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presents

ForsLean®

Forslean® is a Registered Trademark and
Patented Product of Sabinsa Corporation.
U.S. Patent 5,804,596.
European Patent EP0977564

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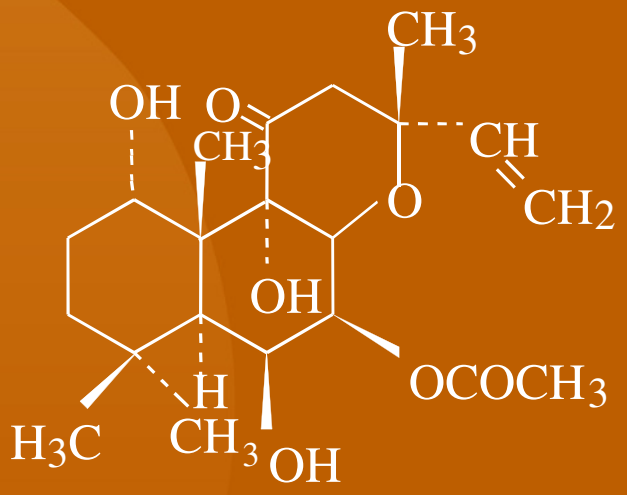
ForsLean®

Coleus forskohlii roots Extract

Role in enhancing lean body mass and in the treatment of mood disorders

Sabinsa U.S. Patent 5,804,596
European Patent EP0977564



Forskolin

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ForsLean® Thomas Alva Edison Patent Award

US Patent 5,804,596, won the Thomas Alva Edison Patent Award (R & D Council, NJ USA) in 2004

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ForsLean® Nutracon Award: Best New Product of 2001

ForsLean®

- ForsLean® is a powdered extract from the roots of *Coleus forskohlii*
- Standardized to contain 10% forskolin
- The intended dose of ForsLean® is one 250mg capsule, twice daily, to support healthy body composition

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Traditional Food and Medicinal Uses

- Coleus forskohlii is cultivated commercially in India
- The roots have a history of food use as a pickle[1]

1. Med Res Rev 3(2); 201-219 (1983)

Acute Toxicity Studies (LD_{50})

- Male and female Wistar rats were given a single oral dose of 2,000mg ForsLean® (10%) / kg body weight
- No deaths occurred
- However, diarrhea, soiling of the anogenital area, and wetness of the mouth and anogenital area were reported

ForsLean® single dose oral toxicity in rats/LD50 in rats. MB Research Laboratories, Spinnertown, PA. MB Research Project No. MB 00-8628.01 unpublished final study report (2000).

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Acute Toxicity Studies

- Earlier studies showed the acute LD_{50} of forskolin (10%) to be 3,100 and 2,550 mg/kg by oral administration and 105 and 92 mg/kg body weight when administered intraperitoneally in mice and rats, respectively

de Souza et al. 1983. Forskolin: A labane diterpenoid with antihypertensive, positive inotropic, platelet aggregation inhibitory, and adenylate cyclase activating properties. *Med. Res. Rev.* **3(2):** 201-219.

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Chronic Toxicity Studies (ForsLean®) (6 months Study)

- No treatment related mortality at and up to 1000 mg/kg (forskolin 10%)
- No incidence of treatment - related adverse clinical effects, ocular abnormalities or neurotoxicity at and up to 1000 mg/kg
- No adverse effect on body weight gain of treatment groups at and up to 1000 mg/kg
- No effect on daily food consumption of any treatment groups at and up to 1000 mg/kg

Cantox Health Sciences International. ON, Canada, August 2004

Mutagenicity Study

- ForsLean® (10%) was reported to be non-mutagenic in the bacterial mutation assay (AMES)
- An independent repeat assay using *Salmonella typhiurium* strains TA98, TA100, TA1535, and TA1537, and *Escherichia coli* strain WP2 uvrA
- Both were in the presence and absence of metabolic activation, at doses of up to 5,000 µg/plate

Wagner and Klug, 2001 BioReliance Laboratories – ForsLean® AMES test

Safety Data: Summary of Clinical Studies

- A number of clinical studies investigating the efficacy of ForsLean® for body composition management have been conducted
- All studies utilized 10% extract of Coleus Forskohlii roots administered at 250mg bid for 8 to 12 weeks
- Although efficacy was the primary purpose of these trials, parameters related to *safety* were also monitored

Safety Data: Summary of Clinical Studies

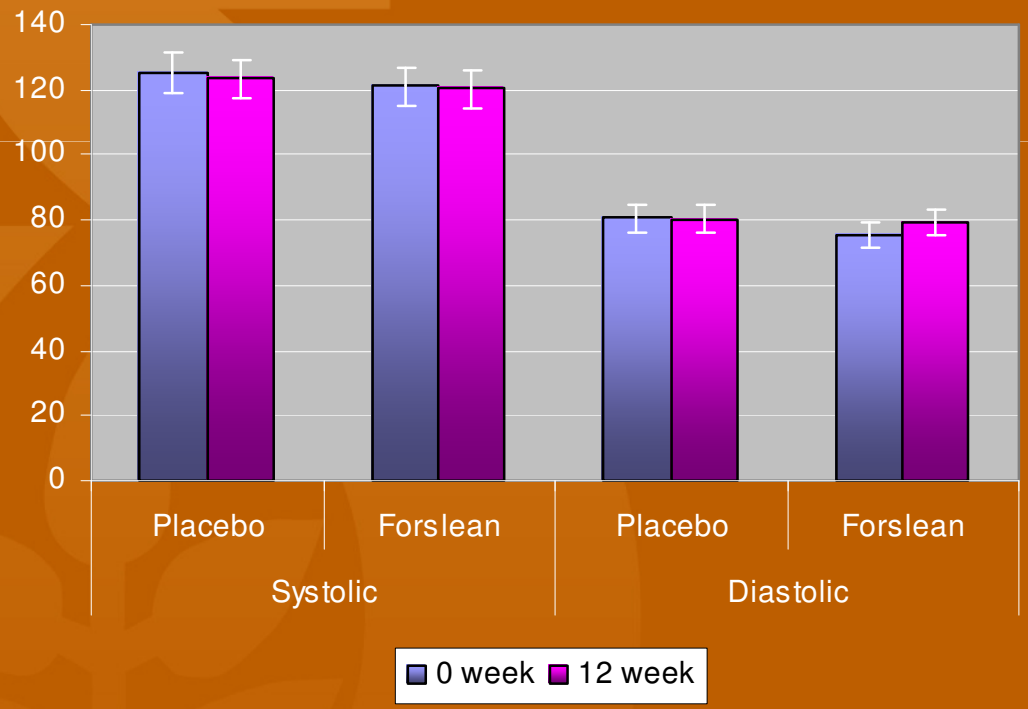
Number of Subjects	Dose of C. forskohlii Extract (mg/day) [dose of forskolin (mg/day)]	Study Design	Study Length	Measured Outcome(s)	Reference
14 Overweight Subjects (1 male, 13 female)	250 [25]	Open-field Study	12 wk	No significant effects on systolic and diastolic blood pressure or pulse rate. No significant adverse effects.	Tsuguyoshi et al, 2001
6 Overweight Women	500 [50]	Open-field Study	8 wk	No significant effects on systolic and diastolic blood pressure or pulse rate.	Badmaev et al, 2002
16 Overweight Men (8/group)	500 [50]	Randomized, Double-Blind, Placebo-controlled Study	8 wk	No significant effects on body weight, heart rate, mean arterial pressure, or systolic and diastolic blood pressure.	Agena, unpublished

