

ForsLean®

*A patented phytonutrient for weight management
by promoting lean body mass*

Best New Product of 2001



Voted Best New Product of 2001
Nutracon Conference and Exhibition, San Diego, CA July 9-11

Description

ForsLean® is Sabinsa's new proprietary composition extract of *Coleus forskohlii* root, standardized for 10 percent forskolin. ForsLean® has shown promising results in three areas; enhancing lean body mass, promoting fat loss and promoting weight loss. In September of 1998 Sabinsa was granted a use patent for this application of forskolin in its ForsLean® composition.

Intended Application

The importance of maintaining or regaining lean body mass has recently come to light for two important reasons. First is the increased recognition that lean body mass plays a vital role in any successful weight training regimen, and second, there is a growing awareness that lean body mass is proportionate to the overall health of an individual.

Lean body mass is composed of muscle, vital organs, bone and bone marrow, connective tissue and body water. The percentage of lean body mass to fat not only determines the body's aesthetic appearance, but more importantly, it is also an index of physical fitness, health status, susceptibility to disease and premature mortality. Because the body's metabolic rate is directly proportional to the amount of lean body mass, there is substantial interest in products that safely increase lean body mass because they are most likely to work. The use of ForsLean® may help to increase lean body mass and optimize body composition¹ with one of the side effects being fat loss and/or weight loss.

A sluggish metabolic rate is an undesired effect of many weight-loss regimens. It was observed in one study that formerly obese subjects had a 3-5% lower resting metabolic rate than control subjects. The occurrence of a low resting metabolic rate is likely to contribute to the high rate of weight regain in formerly obese persons.

Clearly, we need to change and broaden our thinking on the objectives of weight management regimens for both active and not-so-active individuals. In particular, it should be emphasized that healthy functioning of the body depends not so much on a lower fat content, but rather on obtaining a higher percentage of lean body mass. Again, it should be kept in mind that it is not only fat, but also lean body mass that is, or can be, lost through dieting. This fact often escapes our attention when we reduce our total body weight. The loss of lean body mass offsets any benefits derived from the reduction of body weight, and can potentially increase one's chances for diabetes, cardiovascular disease and possibly some forms of cancer due to poor metabolic activity.

Mechanism of Action

"ForsLean® shifts the proportion between lean body mass and adipose, or fatty, tissue in favor of lean body mass, which improves overall health," explains Vladimir Badmaev, MD, PhD, Sabinsa Corporation's Vice President, Scientific and Medical Affairs. "The effect can be measured by decreases in the waist hip ratio and the body mass index."

The mechanism of action on how ForsLean® works is well defined (see *attached stapled diagrams*). Badmaev adds, "Forskolin, the active compound in ForsLean®, is recognized as an adenylate cyclase activator. Adenylate cyclase is the enzyme involved in the production of cyclic adenosine monophosphate (cAMP), a significant biochemical agent in metabolic processes. The role of cyclic AMP is indispensable to many body functions. It induces a chain reaction of biochemical events that trigger metabolic processes and diet induced thermogenesis, thereby providing the means to maintain healthy body composition and lean body mass levels."

Proof of Efficacy Summary

ForsLean® was tested in an open-field study with a population of six overweight women (BMI>25). The tested formula was in the form of two-piece, hard shell capsules; each capsule contained 250 mg of ForsLean®. The overweight, but otherwise healthy women received one capsule twice daily for eight weeks. Participants were instructed to take one capsule in the morning and one in the evening, half an hour before a meal. Each participant was asked to maintain her previous daily physical exercise and eating habits. In addition, physical activity was

monitored based on a questionnaire before and during the trial.

During the eight week trial, the mean values for body weight and fat content significantly decreased, whereas lean body mass was significantly increased as compared to the baseline. Neither the systolic/diastolic blood pressure, nor the pulse rate was adversely affected during the trial. Indeed, a trend was observed of lower systolic/diastolic pressure during the course of treatment. A line graph is attached that shows actual results from this study.

Dosage form/delivery

ForsLean[®], has been clinically evaluated at one dose, 250 mgs twice daily. This provides 50 mgs of forskolin, the primary active compound in ForsLean[®]. Dosage has been in the form of a two piece, hard shell capsule.

Sabinsa also offers standardized *Coleus forskohlii* extracts in concentration of 1%, 20%, 40% and 95% forskolin.

Additional information of interest

Currently two new studies have been undertaken to further explore the efficacy of ForsLean[®], one in the US and the other in Japan. Prior to these two studies, both an LD₅₀ analysis and AMES test were performed by independent laboratories in the US confirming the safe use of ForsLean[®].

The US study is underway at the University of Memphis, Exercise & Sports Nutrition Laboratory. Twenty mildly obese female subjects between the ages of 18 to 40 have been recruited to participate in this study.

The study is designed as a double blind, placebo-controlled investigation of ForsLean[®] versus a similarly matched placebo for 12 weeks. After baseline testing, subjects will be randomly assigned to ingest 2 capsules a day containing either ForsLean[®] or the placebo. (One capsule in the morning and one in the evening, half an hour before a meal). Each active capsule contains 250 mg of ForsLean[®].

Analysis for this trial includes the overall assessment of select parameters, blood pressure, body composition and individual serological and hematological profiles. Subjective questionnaires to determine the subjects' perception of the treatment and quality of life/lifestyle aspects will also be administered.

Dr. Tsuguyoshi Asano, a prominent Tokyo based Japanese physician who specializes in Internal medicine and bariatrics is the principle investigator in a 12-week study protocol including 20 overweight, but otherwise healthy, men and women who have a body mass index (BMI) 25-26. 250 mgs of ForsLean[®] will be administered twice a day in the form of a two-piece hard shell capsule. Each participant will receive a physical examination, and their blood biochemistry and body composition will be analyzed at the inception and after 4, 8 and 12 weeks of the study. ForsLean[®] has been cleared for nutritional use by the Japanese FDA.

As mentioned in the beginning, with Sabinsa's discovery of the lean body mass/weight loss properties of forskolin, which was not a traditional use of the herb, the US Patent and Trademark Office granted to Sabinsa a use patent for this compound. This is not an achievement to be lightly passed over.

Sabinsa has dedicated a website to providing additional information on ForsLean[®]. It is www.forslean.com or www.forslean.net