

Keywords

Forslean
Lean Body Mass
Skin conditioning
Body circumference

Summary

Forslean® is manufactured by a proprietary process and is a standardized extract from the roots of the Coleus forskohlii plant, the only known plant source of forskohlin. ForsLean® is a registered trademark of Sabinsa Corporation and is the only Coleus forskohlii preparation supported commonly by Patent.

Forslean



SABINSA CORPORATION

Description

Forslean® is Sabinsa's new proprietary composition extract of Coleus forskohlii root, standardized for 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 composition with one of the side effects being fat loss and/or weight loss.

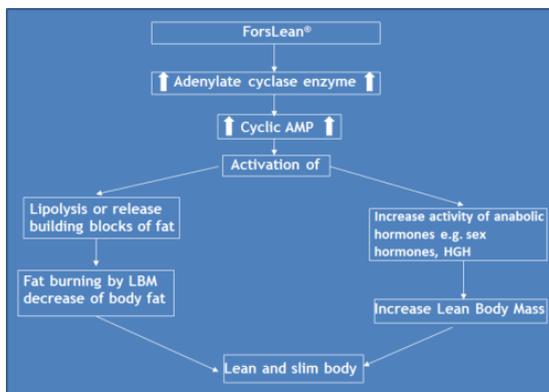
A sluggish metabolic rate is an undesired effect of many weight-loss regimens. It was observed in one study that formerly obese subjects had a 3-5% lower resting metabolic rate than control subjects. The occurrence of a low resting metabolic rate is likely to contribute to the high rate of weight regain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

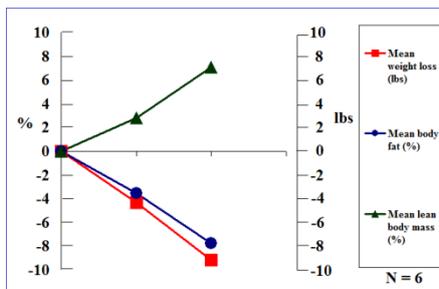
The mechanism of action on how Forslean® works is well defined : "Forskohlin, the active compound in Forslean®, is recog-



nized 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.

Double blind study

Dozen studies are available. In one on 12 weeks, 25-45 y, 60 obese males and female volunteers, Forslean® treated volunteers shed on an average 1.73 kg from their body weight, in comparison placebo group gained 0.25 kg. During the 12 – week period of treatment volun-



teers treated with placebo gained 0.68% of body fat. On the other hand, the Forslean® treated group lost 0.46% of body fat.

In the group of volunteers that received Forslean®, there was an increase in the LBM as compared to the placebo group where, there was a decrease in LBM. HDL cholesterol showed a statistically significant increase in volunteers treated with Forslean®. Other serum lipid profiles remained statistically unaltered in the Forslean® and Placebo treated groups.

Dosage Form

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

Toxicity

Acute toxicity LD50 : 2g / kg

Chronic toxicity : none at 1g / kg on 6 months

Mutagenicity : non-mutagenic (AMES). Salmonella t., and E. Coli also controlled.

Safety : A number of clinical studies investigating the efficacy of Forslean® for body composition management have been conducted, and parameters related to safety have been monitored.

No significant changes in average systolic and diastolic pressures (12 weeks, 60 volunteers). None even on thyroids hormones.

There is a significant positive change (p<0.05) in the concentration of HDL

Cosmeceutical applications

Topical fat reduction in specific areas of the body is a common concern for women. Ronsard8 popularized the term "cellulite" to describe the dimpling and "orange peel" external appearance of the thighs, the cause of which was attributed to the aging process by later researchers9. The structure of subcutaneous adipose tissue accounts for the development of the "orange peel" appearance. Groups of fat cells are attached to the underside of the dermis by fibrous connective tissue. As fat cells enlarge, the fibers are stretched and pull down on the underlying skin. This causes the indentation or dimpling of the skin called cellulite.

It has been demonstrated that adipose tissue metabolism varies from one region of the body to another, for example, in severely obese women losing weight after the jejunoileal bypass surgery, fat was seen to be absorbed more slowly in the thigh region than the abdominal region10. These differences lead to the hypothesis that localized application of agents that trigger lipolysis or fat breakdown could help in cases of fat accumulation at specific subcutaneous sites.

Forskolin accelerates lipolysis through the activation of hormone-sensitive lipase — adrenoreceptors playing important roles in the regulation of lipolysis (adrenoreceptors are neurons that are activated by adrenaline (epinephrine) or similar substance). Based on clinical studies reported in literature, Coleus forskohlii extract 95% is potentially useful in dislodging localized fat deposits immediately under the skin, when applied topically.

Dosage Form

The recommended levels of use as a skin conditioning agent : 0.1 to 0.5% of a topical formulation, such as an ointment, cream or lotion

Sustainability

Sabinsa is growing Coleus in part of its 44 000 acres, and do its own plant selection, so the best sustainability.