Safety Data: Summary of Clinical Studies

Number of Subjects	Dose of C. forskohlii Extract (mg/day) [dose of forskolin (mg/day)]	Study Design	Study Length	Measured Outcome(s)	Reference
19 women [n=12 (controls); n=7 (test)]	500 [50]	Randomized, Double-Blind, Placebo-controlled Study	12 wk	No significant differences between groups in metabolic markers, blood lipids, muscle and liver enzymes, electrolytes, red blood cells, white blood cells, hormones (insulin, TSHa, T3b, T4c), heart rate, blood pressure, or reported side effects.	Kreider et al, 2004
60 obese men and women (30/group)	500 [50]	Randomized, Double-Blind, Placebo-controlled Study	12 wk	No significant effects on blood pressure, liver, kidney and thyroid function or blood lipid profile, with the exception of increased HDL cholesterol and decreased ratio of total:HDL cholesterol.	Bhagwat et al, 2004

Safety Data: Change in Blood Pressure

Changes in average systolic and diastolic pressures during the 12-week treatment of 60 volunteers treated with ForsLean® and Placebo. Changes are not significant.



Bhagwat et al. (2004) 60 subject study, CPBRC Bombay, India.

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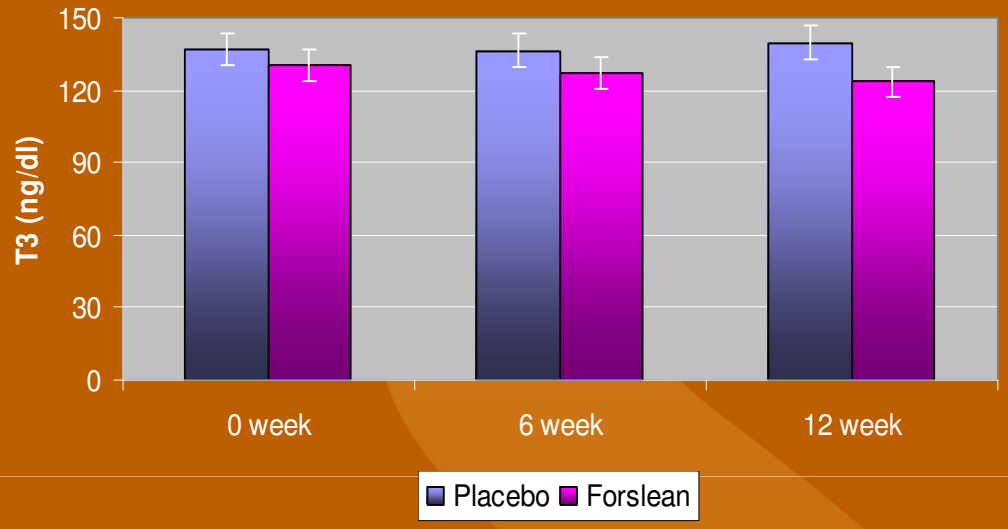
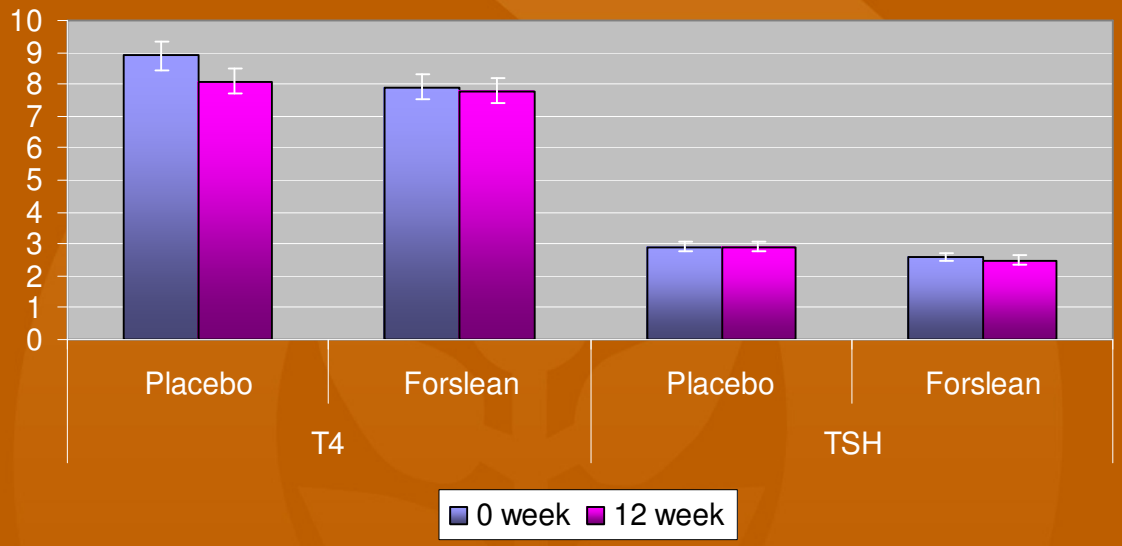
Safety Data: Effect on Thyroid Hormones



T3 changes in Forslean® (pink) and placebo (blue) treated volunteers for 12 weeks. Change is not statistically significant.



T4 (ug/dl) and TSH (UIU/ml) changes in Forslean® and placebo treated volunteers. Change is not statistically significant.

Bhagwat et al. (2004) 60 subject study, CPBRC Bombay, India.

