causing higher blood glucose level.

A research product of

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