

SLO-NIACIN[®]
polygel[®] controlled-release niacin
DIETARY SUPPLEMENT

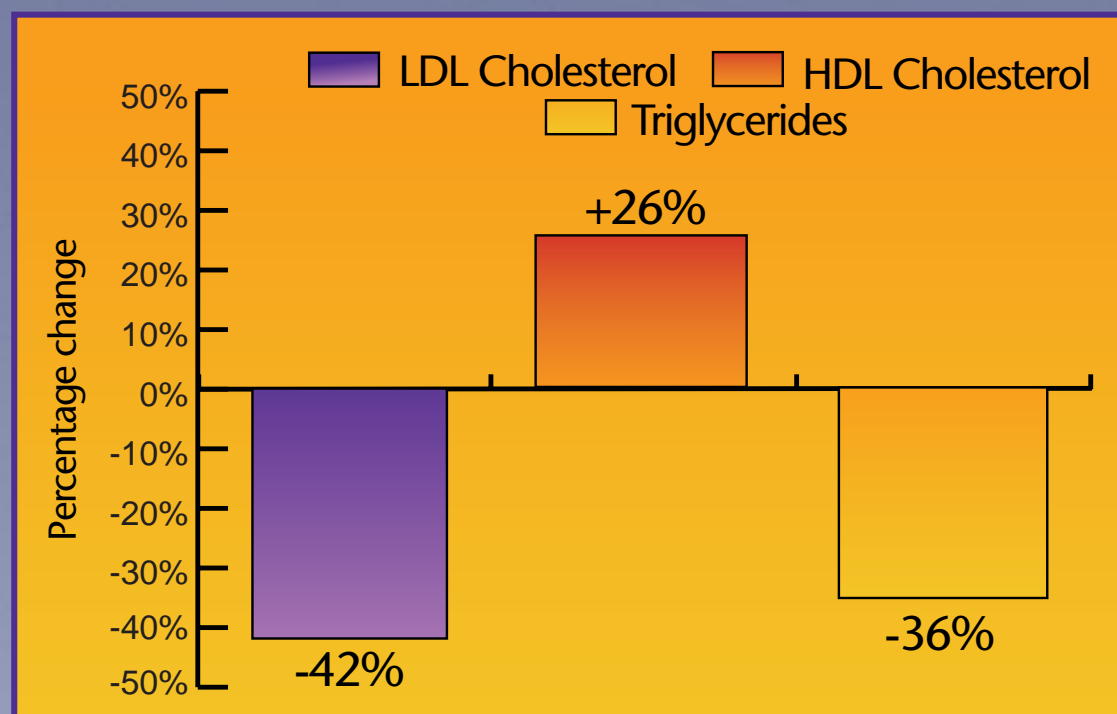


HATS trial data show:

**SLO-NIACIN[®] + simvastatin therapy
improves entire lipid profile**

SLO-NIACIN® + simvastatin lowers LDL and triglycerides, and raises HDL¹

Lipid changes from baseline¹



Average daily dose: niacin* 2400 mg ± 2000 mg; simvastatin 13.6 mg ± 6 mg. N=33.

SLO-NIACIN®...
Clinically proven in monotherapy.
Now confirmed in combination therapy
in the HATS trial¹

Study design:

The HATS trial (HDL-Atherosclerosis Treatment Study) enrolled 160 men (younger than 63 years of age) and women (younger than 70 years of age) with clinical coronary disease (defined as previous myocardial infarction, coronary interventions, or confirmed angina) and with at least three stenoses of at least 30% of the luminal diameter or one stenosis of at least 50%. Twenty-six patients in Canada and 134 patients in the Seattle area were enrolled between January 1995 and January 1997. All patients had low levels of HDL cholesterol (<35 mg/dL for men and <40 mg/dL for women), LDL cholesterol levels of 145 mg/dL or less, and triglyceride levels of 400 mg/dL or less.

*All niacin (both SLO-NIACIN® and NIACOR®) supplied and manufactured by Upsher-Smith Laboratories, Inc.

SLO-NIACIN® + simvastatin for *more beneficial* combination therapy¹

"The clinical and angiographically measurable benefits of simvastatin plus niacin were greater than those that would be expected from statins alone."¹