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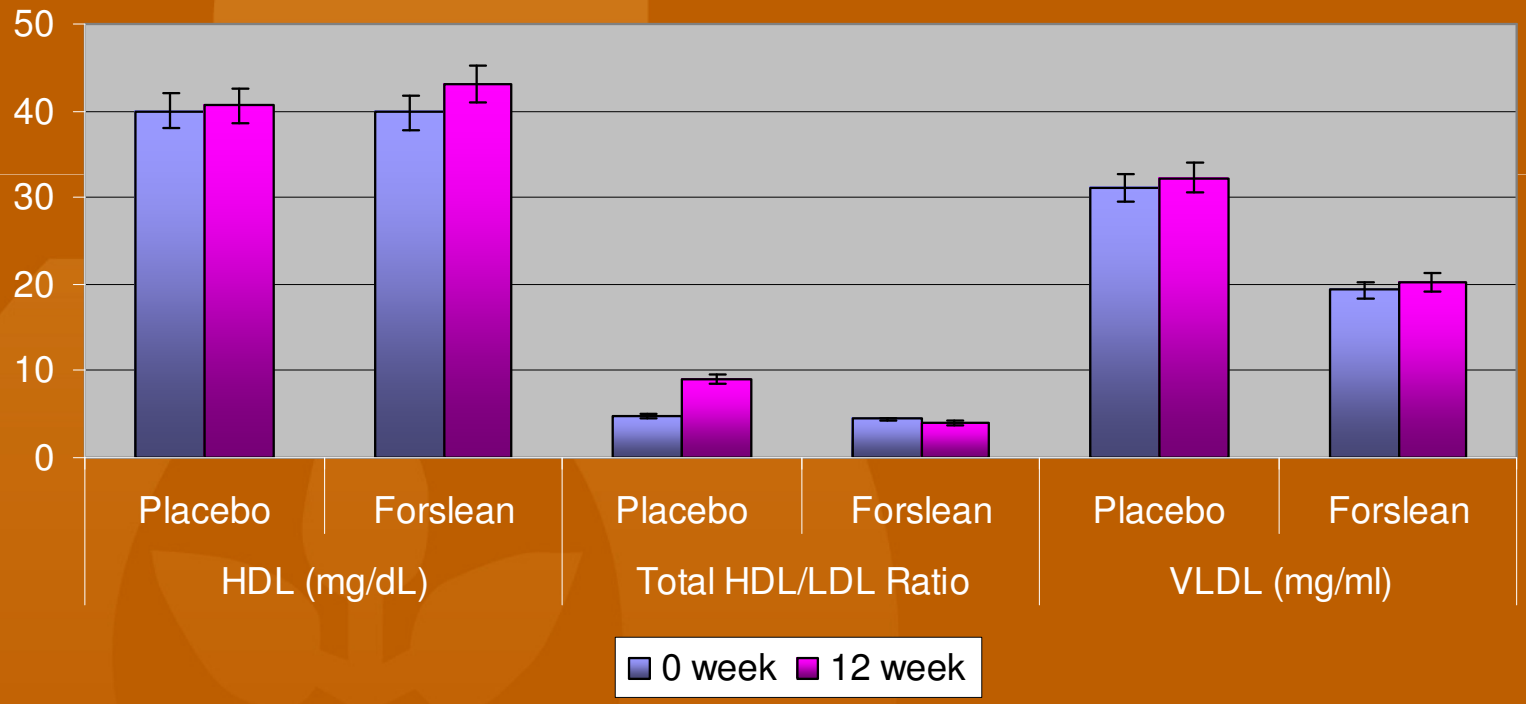
Safety Data: Change in Lipid Profile

Change in lipid profile in volunteers treated with ForsLean® and placebo. There is a significant positive change ($p<0.05$) in the concentration of HDL.



Bhagwat et al (2004) 60 subject study, CPBRC Bombay, India

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Safety Data: Effect Of Treatment On Renal And Liver Profile (N=50, Manipal Study)

Characteristic	ForsLean® (n=25)	Placebo (n=25)
Urea (mg/dL)		
Baseline	19.3 ± 5.1	19.0 ± 6.7
End of Study	20.8 ± 6.7	19.1 ± 6.8
S creatinine (mg/dL)		
Baseline	0.9 ± 0.3	0.9 ± 0.1
End of Study	0.8 ± 0.4	0.8 ± 0.3
Bilirubin (mg/dL)		
Baseline	0.6 ± 0.3	0.6 ± 0.3
End of Study	0.7 ± 0.3	0.7 ± 0.3
SGOT (U/L)		
Baseline	24.8 ± 14.7	19.7 ± 8.2
End of Study	16.7 ± 6.2	16.7 ± 7.7
SGPT (U/L)		
Basline	19.8 ± 9.2	17.7 ± 7.1
End of Study	14.1 ± 4.7	14.9 ± 5.5

Safety Data: Effect Of Treatment On Renal And Liver Profile (N=50, Manipal Study)

Characteristic	ForsLean® (n=25)	Placebo (n=25)
T3 (µg/dL)		
Baseline	1.3 ± 0.2	1.3 ± 0.2
End of Study	1.2 ± 0.3	1.2 ± 0.2
T4 (µg/dL)		
Baseline	8.1 ± 1.4	7.5 ± 1.8
End of Study	6.5 ± 2.1	5.7 ± 2.3
TSH (µIU/L)		
Baseline	2.6 ± 1.7	2.5 ± 1.2
End of Study	2.3 ± 1.2	2.3 ± 1.1

Safety Data: Selected Blood Test Data for Forslean and placebo groups (Krieder et al. J Int. Soc. Sports Nutrition 2(2): 54-62, 2005)

Variable	Forslean	Placebo	Interaction p-level
Direct Bilirubin (mg/dl)	Pre 0.13±0.05 Post 0.09±0.04	Pre 0.08±0.05 Post 0.18±0.14	0.02
Uric Acid (mg/dl)	Pre 4.22±1.0 Post 3.80±1.0	Pre 3.93±1.0 Post 4.46±1.5	0.003
Calcium (mg/dl)	Pre 9.10±0.2 Post 9.30±0.4	Pre 9.32±0.4 Post 9.11±0.2	0.03
White Blood Cells (thous//MCL)	Pre 6.57±1.9 Post 7.94±2.4	Pre 5.92±1.7 Post 5.18±0.8	0.007
Neutrophils (Cells/MCL)	Pre 3792±1276 Post 4468±1737	Pre 3271±1251 Post 2733±596	0.03
Lymphocytes (Cells/MCL)	Pre 2161±434 Post 2771±643	Pre 2084±511 Post 1946±448	0.003

Clinical Studies

1. Open field study (8 weeks) with 6 overweight women subjects
   - Dr. A. Conte, USA

2. Open field study (6 months) with 16 obese subjects
   - Dr. Asano, Japan

3. Pilot clinical efficacy and safety study, 23 women subjects, randomized, double-blind placebo-controlled
   - University of Memphis TN, USA

