

Vayarol™

Phytosterol Esters of Omega 3 Fatty Acids
Prescription Medical Food



Did You Know?

Hypertriglyceridemia is the Fastest Growing Lipid Disorder in the US

Vayarol™ is clinically shown to simultaneously lower:

- Triglyceride (TG) levels (by 19%)
- Several CVD risk factors:
 - Diastolic blood pressure (by ~7%)
 - CRP levels (by 0.6 mg/L)
 - ApoB levels (by 6%)
 - Total cholesterol/HDL cholesterol ratio (by 8%)
- **Vayarol™** is clinically shown to be safe and well tolerated

Vayarol™ effect is not accompanied by **LDL-C elevation**

Vayarol™

study results were published in *Cardiovascular Drug Therapy*¹ and in the *American Journal of Clinical Nutrition*²



1. Bitzur, R., et al., The metabolic effects of omega-3 plant sterol esters in mixed hyperlipidemic subjects. *Cardiovasc Drugs Ther.* 2010 Dec;24(5-6):429-37.

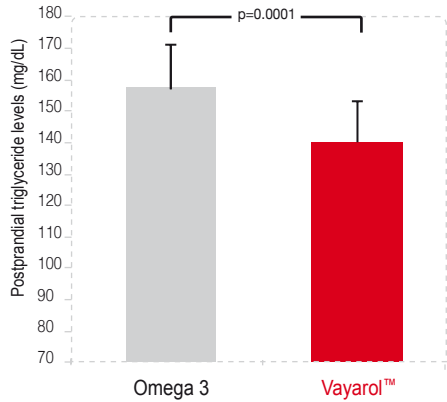
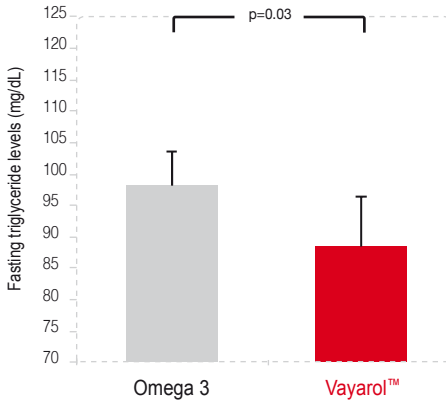
2. Demonty, I., et al., Fish-oil esters of plant sterols improve the lipid profile of dyslipidemic subjects more than do fish-oil or sunflower oil esters of plant sterols. *Am J Clin Nutr.* 2006 Dec;84(6):1534-42.

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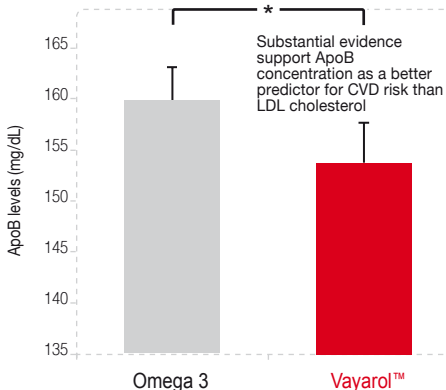
The Metabolic Effects of Vayarol™ in Borderline Hypertriglyceridemic Patients

- Significantly Reduced TG as Compared to Omega 3

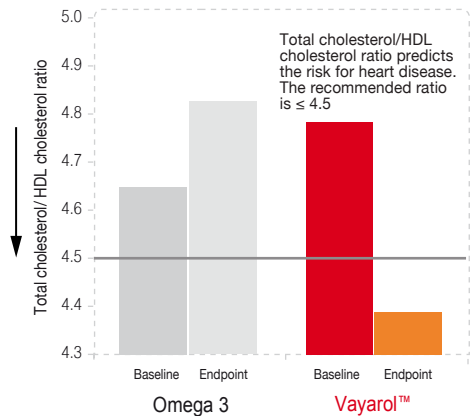


Results are expressed as means ± standard error. p values are based on contrast analyses, following repeated-measures analyses of variance (ANOVA)

- Significantly Reduced ApoB as Compared to Omega 3



- Reduced the Risk for Heart Disease



Results are expressed as means ± standard error. * p<0.05 for Vayarol™ as compared to Omega-3 group. p values are based on contrast analyses, following repeated-measures analyses of variance (ANOVA)