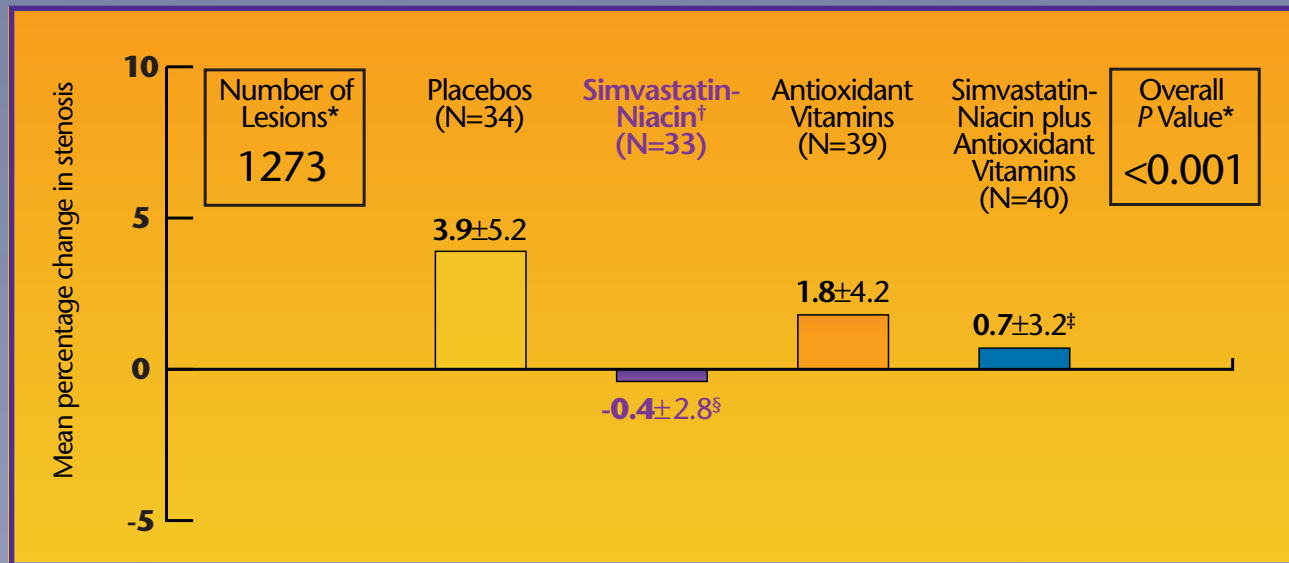
- 42% LDL-C **reduction**
- 36% triglycerides **reduction**
- 26% HDL-C **increase**



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SLO-NIACIN® + simvastatin therapy halted progression of stenosis¹

HATS stenosis changes from baseline¹



*Overall P values were calculated by a one-way analysis of variance.

[†]All niacin (both SLO-NIACIN® and NIACOR®) supplied and manufactured by Upsher-Smith Laboratories, Inc.

Average daily dose: niacin 2400 mg ± 2000 mg; simvastatin 13 mg ± 6 mg.

[‡]Unadjusted P<0.001 by the pooled t-test for the comparison with the placebo group.

[§]Unadjusted P<0.005 by the pooled t-test for the comparison with the placebo group.

Percentage of patients who developed a first cardiovascular event (clinical endpoint*)

Placebos	Simvastatin-Niacin	Antioxidant Vitamins	Simvastatin-Niacin + Antioxidant
24%	3% p=0.04	21% p=NS	14% p=NS

*The endpoints were arteriographic evidence of a change in coronary stenosis and the occurrence of a first cardiovascular event (death, myocardial infarction, stroke, or revascularization). NS=not significant.

- Simvastatin + niacin offers both clinical and angiographically measurable benefits in patients with coronary disease, low HDL levels, and moderate LDL levels¹
- Benefits of simvastatin + niacin were **greater** than monotherapy with antioxidants or simvastatin-niacin-antioxidant combination therapy¹



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SLO-NIACIN® + simvastatin reduced the risk of a cardiovascular event by 90% compared to placebo¹

More beneficial than statins alone¹

- Reduction in the rate of events of 60% to 90%—instead of the anticipated 24% to 34%¹
- Benefits of simvastatin *plus* niacin were **greater** than monotherapy with antioxidants or simvastatin-niacin-antioxidant combination therapy¹

HATS trial results¹ combined primary and secondary composite endpoints.

Numbers of patients with at least one event (during 38-month follow-up period).*

	Cardiovascular Event Composite of death from cardiovascular causes, nonfatal infarction, revascularization procedure, or hospitalization for confirmed ischemia
Placebos (N=38)	12
Simvastatin-Niacin (N=38)	1[†]
Antioxidant Vitamins (N=42)	11
Simvastatin-Niacin plus Antioxidants (N=42)	6

*All enrolled patients were included in this intention-to-treat analysis.
[†]P=0.003 by Fisher's exact test for the comparison with the placebo group (adjusted for multiple comparisons).

Average daily dose: niacin 2400 mg ± 2000 mg; simvastatin 13.6 mg ± 6 mg.



Effective, economical, trusted niacin delivery

- Polygel® controlled-release system delivers gradual, measured doses over time, minimizing side effects
- Economically priced, similar to copayment*
- SLO-NIACIN® is the niacin of choice for many managed care organizations²

Recommend The clinically proven choice



These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Simvastatin plus niacin caused small but consistent increases in the levels of aspartate aminotransferase, creatine kinase, uric acid, homocysteine, and insulin, but not glucose.

*May not reflect actual retail prices.

NOTE: Doses of immediate-release niacin and controlled-release niacin may not be comparable.

SLO-NIACIN®
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SLO-NIACIN[®]—the extended-release niacin formulation confirmed in combination therapy in the HATS trial¹



Recommend The clinically proven choice SLO-NIACIN[®] + simvastatin...

- Improved entire lipid profile
- Halted the progression of stenosis
- Reduced the risk of a cardiovascular event by 90% compared to placebo

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References:

1. Brown BG, Zhao X-Q, Chait A, et al. Simvastatin and niacin, antioxidant vitamins, or the combination for the prevention of coronary disease. *N Engl J Med.* 2001;345(22):1583-1592.
2. Data on file, Upsher-Smith Laboratories, Inc.

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