4. Preclinical Toxicology Evaluation
   - CBPRC, Bombay

Clinical Studies cont'd

5. 60 subject clinical efficacy study
   - CBPRC, Bombay

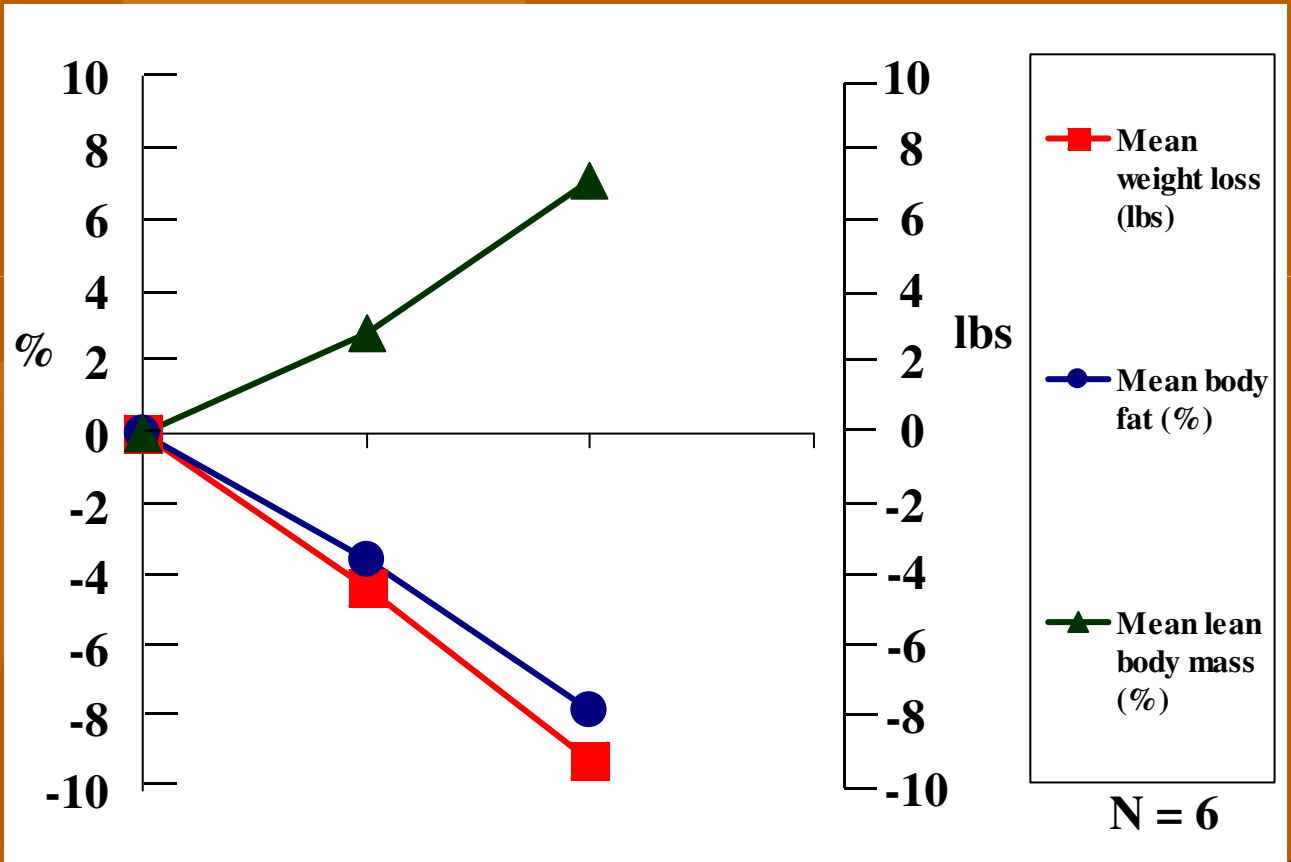
6. 24 subject body composition evaluation and body weight
   - Northern Michigan University, USA

7. Double-blind placebo-controlled study, 30 obese/overweight subjects
   - Kansas State University, USA

8. Efficacy and safety study, effects on lean body mass
   - Kasturba Medical College and Hospital, Manipal, India

Effects on Body Weight, Body Fat and Lean Body Mass

Open field study, 6 overweight women subjects, 500 mg ForsLean® corresponding to 50 mg forskolin/day for 8 weeks



Badmaev et al., USA. Nutracos, February 2002, pg 6

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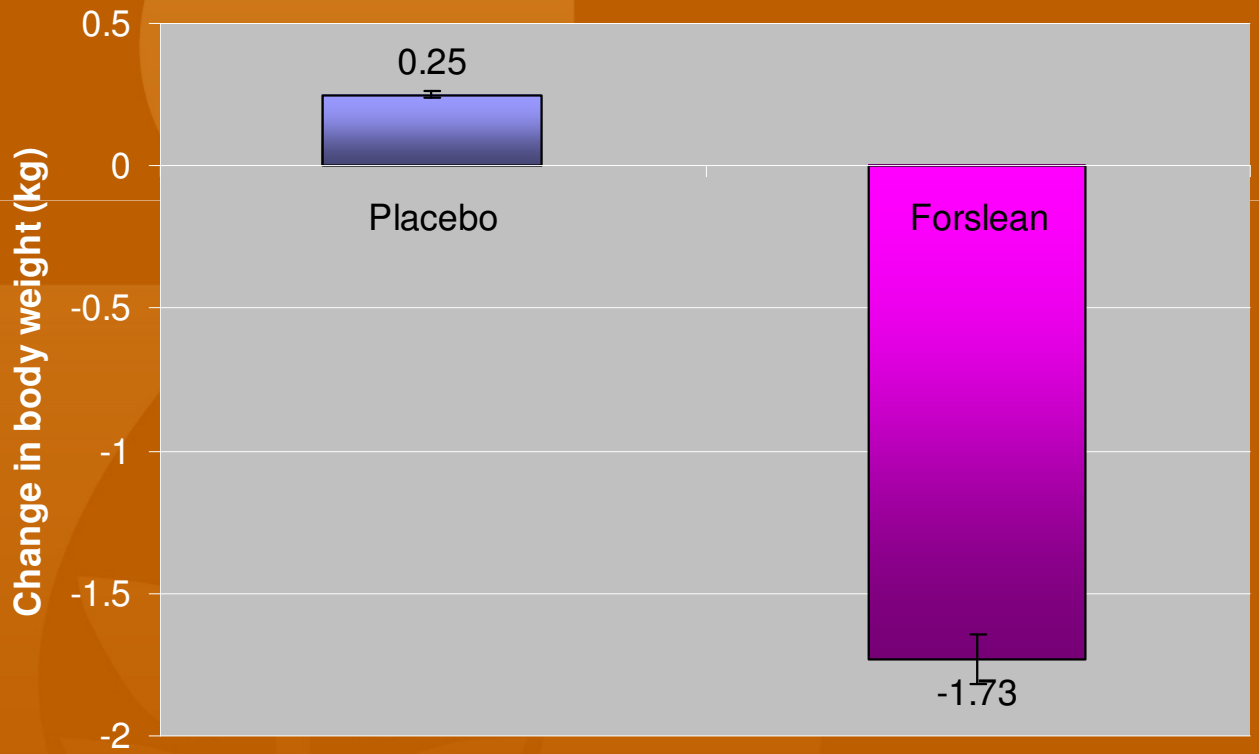
Randomized double-blind placebo-controlled study

CB Patel Research Center, Mumbai, India (2004)

Change in Body Weight

Mean change in body weight of volunteers treated with ForsLean® (pink) and placebo (blue). Change is statistically significant ($p<0.05$).