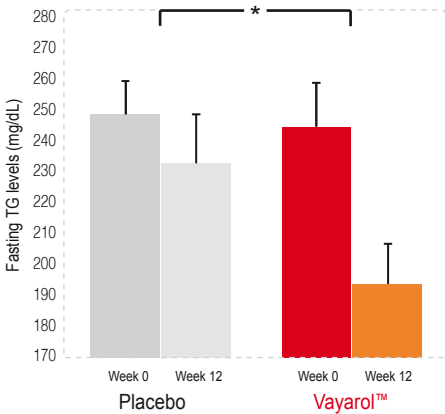
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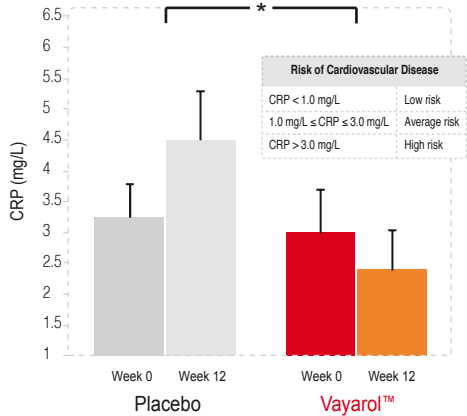
The Metabolic Effects of Vayarol™ was Evaluated in 91 Mixed Hyperlipidemic Patients* A double blind, placebo-controlled, study of 12 weeks

*150 mg/dL > triglycerides < 500 mg/dL, 130 mg/dL > LDL-C < 190 mg/dL

- Significantly Reduced TG Levels by 19%
- Reduced Inflammation

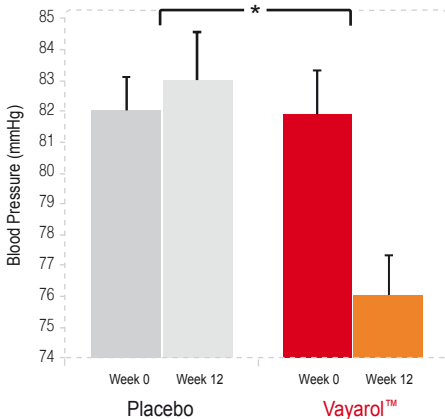


The values are presented as mean ± standard error. * p = 0.025 refers to the difference in the change from baseline between Vayarol™ and placebo groups

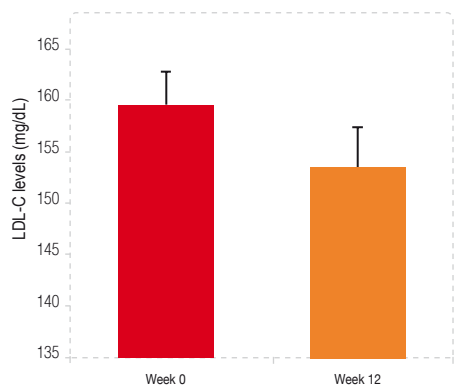


The values are mean ± standard error. *p = 0.011 refers to the difference in change from baseline between Vayarol™ and placebo groups

- Reduced Diastolic Blood Pressure by 7%
- Reduced TG Levels Without Elevating Plasma LDL-C Levels



The values are presented as mean ± standard error. * p = 0.025 refers to the difference in the change from baseline between Vayarol™ and placebo groups



The values are presented as mean ± standard error

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Vayarol™ is Safe and Well Tolerated

Reported adverse events

Treatment group	Vayarol™ (n=46)	Placebo (n=45)
Itching rash	1	0
Fatigue	1	0
Epigastric pain	1	0
Mild abdominal discomfort	0	1
Urticaria	0	1

*Judged by the study physicians as related or probably related to the study treatment



Dosage and Administration

- **Vayarol™** is available as soft gel capsules
- **Vayarol™** is supplied in bottles of 60 capsules
- **Vayarol™** recommended dose is 2 capsules daily or as directed by a physician
- **Vayarol™** is an orally administered prescription medical food for the dietary management of hypertriglyceridemics in need of omega 3 and who are potentially at risk for having adversely affected blood low density lipoprotein-cholesterol levels



Two soft gel capsules contain:

Phytosterol esters.....1.26 gr
Docosahexaenoic acid (DHA).....465 mg
Eicosapentaenoic acid (EPA).....185 mg

This information is intended for Healthcare Professionals only

<http://www.vayapharma.com>

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