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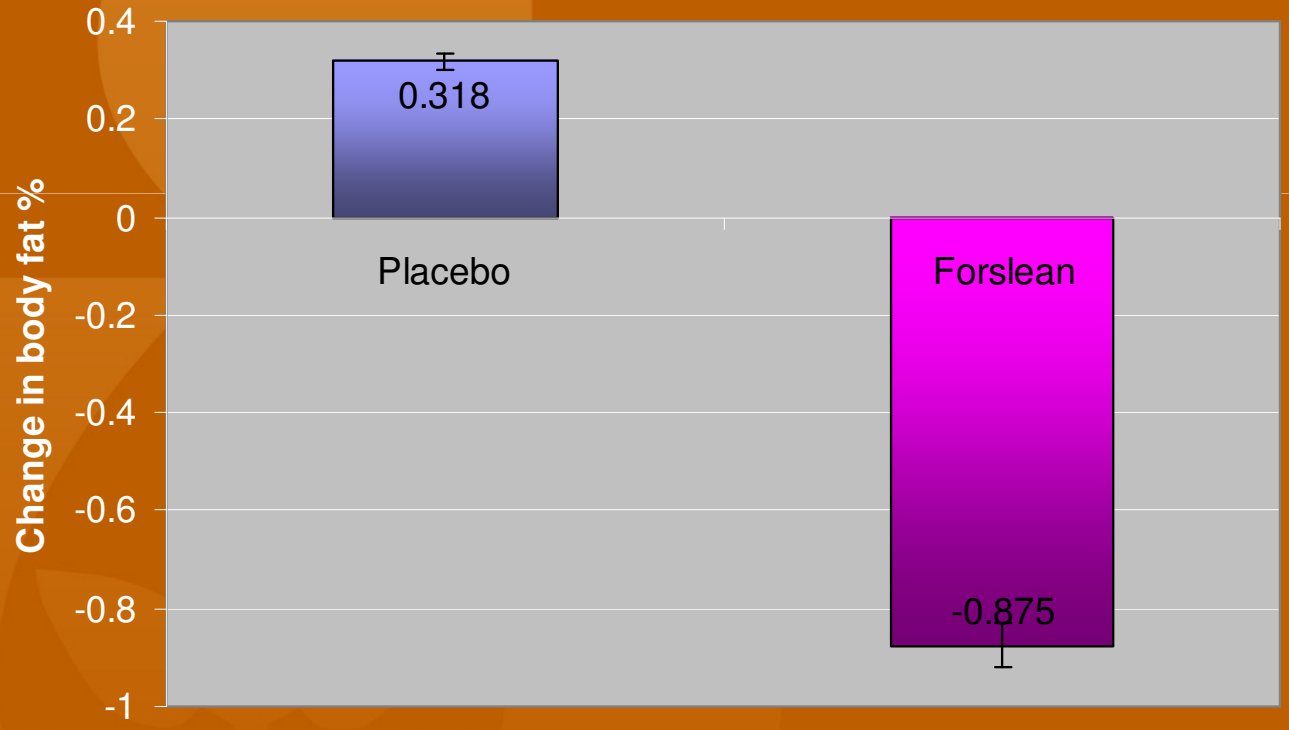
Change in Body Fat

Mean change in body fat of volunteers treated with ForsLean® (pink) and placebo (blue). Loss in fat is statistically significant ($p<0.05$).



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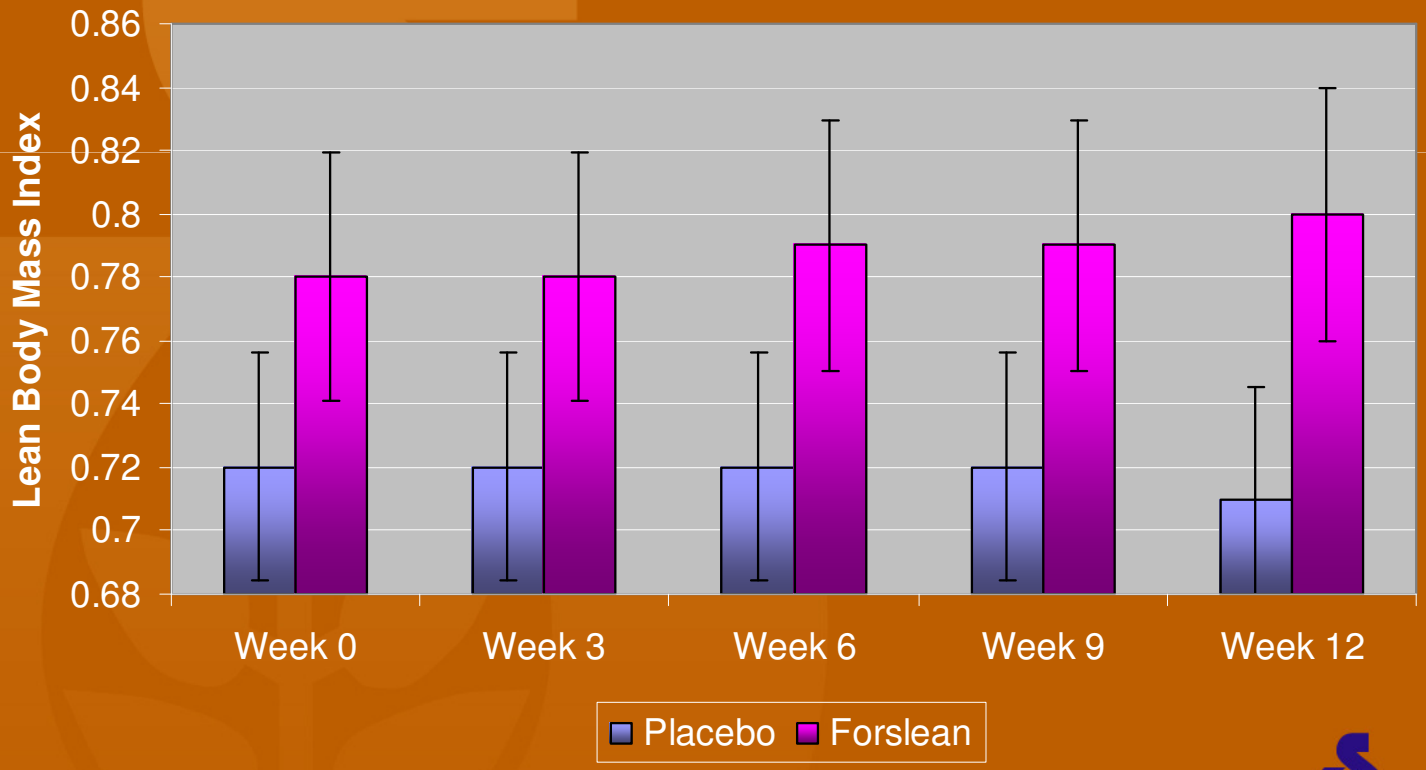
Change in Lean Body Mass Index

Mean changes in lean body mass in volunteers treated with ForsLean® (pink) and placebo (blue). Changes in the ForsLean® group are statistically significant within group ($p<0.05$).



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Body Composition and Hormonal Adaptations Associated with Forskolin Consumption in 30 obese/overweight subjects

Kansas State University, USA (IND 71,458)

Godard M. et al Obesity Research 13(8): 1335-1343.

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Body composition values including body weight, LBM and fat mass at each time point

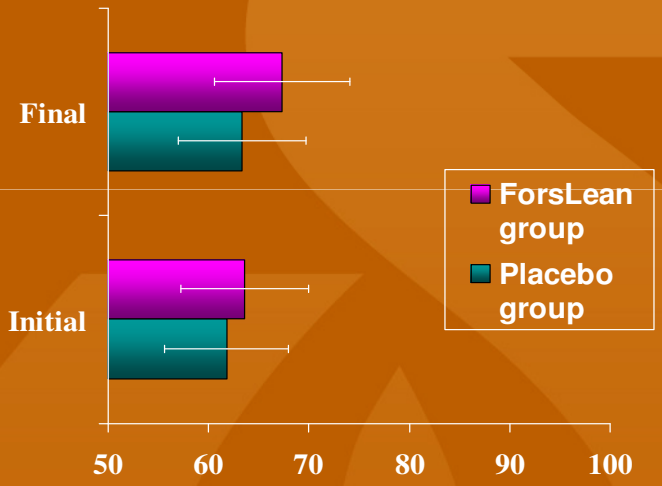
Table 1. Body composition values including body weight, LBM, and fat mass at each time-point

	Pre	Mid	Post	Change (pre − post)	Percent change (pre − post)
Forskolin					
Body weight (kg)	103.98 ± 14.89	104.23 ± 15.04	103.91 ± 15.06	−0.07 ± 2.39	−0.08 ± 2.44
LBM (kg)	63.61 ± 5.94		67.32 ± 8.29†	3.71 ± 4.07	5.65 ± 6.32
Fat mass (kg)	37.43 ± 12.65		32.91 ± 11.29†	−4.52 ± 5.74*	−11.23 ± 13.20*
Bone mass (kg)	3.41 ± 0.43		3.68 ± 0.43†	0.27 ± 0.31*	8.63 ± 10.46
Placebo					
Bodyweight (kg)	100.95 ± 9.30	102.09 ± 9.75	102.15 ± 9.65	1.20 ± 2.33	1.20 ± 2.35
LBM (kg)	61.82 ± 6.44		63.39 ± 7.07†	1.57 ± 2.56	2.56 ± 4.39
Fat mass (kg)	35.65 ± 9.99		35.14 ± 10.56	−0.51 ± 1.91	−1.73 ± 5.64
Bone mass (kg)	3.41 ± 0.55		3.60 ± 0.51	0.20 ± 0.53	7.46 ± 18.78

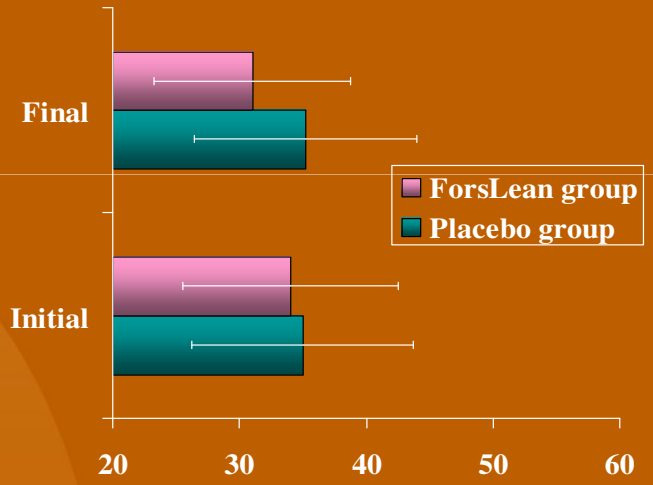
The actual change from pre- to post-measurement and the percent change are also included.
All values are presented as means ± SD.
* Significant difference between groups and † significant difference within groups across time ($p \leq 0.05$).

Changes in Body Composition

Randomized, double-blind, placebo-controlled; 30 overweight/obese male subjects; 12 weeks, Active therapy: 250 mg ForsLean® twice daily



Lean Body Mass (kg)
(significant increase in treated group, $P \leq 0.05$)



Body Fat %
(significant decrease in treated group, $P \leq 0.05$)

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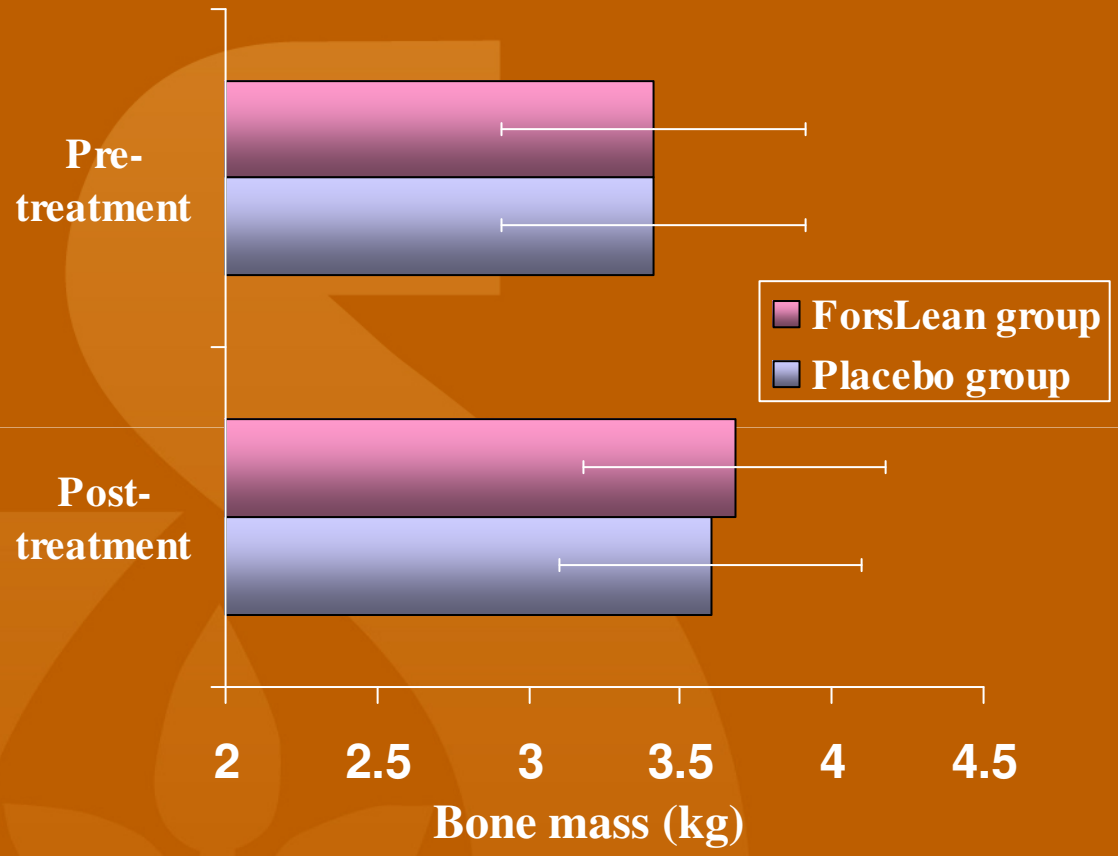
Effect on Bone Mass



Significant increase with ForsLean, $P \leq 0.05$

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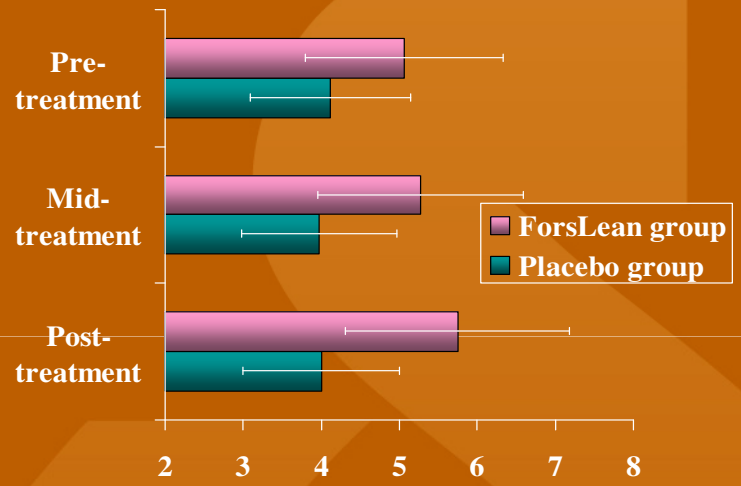
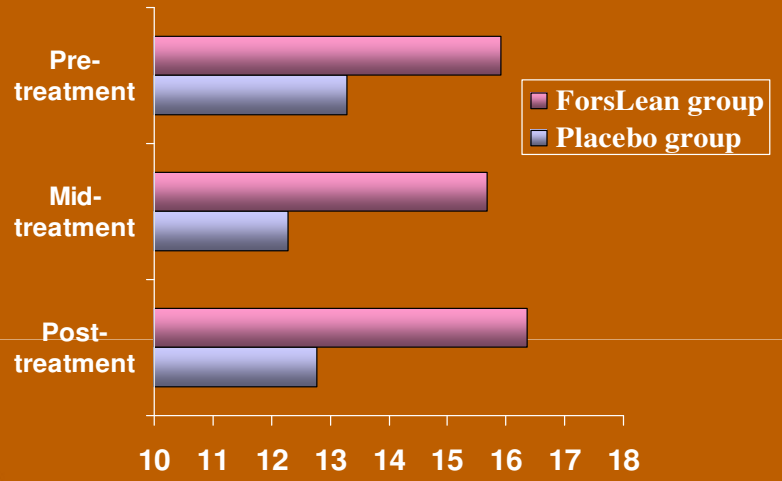
Effect on Serum Testosterone Levels



Total testosterone (ng/ml), Trend to increase with ForsLean®



Free testosterone (pg/ml), Significant increase, P ≤ 0.05

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The efficacy and safety of ForsLean® in increasing lean body mass

Kasturba Medical College & Hospital
Manipal, India
(2005)

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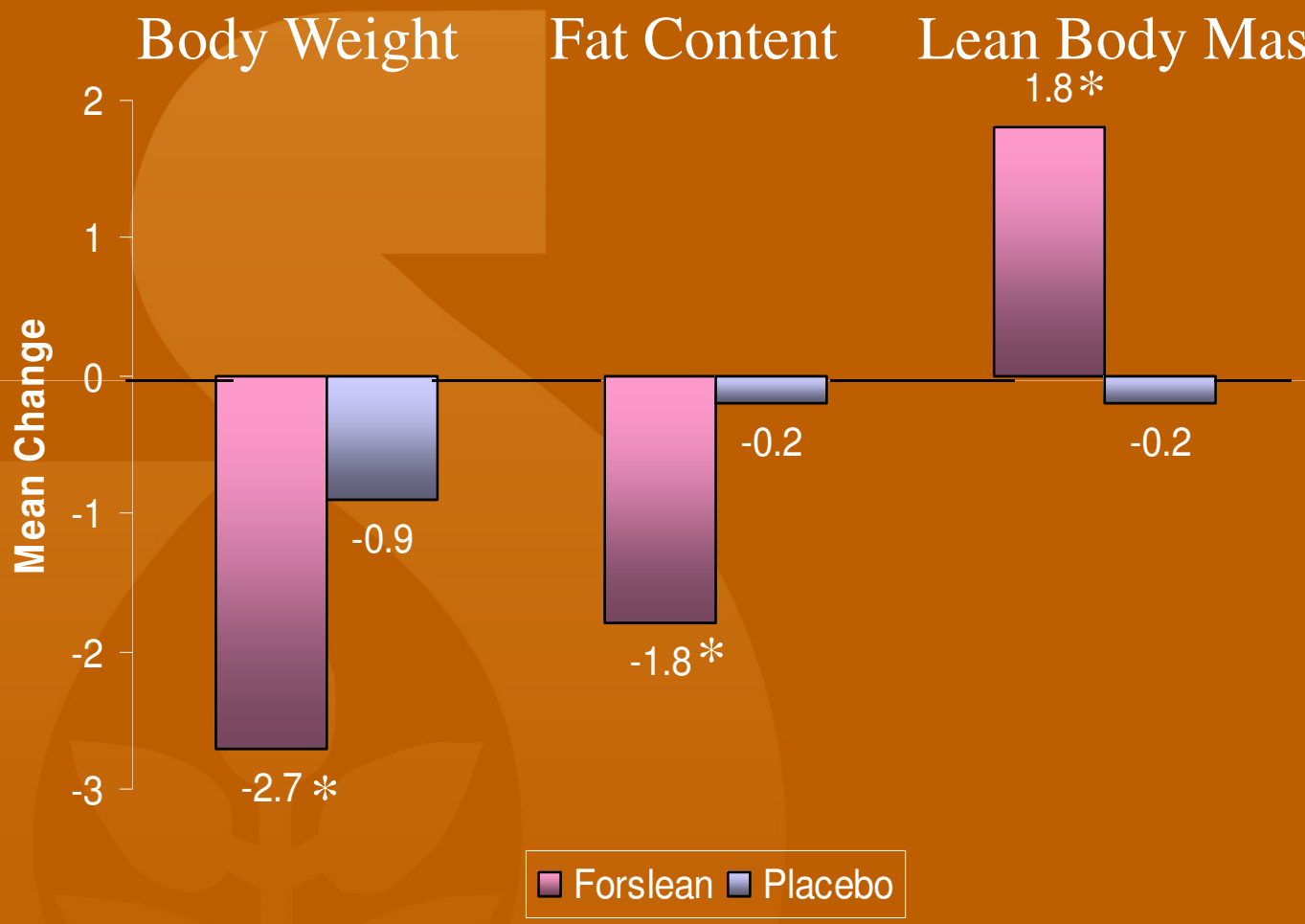
Mean Change in Lean Body Mass, Fat Content and Body Weight (n=50)



P ≤ 0.05 for difference between the two treatment groups

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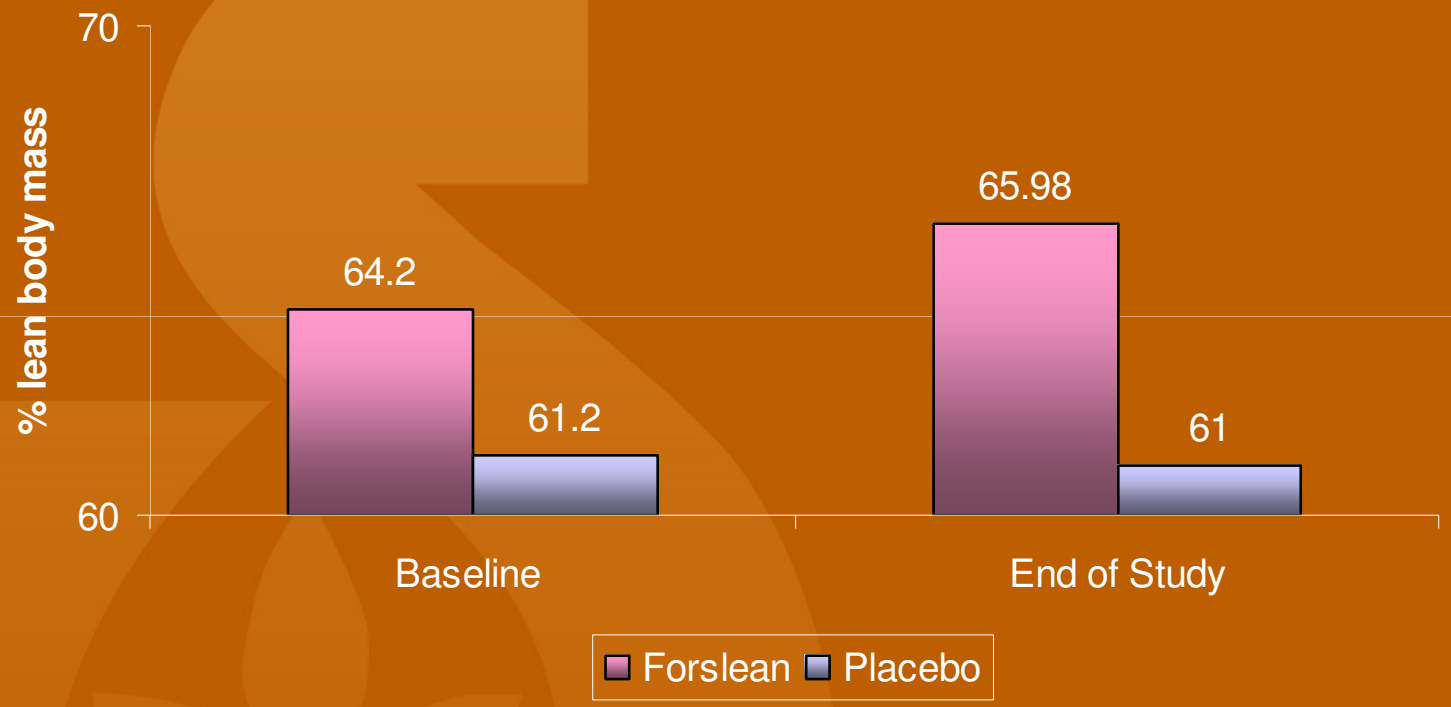
Mean Increase In Lean Body Mass Percentage



P ≤ 0.05 for difference between the two treatment groups

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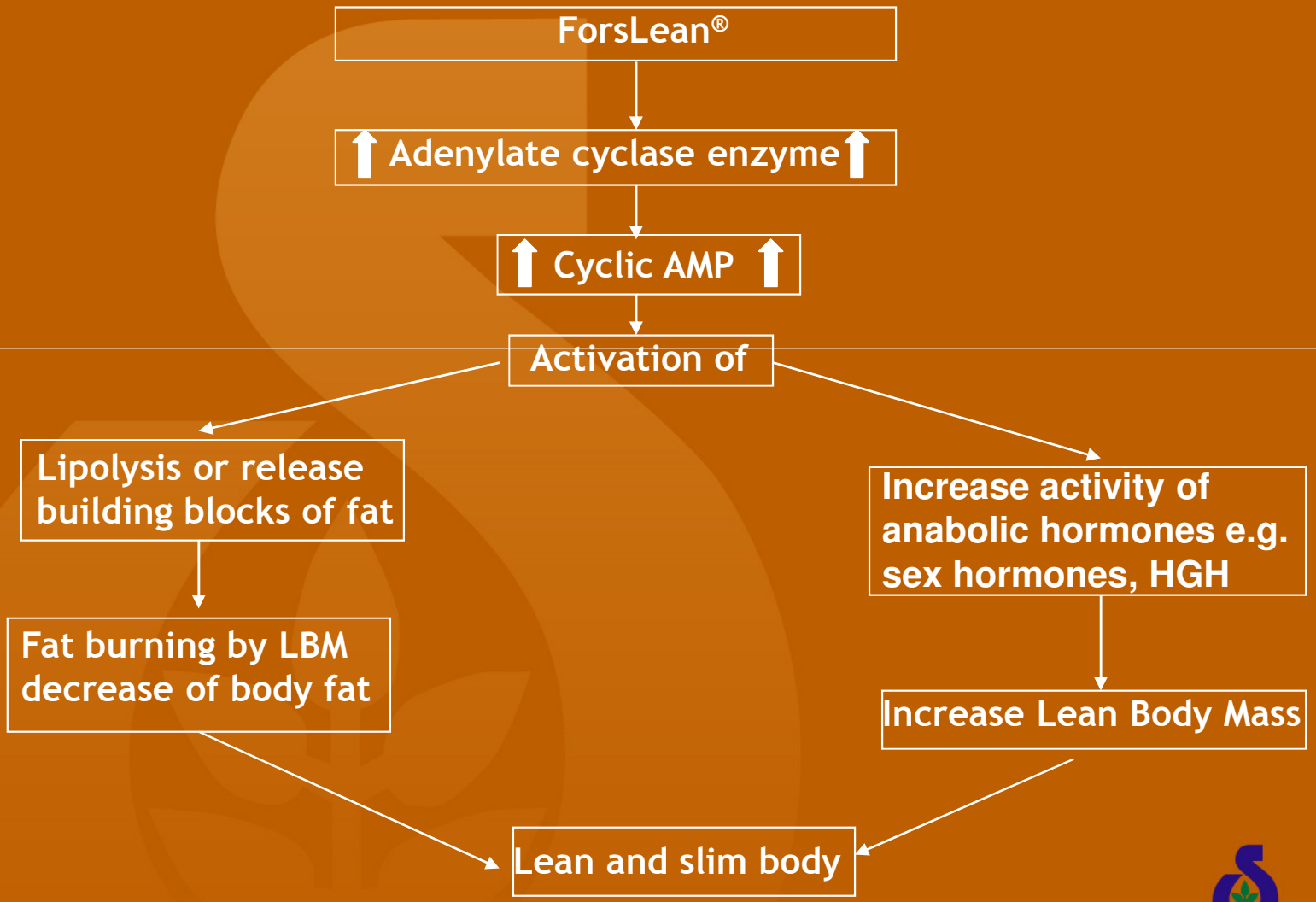
Forskolin - Mechanism of Action



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Conclusions:

- The available toxicological studies in animals and clinical studies at the intended level of use indicated that *C. forskohlii* 10% extract is well-tolerated and without adverse side effects

- Clinical studies with ForsLean® administered in doses of 500mg/day for up to 12 weeks have demonstrated no significant effect on chemistry or hematological parameters

- There was also no significant effects on blood pressure or thyroid function

Expert Review Report from Cantox Health Sciences International ON, Canada, August 2004

Conclusions:
What ForsLean® is NOT

- A sympathomimetic
- Your typical body weight management ingredient
- Just a passing fad
- Prone to being spiked
- A total treatment for obesity

Conclusions:
What ForsLean® IS

- A safe, naturally derived, effective dietary ingredient composition
- Patented for use in promoting lean body mass (health)
- Clinically tested in humans (multiple studies)
- Kosher certified
- A tried and tested ingredient that manufactures, retailers and consumer can have confidence in

Conclusions:

- In the absence of developmental or reproductive studies, the product should be labeled with a warning against use by pregnant women
- Safe use of forskolin is supported by a long history of use of the plant roots as pickles
- In the US, 10's of millions of dosages per year have been consumed without Adverse Effect Reports(AERs)
- In summary, with appropriate labeling to address contraindications, period of time of consumption, etc. the information supports the safety of ForsLean® at the intake level of 500mg per day

Expert Review Report from Cantox Health Sciences International ON, Canada, August 2004

ForsLean® has legitimate application in the field of healthy nutrition, particularly since we are becoming increasingly aware of the role of lean body mass in our health

THANK YOU